SRU

German Advisory Council on the Environment

Precautionary Strategies for managing Nanomaterials

Chapter 7: Conclusions and Recommendations

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7 Conclusions and recommendations

694. In this special report, the German Advisory Council on the Environment (SRU) has investigated the application of the precautionary principle to a new technology by the example of nanomaterials. The first section of this chapter brings out the importance of the precautionary principle in dealing with nanomaterials. The report's findings on the opportunities and risks of nanomaterials are then mirrored against the requirements of the precautionary principle. It is established that action is needed in order to apply the precautionary principle to nanomaterials, and possible options are outlined in general terms. Finally, the SRU's specific recommendations for the application of the precautionary principle to nanomaterials are set out in relationship to various areas of policy and social activity.

7.1 The precautionary principle as a guiding principle in dealing with nanomaterials

7.1.1 Uncertainty and unknowns in the context of new technologies

695. New technologies almost always involve unknowns and therefore uncertainty. Some are described for good reason as risk technologies, and there has been a corresponding trend in law towards risk-related legislation with risk-related decisions based upon it. Typical examples include legislation governing nuclear power, chemicals, pharmaceuticals, and green genetic engineering.

All the same, merely because a technology, a process, a substance or a product based upon it is new does not mean that the state must take regulatory action, at least not to any major degree. In many cases, unknowns can continue to be dealt with by trial and error. However, any changes involved must be small and largely reversible for trial and error to remain politically acceptable – and also legally acceptable with regard to the state's obligation to give protection under Article 2 (2) and Article 20a of the German Basic Law (*Grundgesetz*). If from the outset there is good reason to expect specific projects, techniques or activities to have global and irreversible impacts, then an approach based on trial and error is clearly irresponsible. With a view to such new challenges posed by today's risk society, the state's traditional role of ensuring public safety is mirrored in the precautionary principle enshrined in German constitutional law and European law (Article 20a of the German Basic Law and Article 191 (2) of the Treaty on the Functioning of the European Union (TFEU)).

Exploring policymaking and the law as they relate to nanotechnology, or nanomaterials, can help in modelling how uncertainty and lack of knowledge are dealt with in today's risk society. This report analyses to what extent the precautionary principle is already in use today, where deficits and gaps exist, and how they can be closed.

7.1.2 General requirements of the precautionary principle

696. The question therefore arises of whether and at what point the state can or indeed must, in the face of uncertainty and lack of knowledge, restrict economic freedom, and hence the ability to exploit innovation opportunities, in order to counter dangers or risks from the use of new technologies. As shown in detail in section 2.3, this makes it necessary to distinguish between conventional approaches to averting danger and the precautionary approach, which allows earlier state intervention.

In conventional approaches to averting danger, the state (legislature or administration) must respond (e.g. by legislating or taking specific action) when there is a real or impending *danger* to human health and life or to the environment. This constitutional responsibility of state institutions follows from their obligation to give protection under Article 2 (2) and Article 20a of the German Basic Law. If, however, there are no experiments and no scientific findings to back a causal link, or if findings contradict each other and so fail to support science-based inferences and action, then the resulting uncertainty means that the assessment falls short of the *probability level* needed to assert that there is a *danger*. This presents an almost insurmountable barrier for state intervention to avert danger in conditions of uncertainty.

This is where the precautionary principle comes into play – the principle applied when dealing with risks. The precautionary principle is recognised today as a basic principle of environmental, health protection and consumer protection law in many jurisdictions, including Germany, the EU and many other states (on the subject of precaution as a principle shaping the law, see section 2.3.2.2). Together with the related requirement for impact assessments on new technologies, the precautionary principle goes beyond the conventional approach to averting danger by demanding that risks of new technologies should be avoided or at least minimised. Following the definition of danger applied in German law, *risk* may be defined as a situation where, if events are left to run their course, a certain condition or certain conduct could *possibly* cause harm. The crucial change introduced by the precautionary principle compared with this definition of danger is the replacement of an identifiable, sufficient *probability* of harm in the case of danger with the mere *possibility* of harm – an *abstract concern* – in the case of risk. The key effect of extending the conventional approach for averting danger by invoking the precautionary principle is that it allows the state to act earlier (on the subject of identifying an abstract concern, see section 2.3.4.1).

Over and above this, the precautionary principle also comes into play in situations where the law does not provide an answer because the available scientific evidence concerning an abstract concern is contradictory, making it impossible to resolve the prevailing uncertainty. In such situations, the precautionary principle can act to shift the burden of proof by creating a rebuttable presumption of danger (on reversal of the burden of proof in application of the precautionary principle, see section 2.3.4.2). Based on this presumption of danger, the state

can act on a precautionary basis, for example by establishing a suitably designed authorisation procedure within which producers must be given the opportunity to rebut the presumption of danger by presenting new facts. Shifting the burden of proof by applying the precautionary principle in this way thus gives producers an incentive to supplement their product development activities with research on impacts.

To avoid exercising precaution for precaution's sake – that is, to avoid putting nanomaterials under blanket suspicion, which would mean missing out on the opportunities they present, together with the resulting innovations – it is first necessary to specify trigger criteria for precautionary intervention (see section 2.3.4.1). Based on prevailing legal thinking and also with a view to policymaking practice, this involves a two-stage process: a risk assessment and normative risk evaluation. Risk assessment, the 'objective' part of the process, is science-based and consists of gathering knowledge by looking at all available sources of evidence and scientifically appraising them. Risk evaluation, the 'subjective/normative' part, is policy-based and means weighting and balancing the established facts and mechanisms, the remaining unknowns and uncertainties, and individual and public interests.

The precautionary principle is a way of dealing with uncertainty in policymaking and the law. It can balance opportunities and risks and so guide the social and policy debate on new technologies along rational lines. This report has shown how this works in detail, taking the use of nanomaterials as an example.

7.1.3 Applying the precautionary principle to nanomaterials

7.1.3.1 Nanotechnologies and nanomaterials

697. Nanotechnology is the collective term for a broad range of technologies that are applied in natural sciences such as physics, chemistry, biology and medicine and whose shared feature is that they deal with structures and processes at the nanometre scale. A nanometre (nm) is one billionth of a metre (10^{-9} m), or about 100,000 times smaller than the diameter of a human hair. The properties of materials can change substantially at the nano scale because of particles' larger specific surface area. It also ceases to be possible to describe the behaviour of materials with the laws of classical physics, because quantum effects can come to dominate (section 3.2.2).

A significant portion of nanotechnology relates to the manufacture and use of nanomaterials. A general and internationally accepted definition of nanomaterials is so far lacking. The SRU therefore considers it necessary to formulate an overarching definition for regulatory purposes. This definition can be further restricted for specific applications and regulatory needs (see section 7.2.3.1).

7.1.3.2 Opportunities and risks of nanotechnology

698. Nanotechnologies involve dealing with the opportunities and risks of a new cross-cutting technology considered to be one of the most important technological developments of the 21st century. Nanotechnologies mark a further step in a process of miniaturisation with regard to the use of materials that essentially started with the computer age. The fact that miniaturisation down to the nano scale has led to the discovery of materials with fundamentally different properties from their macro counterparts is one reason why nanotechnology sparks such widespread interest.

Public debate about the opportunities and risks of nanotechnology has started at a point when a large number of nanomaterials and consumer products containing them have already been on the market for some time. Examples include paints, car tyres, tennis rackets, textiles, and sunscreens (for more on nanoproducts already available, see section 3.4.1). Their diverse applications also mean that nanotechnologies have considerable economic potential (for more on market potential, see section 3.5).

In many products sold as ‘nano’ today – such as household items with antibacterial coatings – the nanotechnology component is of limited or disputed benefit. Consumer products of this kind, however, only make up a small share of the nanotechnology spectrum. Technologically and economically more important are applications where the incorporation of nanoprocesses and nanomaterials is less obvious, as with electronics and in the development and manufacture of many different products from construction materials to coatings. There is no doubt that nanotechnologies and nanomaterials have great innovative potential and open up a vast range of new technological opportunities in the long term. It is expected moreover that in some areas, nanotechnologies will not only be a source of profit economically, but will also bring large social benefits, as with pharmaceuticals, medical technology and water purification.

There are also hopes that nanotechnologies will make an important contribution to protecting the environment. However, these hopes have not yet been matched by significant real life applications. The few life cycle assessments done to date do not show nanotechnology applications to generally have a smaller environmental footprint. In some cases the manufacture of nanomaterials is highly energy and resource-intensive in its own right. Nonetheless, the high level of public R&D spending on nanomaterials and nanoprocesses for environmental protection is expected eventually to result in decisive improvements in fields such as solar technology, energy storage, air purification, water treatment and cleaner production.

While great expectations are placed in the potential of nanotechnologies, there are also increasing warnings of possible risks due to insufficient knowledge about the effects of these technologies on the human organism and the environment.

7.1.3.3 Findings from risk research on nanomaterials

699. Nanomaterials embrace a very wide range of different nanoscale structures, including nanoparticles, nanofibres, nanolayers, and nanoporous or nanotextured materials (see para. 3.2.1). The focus of risk analysis is currently on nanoparticles and nanofibres – free structures in the shape of particles, fibres, rods or tubes smaller than a few hundred nanometres along two or three dimensions – these being the only forms in which materials with nano-specific properties can enter the body or organism. The SRU has therefore restricted itself in this report to addressing risks from materials of this kind. Agglomerates and aggregates (more or less coherent clusters), though not always mentioned, are generally included in the analysis. Risks from nanoplatelets, nanolayers and nanopores, on the other hand, are not considered in detail.

700. Available knowledge on the risks of nanoparticles and nanofibres varies in extent, and in many cases, notably regarding exposures, there are major gaps in that knowledge. A distinction can be made between materials that have been on the market for some time, where there are already toxicology and exposure studies, and new materials where hardly anything is known about toxicological profiles and environmental behaviour.

701. From the research findings to date, there is no proof of adverse changes in the environment or in human health as a result of the manufacture and use of nanoparticles and nanofibres currently on the market. This cannot be taken as an all-clear, however, because understanding of the risks of these materials remains very incomplete and some research findings raise substantial concerns. In general, nanoparticles and nanofibres have been found to differ from the same material at macro scale not only physically and chemically, but also in behaviour and effects in living organisms and the environment. Nanoparticles and nanofibres cannot therefore be bracketed together with the equivalent macro scale or bulk materials and from a biological point of view should be treated instead as new substances. However, it is not yet clear where the dividing line between nanoscale and macroscale materials is to be drawn. The differences in behaviour in the human organism and the environment consist firstly in increased reactivity (see para. 4.2.1) and secondly in that nanoparticles and nanofibres do have a higher mobility within the organism due to their small size. These and other properties mean that some nanomaterials and nanoproducts can raise significant concerns.

702. There are already initial efforts at classifying nanoparticles and nanofibres into risk categories. Such materials should nonetheless be subjected case by case to science-based risk assessment for the time being, as too much information on risk-determining characteristics is lacking and even very small differences, such as a coating, can critically alter a material's effects in biological systems. It is possible, however, to draw up a provisional prioritisation of nanoparticles and nanofibres based on selected criteria.

Classification of a material as high priority could then justify use of the precautionary approach with that material and hence further need for research.

703. The most obvious hallmark of nanoparticles and nanofibres is their exceptionally large specific surface area. Because chemical reactions take place at the surface of particles or fibres, nanomaterials are more reactive than their macroscale counterparts. This has been confirmed in various toxicity tests comparing nanoparticles and nanofibres with like material of larger particle size. Generally, however, reactivity is determined not only by particle surface area, but also by chemical composition and form. Reactivity can also be changed significantly by a coating. A further criterion is the tendency of nanoparticles and nanofibres to form aggregates or agglomerates, which alter their ability to enter environmental media and biological systems and also once again modify their reactivity. In the main, the reactivity of aggregates and agglomerates is probably between that of nanoscale and macroscale materials.

704. Aside from their large specific surface area, nanoparticles and nanofibres can also have other differences in physical and chemical properties that influence their reactivity and therefore their effects. This applies for example to the photocatalytic activity of titanium dioxide nanoparticles and the exceptional length-to-cross-section ratio of carbon nanotubes (CNTs). Conversely, no proof has so far been found that nanoparticles and nanofibres, once they have entered the organism, induce different endpoints to those already known. Animal tests, for example, have primarily shown oxidative stress and inflammatory reactions – effects that are also triggered by conventional macroscale and insoluble materials. For titanium dioxide nanoparticles and some carbon nanotubes there are also indications of genotoxic and carcinogenic potential that is probably connected with oxidative stress and inflammatory reactions and needs to be taken seriously especially in the case of CNTs. Nanoscale fibrous structures with high persistency and a very small cross-section relative to their length are suspected per se of being capable of inducing tumours.

705. A crucial property for science-based risk assessment is the ability of nanoparticles and nanofibres to reach parts of organisms and cells where comparable materials at a larger scale are not encountered. This includes the fact that the materials are free and unenclosed by a membrane within the cell and can cross certain barriers within the organism such as the alveolar epithelium (the barrier between alveolar sacs and blood vessels in the lungs) and the blood-brain barrier. In the same way as ultrafine particulates, nanomaterials that enter the lungs are therefore able to affect other organs. Very little is known to date, however, about the particle characteristics that determine absorption and the concentration levels attained in the blood and other organs. Similarly little is known of the potential effects of nanoparticles or nanofibres entering the brain, particularly after chronic exposure. It has not so far been possible to demonstrate penetration of healthy skin by titanium dioxide or zinc

oxide nanoparticles; the few studies available so far on behaviour with diseased skin do not demonstrate penetration but do demonstrate relatively deep penetration into the skin.

706. Some materials, such as zinc oxide and silver nanoparticles are able in physiological media to release ions that interact with cell components and thus induce effects. Investigation is therefore needed into whether such nanoparticles can reach and release ions in locations where no ions would previously have been encountered. In comparative studies carried out so far, some of these materials had a similar effect to comparable, soluble materials, which speaks in favour of the hypothesis that ions released by the nanoparticles concerned determine their toxicity. For silver nanoparticles there are also indications that not only the released ions but also particle phenomena are responsible for the effects.

707. There is as yet very little knowledge about the effects and behaviour of nanoparticles and nanofibres in the environment. Tests for acute toxicity on aquatic organisms at various trophic levels mostly indicate low toxicity. Only isolated studies are so far available on chronic toxicity. A number of problems have also been encountered in study design, notably in producing test suspensions. Even less information is currently available on toxicity to soil organisms. For an assessment of environmental risk, indications need to be investigated that nanoparticles and nanofibres are capable of promoting the accumulation of pollutants.

708. No measurements have been carried out to the SRU's knowledge of concentrations of nanomaterials in the two environmental media water and soil. This is partly because the necessary trace analysis is very intricate and nanomaterials are hard to tell apart from background levels of the same material (such as iron particles), both natural and anthropogenic. Some initial modelling of environmental concentrations has been done but shows weaknesses due to major gaps in the data. For example, there is a lack of reliable data on production quantities of nanomaterials. Important questions to answer in order to assess the environmental risk of nanoparticles and nanofibres include whether the materials keep their size, structure and reactivity in the different media and whether the latter already feature very similar colloids or finely distributed particles. Key characteristics of nanoparticles and nanofibres in this connection include persistency, solubility, tendency to agglomerate or aggregate and surface adsorbability. For the aquatic environment, naturally occurring colloids are of major relevance to the behaviour of nanoparticles and nanofibres in water. The initial indications are that certain nanomaterials such as carbon nanotubes and quantum dots are highly persistent in the environment.

Very few studies have investigated the behaviour of nanoparticles and nanofibres in the soil. In principle, most nanoscale materials have a strong affinity to adsorb onto organic solids, although this is influenced both by the characteristics of the soils and by the nanomaterials.

709. A pivotal issue in risk assessment of nanoproducts is potential exposure. The exposure situation is one area where there are notable knowledge gaps. It is possible for nanomaterials to be released as early as in production or processing. According to initial

studies, established protective measures are likely to reduce this risk significantly, but appraisal is still needed to make sure that occupational safety standards are in place for all application areas and are systematically applied.

For nanoproducts, a priority issue is whether nanoparticles or nanofibres are free within the product and if so in what form. Where nanomaterials are firmly bound in a matrix, exposure risk for consumers and the environment during use of the product is negligible. However, how more loosely bound nanoparticles and nanofibres behave in products and to what extent they migrate is unknown in most cases. Open-environment applications, for example the use of iron nanoparticles in environmental remediation, require thorough science-based risk assessment. Similarly little is known about the behaviour of nanomaterials on product disposal.

710. It is already possible to state that some nanoproducts raise concern. This includes the use of nanoparticles or nanofibres in consumer aerosols, as in sprays. For the aquatic environment, attention focuses among other things on the steadily increasing use of silver nanoparticles in a wide range of products. With regard to protecting human health, there is special concern about potential carcinogenic effects of carbon nanotubes and similar fibrous structures. The manufacture and use of such materials therefore requires special precautions and the observance of strict protective measures.

711. Summarising with regard to nanoparticles and nanofibres:

- Many questions remain unanswered as to behaviour and effects in the environment and the organism – especially given the great variety of potential materials and products;
- Various characteristics of nanomaterials relevant for risk assessement cannot be inferred from the corresponding macromaterial;
- There are already findings with regard to different absorption and distribution in the organism compared with similar, larger-scale materials;
- Due to their larger specific surface area and other nano-specific properties, such as photocatalytic activity, nanoparticles and nanofibres can have a higher reactivity compared with the bulk material. At the same time, their different absorption in the organism and their tendency to aggregate or agglomerate can lead to different dose-effect relationships.

Assessment of the environmental and health risks of nanoparticles and nanofibres cannot be solely based on established methods for conventional materials and must currently be performed separately for each material and each product. One of the great challenges consists of identifying potential risks of new nanoscale materials at an early stage; this can be achieved by classification according to nano-specific risk criteria that are yet to be established (see para. 4.5.3). There are already indications of serious concerns regarding a

number of nanoparticles, nanofibres and nanoproducts and hence of an abstract concern in the legal sense.

7.1.4 Need for action identified by the SRU

712. As the foregoing analyses have shown, it is not possible to make general statements about the risks of nanomaterials or of products that contain them. Science-based risk assessment necessarily involves uncertainty and to date requires case-by-case examination. Given the diversity of materials and applications, it has only been possible to look at a selection in any depth in this special report. For the materials and products covered in chapter 4, the SRU arrives at the appraisal that considerable knowledge gaps remain in large areas. In certain cases there is sufficient concern to justify a specific need for action. Such cases include in SRU's opinion the use of nanomaterials in consumer sprays and growing sales of consumer products containing silver nanoparticles. In the case of CNTs, there are concerns that some of the materials involved are thought to have carcinogenic potential. As CNTs are currently restricted to products where they are bound within polymers, the concerns mainly relate to the possibility of exposure in production and processing. Use of nanoscale iron (oxide) in open-environment applications, as practised in some countries, would likewise be incompatible with the precautionary principle.

713. This special report does not limit itself, however, to identifying areas where there are scientific indications of environmental and health risks. A further focus of study is on bringing out the structural legal and procedural deficits that stand in the way of precautionary management of nanomaterial-related risks. A primary aim is also to highlight avenues for reform that go beyond the thematic area of nanomaterials and are relevant to other new technologies and risks. The analyses in this report show that two types of deficit can be identified in current risk management practice relating to nanomaterials: Nano-specific regulatory gaps, and general deficits in application of the precautionary principle.

714. Due to the modified characteristics of materials in nanoscale form and the resulting knowledge gaps, it must be assumed that concerns raised by certain nanomaterials are only partly addressed by existing legislation. With few exceptions, nanomaterials are not dealt with separately in prevailing law, but in common with their macroscale counterparts. Where obligations exist relating to a specific material, the obligations apply equally for the material in nanoscale and macroscale form. The absence of a legal distinction between nanomaterials and macroscale materials leads in certain instances to gaps in the safety net that need to be closed (see recommendations in para. 7.2.3.2). In some cases, this has already been done in revisions to legislation where obligations relating to a substance now additionally apply to its nanoscale form. Where regulatory gaps persist, the legislature should move to ensure that nanomaterials are dealt with separately in the law.

715. Over and above this, analysis of the regulatory framework has also shown that besides deficits relating to nanomaterials in particular, there are also deficits in application of the precautionary principle in general. General deficits of this kind tend most to arise where rules and regulations turn solely around the legal concept of danger, thus failing to address the issue of scientific uncertainty. Ways must be found to close such deficits where they exist. This creates a need for precautionary instruments that are tailored to nanomaterials (see recommendations in para. 7.2.3.3). But the SRU has also pinpointed deficits in application of the precautionary principle not only for nanomaterials, but also for other chemical substances in instances where knowledge is incomplete. The position regarding these substances is likewise unsatisfactory and so it would make sense to take the provisions developed for application of the precautionary principle to nanomaterials and use them as a model in regulation of other substances. The focus of this special report, however, is on deficits in application of the precautionary principle in the regulation of nanomaterials – deficits that need to be addressed given the rapid development of more and more new materials.

716. As chemicals legislation and product legislation are enacted at European level for the purposes of the Single Market, the German government should concentrate its efforts targeting application of the precautionary principle to nanomaterials at European level, while also taking action of its own where it still has the scope to do so or by way of additional protection.

717. Managing the risks of nanomaterials is not only a matter of legislation, however; it also affects other areas of policy and society. Especially where traditional arrangements come up against their limits due to rapid technological advancement, and due to scientific uncertainty and problems of delineation and definition, a greater role should be accorded to ‘soft’ policy instruments and social dialogue processes. The SRU sees potential in this context for further development of precautionary-based governance approaches.

7.1.5 Policy instruments on the basis of the precautionary principle

718. Regulatory decisions on the basis of the precautionary principle should follow an analytical and a normative process as outlined in schematic form in figure 7-1 (see also section 5.2). The adoption of precautionary measures in a given instance crucially depends, however, on whether criteria can be found to demonstrate abstract concern and hence a need for precautionary action. Risk-related decisions should follow a science-based assessment of the concerns while also taking economic, social and political considerations into account (for example cost-benefit ratios, alternatives, and public acceptance). Such criteria, incorporating mitigating factors as well as factors that indicate concern, can then be used in the development of formulae for identifying the abstract concern. Decision rules along the lines of ‘the more/the less’ can be used to determine how far it is reasonable to

restrict fundamental rights and ensure that the proportionality principle is upheld when action is taken in a specific case. Such rules permit various regulatory objectives (see Fig. 7-1): Improving information and traceability, securing freedom of choice for consumers, restrictions on use or sale, or prohibitions. They must be applied bearing in mind what it is that the law is aiming to safeguard in each instance.

Figure 7-1

Model for the identification of precautionary action by the state

STEP 1: Science-based risk assessment	STEP 2: Normative risk evaluation	STEP 3: Risk management: Choice of instruments	STEP 4: Risk management: Specific design
Objective: Science-based assessment of the cause for concern	**Objective:** Analysis of cause for concern against benefits	**Objective:** Choice of type of instrument	**Objective:** Specific implementation according to substance
Criteria - General (eco)toxicological concern **- Nano-specific concern (substance) (see Fig. 4-2)**	**Criteria** - Science-based concern - Cost-benefit analysis - Availability of alternatives - Public acceptance - Risk context	**Criteria** - Proportionality - Non-discrimination - Transparency - Coherence	**Criteria** - Proportionality - Coherence - Effectiveness - Efficiency
Outcome: Description of potential risks and severity classification	**Outcome:** Decision on regulatory objective	**Outcome:** Choice of instrument(s)	**Outcome:** Specific design of the instrument
Minor concern (→ no regulation or regulatory objective 1)	No regulation	No action (possibly incentives for voluntary action)	E.g. guidelines, voluntary commitments
Moderate concern (→ regulatory objectives 1, 2 and/or 3)	Regulatory objective 1: Improve information and ensure traceability	Action including: - REACH registration - Data requirements	E.g. lowering of REACH quantity threshold for nanomaterials
	Regulatory objective 2: Secure freedom of choice for consumers	Action including - Classification, labelling and packaging (CLP)	E.g. new category for nanomaterials (CLP)
Major concern (→ regulatory objectives 1, 2, 3, and/or 4)	Regulatory objective 3: Restrict sale and/or use	Action including: - Restrictions - Restricted approval	E.g.. special restrictions within REACH
	Regulatory objective 4: Prohibition	Action including: - Prohibition	E.g. mandatory authorisation (and no authorisation granted) under REACH

SRU/SR 2011-2/Fig. 7-1

Various policy instruments go to make up the regulatory toolkit for management of nanomaterials and nanoproducts:

- *Notification requirement:* Establishment of a notification requirement and a register for products containing nanomaterials, for the information of authorities and/or the public.
- Labelling obligation: Product labelling to inform consumers of nanoscale substances in products and to ensure that consumers can exercise free choice.
- Registration obligation: Comprehensive application of the ‘no data, no market’ principle for nanomaterials.
- General authorisation: Restriction of the use of nanomaterials to those included in a ‘positive list’ following safety assessment.
- Individual authorisation: Nanomaterials for which there is an abstract concern or where scientific opinions on their hazardousness are contradictory are presumed to pose a danger. To use such substances, a producer or user must present facts to rebut this presumption.
- Strict liability: Rules that hold producers or users responsible regardless of negligence or fault.. For nanomaterials and nanoproducts that are not subject to authorisation, strict liability creates an incentive to carry out research into effects before putting materials or products on the market.
- Mandatory permits for installations/notification requirement: Authorities should know what installations nanomaterials are produced or used in and must be able to stipulate emission or pollution limits to protect the environment.
- Statutory prohibitions/restrictions: Prohibitions or restrictions on the use of nanomaterials in specific products or for specific purposes in order to protect people and the environment from exposure.
- Planning: Adoption of measures for the management of nanomaterials and nanoproducts in order to protect water supplies.
- Need assessment: As part of the authorisation procedure, producers of nanomaterials and nanoproducts can be required to prove socioeconomic benefits in specific instances and authorisation withheld if the benefits are small compared with the risks.

7.2 Recommendations for a precautionary approach to nanomaterials

719. The recommendations for application of the precautionary principle to nanomaterials set out in the following relate partly to the various state risk control activities (risk assessment, risk evaluation and risk management) but also take in the importance of

processes of social dialogue, the role of the consumer, and industry responsibility. They correspondingly affect various areas of policy making and society.

7.2.1 Improving knowledge

720. Knowledge remains patchy about the effects and behaviour of nanomaterials in the environment and in the organism. More is known about long-established materials, however, than new materials. For example, there are a large number of toxicity studies, both *in vitro* and *in vivo*, on titanium dioxide, gold and silver nanoparticles. The main deficit with regard to these nanoparticles is the lack of long-term animal model studies at low or realistic exposure concentrations. Some studies have also been done with other materials, including on their environmental effects, such as short-term ecotoxicology tests. Growing interest in the risks of nanomaterials in recent years has prompted a steady increase in research projects and published studies. However, one of the reasons why nanotechnology attracts special attention is the sheer diversity of structures in research and development. A change of coating alone can produce materials of identical dimensions but with potentially very different biological effects. Keeping up with this trend as far as possible is with any doubt a special challenge for risk research and one for which special conditions must be created.

721. A first important step in the management of nanomaterials is to standardise the terminology. An ISO standard has already been published for manufactured nano-objects (MNOs) and a further standard for nanomaterials has been proposed. However, there is still a lack of standardised methods for ecotoxicity and toxicity testing and of the related material standards. The importance of this is demonstrated among other things by the limited intercomparability of various studies in which very different methods have been used to produce test suspensions. In a first step towards addressing such deficits, the Organisation for Economic Cooperation and Development (OECD) at an early stage set up working groups dedicated to the standardisation of test methods and materials. These working groups have already published initial results. It is important that this process should be fully completed as soon as possible.

722. If suitably implemented, registration under the REACH Regulation can serve as a key means of generating data on the properties and effects of nanomaterials. This provides a way of assigning the obligation for generating such data to producers. The SRU therefore proposes a revision to the REACH Regulation requiring nanomaterials to be registered with their own dossier and to make the necessary changes in particular regarding thresholds and standard information requirements. A core data set should additionally be provided for industrially manufactured nanomaterials (see para. 7.2.4.2 for details).

723. Publicly funded research is a further important means of closing knowledge gaps in risk research. In nanotechnology, the SRU advocates making risk research a central focus alongside basic research among the programmes funded by the Federal Ministry of

Education and Research (BMBF). A third focus area could comprise applications of nanotechnologies where there is special public interest, as with the development of technologies for environmental protection.

724. Various suggestions have already been proposed for research projects on environmental health risks. In the following, the SRU would like to highlight a number of focus areas for risk research relating to nanoparticles and nanofibres:

- Production of material standards for toxicity and ecotoxicity testing;
- Identification of parameters for determining toxicity in order to categorise nanomaterials by risk;
- Migration from products;
- Behaviour and toxicity following oral ingestion;
- Penetration of damaged or diseased skin;
- Chronic toxicity following inhalation, with realistic exposure concentrations;
- Behaviour in natural aquatic systems and soils and identification of parameters determining behaviour in these media for categorisation purposes;
- Chronic effects on aquatic and terrestrial organisms;
- Development of reliable detection methods for nanomaterials in foods and environmental media and for metering the exposure of individual workers when working with nanomaterials;
- Behaviour of nanomaterials and products containing nanomaterials in waste disposal (collection, transportation, mechanical processing, recycling and recovery, incineration, and landfilling) (see also para. 7.2.3.2).

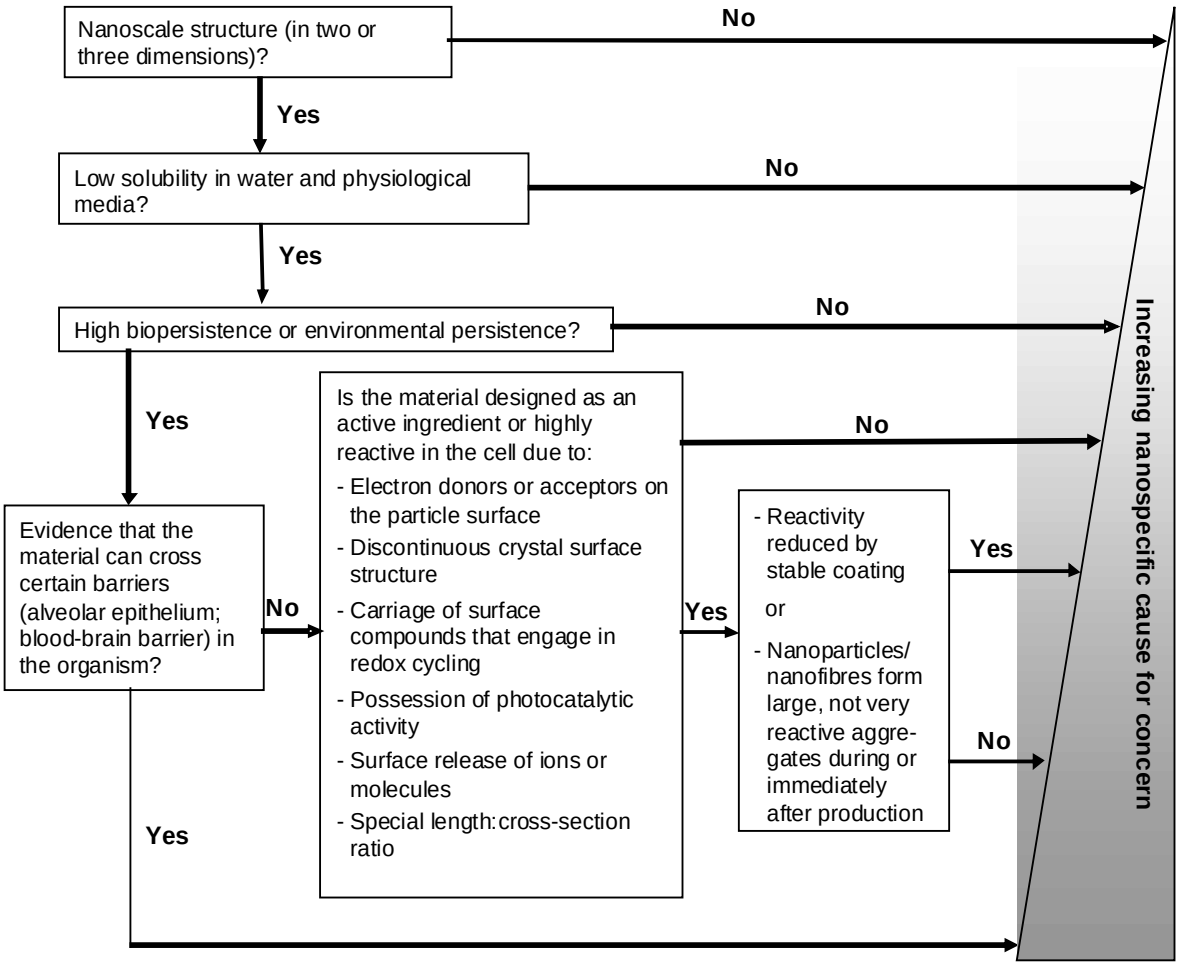
7.2.2 Development and application of science-based criteria for precautionary risk assessment

725. Dealing with newly developed nanomaterials with little or no risk data poses a special challenge. For this purpose, the SRU proposes criteria for preliminary science-based risk assessment (see Fig. 7-2) that help apply the precautionary principle to such materials by making it possible to identify abstract concerns. The criteria should relate to easily determined material properties so that initial risk analysis can be carried out at a very early stage. In terms of inherent properties, this means size, solubility, persistence and surface reactivity of nanoparticles and nanofibres. Evidence of high reactivity includes the presence of electron donors or acceptors on the particle surface (such as metals) or for fibrous materials a certain ratio of length to cross section. Mitigating criteria, on the other hand, include stable, reactivity-reducing coatings and a strong tendency to form aggregates or agglomerates. Important factors in assessing products and determining exposures include

production quantities, how a product is used and how firmly the nanomaterial is bound within the product or in a matrix (see Fig. 7-2).

Figure 7-2

Decision tree for risk categorisation of nanoparticles and nanofibres



SRU/SR 2011-2/Fig. 7-2

Before these criteria can be used in practice, of course, they need to be made specific and quantified to enable priority setting. If information on a given criterion is lacking, the criterion should be estimated on a precautionary basis. One aim could be to build such indicators into guidance for dealing with nanoparticles and nanofibres in development, production and processing.

726. Another option for application of risk criteria to nanomaterials in the SRU's opinion is registration under the REACH Regulation. This so far requires a chemical safety assessment, including an evaluation of exposure and risk, for all hazardous substances. The above risk criteria could be used to carry out a preliminary risk assessment for a nanomaterial and to determine whether the manufacturer needs to perform a chemical safety assessment. The risk criteria should also play a part in authorisation under the REACH

Regulation. In conjunction with an authorisation procedure that places greater emphasis on the precautionary approach, the criteria should for example be capable of making nanomaterials subject to authorisation where a preliminary risk assessment identifies high priority.

727. Similar importance should be placed on the criteria in product legislation. In this connection, the SRU recommends for weakly regulated nanomaterials that producers should be required to perform a preliminary risk assessment and in high risk cases a product risk assessment. These precautions should be built into initiatives to promote corporate responsibility with regard to nanomaterials, and stricter liability rules should be enforced in order to secure compliance. The criteria could also be used for market monitoring in connection with product legislation. Finally, if supervisory authorities are to issue prohibitions and restrictions based solely on an abstract concern, such criteria can usefully be applied in narrowing down that concern.

7.2.3 Closing regulatory gaps and promoting precautionary risk minimisation

7.2.3.1 Shaping the regulation of nanomaterials

Need for coherent legislation on nanomaterials

728. Given the diversity of products using nanomaterials and the various pathways by which they can enter environmental media, it would at first seem logical to refrain from developing a uniform regulatory regime either at national or at European level. Regulation of nanomaterials should as far as possible be based on and build upon existing legislation. This applies all the more in areas where it is first necessary to close nano-specific regulatory gaps. Special policy instruments applying solely for nanomaterials can of course be integrated into the relevant legislation on a sector-specific basis. However, the complexity arising from the number of affected sectors and bodies of legislation involved results in a loss of transparency for the public. A framework is also lacking that lays down certain ground rules for the management of nanomaterials.

For the reasons stated, the SRU proposes the enactment of cross-sectoral legislation, partly to amend the various elements of sector-specific legislation but also so that certain cross-sectoral stipulations can be covered at a general level. These general stipulations should include:

- A definition of nanomaterials, on the basis of which the scope of sectoral legislation can be stipulated separately from case to case.
- A blanket clause that the precautionary principle is to be applied to ensure safe management of nanomaterials in view of the still open knowledge gaps.

- Notification requirement for the use of nanomaterials in products and based on it the establishment of a nanoproduct register.
- Powers to take precautionary action on a case-by-case basis to protect health and the environment from products where an abstract concern has been identified.

This legislation should preferably be enacted at European level. However if this should prove not to be feasible in the foreseeable future, a possibility would be an omnibus act in Germany. For this purpose, the scope remaining for national action should be explored and an appraisal should be carried out to determine how far existing European legislation can be supplemented at national level to provide additional safeguards.

Making nanomaterials the focus of specific legal obligations

729. Existing chemicals legislation is not sufficient for precautionary regulation of nanomaterials as the nanoform of chemicals. This is partly because it is often unclear how nanomaterials should be dealt with under the law. By definition they are substances and as such are generally subject to regulation but – with few exceptions – they are legally not considered separately from their macroscale counterparts. This is not justified given that they can potentially have modified properties and nano-specific features. Nanomaterials should therefore generally be treated *as* separate substances *in their own right*. An exception is REACH, where for systematic reasons the SRU recommends that nanomaterials are treated, by way of a legal fiction, *as if* they were substances in their own right (see para. 6.2.1.1.13). This equivalence does not achieve the same level of safeguard, however. The rules laid down for macroscale substances are not applicable without modification to nanomaterials (e.g. mass concentration limits and quantity thresholds in tonnes). Nanomaterials being a class of substances about which little is yet known, it is also necessary in some instances to provide for special instruments for risk control. For this reason, nanomaterials as such should be made the focus of specific provisions.

As a first step, nanomaterials need to be given a uniform definition. The SRU supports the European Commission's proposal of adopting a uniform European definition of nanomaterials that provides a framework for policy making and legislation (para. 3.3). However, the SRU considers the European Commission's proposed size limit of 100 nm to be too small to serve such a framework covering a wide variety of purposes such as research funding, product notification and chemical or product regulation. For precautionary reasons, nanomaterials should at least be investigated and monitored up to a size of 300 nm. The size limit should be made to relate solely to primary particles. Agglomerates and aggregates of primary particles should be covered by the definition without any size limitation. The definition can then be adapted as necessary for specific regulatory purposes (see section 3.3).

In a second step – to the extent that this makes sense with regard to the individual provisions for substances within the specific areas of law – it should be made clear that nanomaterials

are to be treated as independent substances (by way of a legal fiction). Where modifications and additional instruments are needed, these can be introduced separately for precautionary regulation of nanomaterials.

Development of a nomenclature for nanomaterials

730. No official nomenclature currently exists for nanomaterials. This is misleading to the extent that the nanoscale form of a substance is subsumed under its macroscale form. This has implications for example when substances are included in positive lists or products are labelled with the substances they contain. The nomenclature for substance identification therefore needs to be extended. For chemicals, the options in this regard consist of using CAS numbers, IUPAC names and EC numbers. The SRU proposes that EC numbers should be used preferentially as their assignment is controlled by the EU. Alongside assignment of separate EC numbers for specific nanomaterials, it would be desirable in the interests of transparency for the numbers to be appended with the letter ‘n’. Where a substance is designated by name, the affix ‘nano’ should be used to indicate its nanoscale nature. Targeted designation of nanoscale substances should also be possible for foods. In this connection it would be useful to make use of both product names and E-numbers. The SRU therefore proposes for nanomaterials that E-numbers should be appended with an ‘n’ and product names should likewise carry the suffix ‘nano’. In this way, indication of the nanoscale nature of a substance is directly contained in the designation.

7.2.3.2 Closing nano-specific regulatory gaps

Assessing the safety of nanomaterials

731. For legal obligations to be proportionate, they must correspond to the potential level of hazard involved. So that this can be determined for individual measures, it is necessary to collect the data needed to assess the safety of nanomaterials. The instrument for collecting data on substances is the registration obligation under the REACH Regulation. This is not however designed in such a way as to ensure the compilation of all data relevant to safety assessment (see section 6.2.1.1.3). To remedy this situation, the SRU advocates:

- *Separate dossiers with standard information:* Nanomaterials should in all instances be registered with a separate dossier independent of their macroscale counterparts. Alongside separate registration, it must also be ensured that the transitional periods applicable for phase-in chemicals and the exceptions formulated for certain chemicals (annexes IV and V of the REACH Regulation) do not apply for newly manufactured nanomaterials. Quantity thresholds also need to be lowered for nanomaterials. In parallel, it should be examined to what extent other parameters are suitable for triggering the staggered information requirements. The standard information requirements for registration must also be revised and modified or supplemented with a view to the special features of nanomaterials (see below under “testing requirements”).

- *Core data set for nanomaterials:* For industrially manufactured nanomaterials, regardless of any quantity thresholds, the European Chemicals Agency (ECHA) should be provided with a core data set whose scope can vary according to the size of the nanomaterials. For nanomaterials up to 100 nm, an extended core data set should be provided on the basis of which registrants can carry out a preliminary risk assessment. The information to be provided must therefore include data on a nanomaterial's size distribution, solubility, biopersistence, toxicokinetiks and acute chronic toxicity. As it is legitimate to at least monitor larger nanomaterials on precautionary grounds, a simplified core data set should be submitted for nanomaterials up to a size of 300 nm, providing physical and chemical data for characterisation of a material and information on its use. The aim of this simplified core data set is to extend the body of knowledge on nanomaterials as quickly as possible.

Based on the compiled data, a nanomaterial's manufacturer or importer should carry out a safety assessment and derive a hazard classification. The main instrument here alongside the requirement to do a chemical safety assessment as part of registration under the REACH Regulation is classification under the CLP Regulation. This is initially the manufacturer's or importer's own responsibility. For certain substances, however, an official safety assessment is provided for. The relevant instrument here is substance evaluation under the REACH Regulation, although ultimately this can only be carried out for a fraction of all substances. By virtue of the requirements for the various safety assessment instruments and the way they are implemented, nanomaterials must currently be assessed neither by manufacturers, nor importers, nor authorities. As safety assessment of nanomaterials is a precondition for adequate risk management, this situation is unacceptable. The SRU therefore calls for the following specific changes:

- *Chemical safety report for all nanomaterials for which there is abstract concern:* A chemical safety assessment encompassing an exposure and risk assessment as set out in Article 14 (4) of the REACH Regulation should be carried out for all nanomaterials that raise concern. To narrow down that concern, the SRU proposes the use of the material-oriented criteria for precautionary risk assessment as presented in section 7.2.2.
- *Classification:* In instances where they can be assigned to a hazard class and category according to the classification criteria in the CLP Regulation, nanomaterials must be classified like other substances. The classification criteria should therefore be appraised to ensure that they are adequate to the special characteristics of nanomaterials. If new endpoints are discovered for nanomaterials (for example other than infections), new hazard classes must be introduced to provide for them. Classification among the various hazard categories already includes a number of precautionary elements (safety margins and classification if there are grounds for concern). These should be enhanced and expanded upon, however.

- *Substance evaluation:* The ECHA and the member states should ensure in the development of criteria for selecting substances for official evaluation that nanomaterials also meet those criteria.

Ensuring the safety of especially sensitive consumer products

732. Manufacturers of products are under a general obligation to ensure the safety of the products they manufacture under their statutory producer responsibility and also under liability law. The legislature has nonetheless chosen to introduce authorisation procedures for especially sensitive consumer products such as foods and food contact materials. The same applies for certain ingredients of cosmetics. The aim here is to protect consumers from substances that are potentially hazardous to health. With a view to these established authorisation procedures, it must be ensured that nanoscale materials, too, are only allowed to be used when their safety is guaranteed. For these areas of law, the SRU advocates:

- *Separate authorisation of nanomaterials:* To apply the same safeguards as for macroscale materials, steps must be taken (where this has not already happened) to ensure that nanomaterials require separate authorisation when used in the especially sensitive consumer products mentioned above. This is the only way to guarantee that a separate safety assessment is required for nanomaterials in advance of authorisation.
- *Authorisation requirements:* Authorisation should only be granted when the use of nanomaterials is proven to be safe. This means that testing requirements and safety assessments must be sufficiently tailored to the special characteristics of nanomaterials. As long as this cannot be ensured due to a lack of risk assessment methods, authorisation should only be granted if manufacturers can prove – according to the concept of the rebuttable presumption of danger – that on current knowledge the risk assessment methods used adequately address the special characteristics of nanomaterials. Additionally, authorisation should be granted subject to review on the emergence of new findings. Authorisation should also be made subject to the disclosure of methods to detect the presence of nanomaterials in products. This creates an incentive to develop such methods and gives the authorities the ability to monitor compliance with the terms of authorisation.
- *Testing requirements:* Key factors with regard to testing requirements are the solubility of nanomaterials, their distribution in biota and the environment, and chronic toxicity. Data on these aspects should be presented and the test design tailored to the special characteristics of nanomaterials.

Regulating the manufacture and use of nanomaterials in industrial facilities

733. Nanomaterials are already produced in industrial facilities, in some cases in large quantities. However there are no statistics on the numbers of such facilities involved. Requirements for plant construction and operation are decisive to the safety of the

environment and of the population in the surrounding area. The manufacture and use of nanomaterials in industrial facilities should therefore be subject to official monitoring where necessary. The SRU proposes the following specific measures:

- *Powers to require permits and/or a notification requirement:* As the focus of risk analysis for synthetically manufactured nanomaterials is currently on poorly soluble or insoluble nanoparticles and nanorods, at least the manufacture and use of these should be brought under the pollution law powers to require permits under paragraph 4 of the German Federal Immission Control Act (BImSchG). Over and above this, consideration should be given to establishing a notification requirement for the industrial manufacture and use of all other nanomaterials. This would help in judging the relevance of nanomaterials in pollution control. Granted permits and submitted notifications should be kept in a central register.
- *Safe use:* In order to ensure that plant operators take safety precautions to prevent accidents from happening and, for the event that accidents do occur, in order to minimise their impacts on the population and the environment, the German Major Accidents Ordinance (Störfallverordnung) should be made to apply to facilities that make or process nanomaterials about which there is abstract concern for the purposes of the precautionary principle and which are used in facilities in significant quantities. The latter point in particular requires the definition of appropriate parameters and related thresholds.
- *Management of substances hazardous to waters:* It should be ensured that nanomaterials are separately classified according to the various water hazard classes. Classifying nanomaterials in this way will trigger the application of appropriate requirements for industrial facilities. If a nanomaterial cannot be classified with certainty, any facilities manufacturing or processing it must come under the strictest requirements.

Minimising environmental releases of synthetic nanomaterials

734. Substances can never fully be prevented from entering the environment. To ensure the best possible level of environmental protection despite this, prohibitions and quality standards are supplemented with emission limits that are generally based on currently available knowledge. Too little is so far known both about the release of nanomaterials and about their behaviour in the environment. Normative stipulation of prohibitions, quality standards and emission limits, however, requires an adequate basis for decisionmaking and hence science-based knowledge. In this situation, to protect the environment as far as possible from releases of nanomaterials, the SRU proposes the following:

- *Clarification of scope:* First, legislative clarification is needed that authorities' powers of intervention also apply in the case of nanomaterials. Authorities can then make decisions on a case-by-case basis until normatively stipulated prohibitions, quality standards and emission limits are in place.

- *Emission minimisation requirement:* There should be a binding rule that emissions of nanomaterials about which there is abstract concern are to be limited as far as possible, subject to observance of the proportionality principle.
- *Research:* In-depth research is needed into the effects of nanomaterials on the environment in order to determine environmental thresholds. This is a precondition for being able to issue prohibitions, quality standards or emission limits for individual nanomaterials or identifiable groups of nanomaterials. In particular, suitable parameters need to be found for the stipulation of emission limits. There is a need to delineate the current state of knowledge and develop suitable testing methods.
- *Guidelines for authorities:* Authorities should be given guidelines to refer to in formulating requirements on a case-by-case basis. They should be assigned comprehensive information rights for this purpose.

Preventing waste containing nanomaterials

735. Nanomaterials are already used in a very wide range of products. Even if a nanomaterial is firmly bound inside a product, its release can no longer be ruled out once the product enters the waste stream. Efforts to prevent nanomaterials that raise abstract concern from entering the environment through the waste pathway must therefore start as early as in the product design stage. The SRU therefore advocates investigating to what extent the use of nanomaterials in products – where they can be substituted by more environmentally compatible and equally suitable other materials – needs to be prohibited or restricted with a view to the waste stream. This may require an assessment of alternatives in which risks and opportunities are compared over the entire lifecycle.

Environment-friendly management of waste containing nanomaterials

736. Little is yet known about the behaviour of nanomaterials in the waste stream, and there are no specific rules as a result. Instead, waste containing nanomaterials must be recycled, recovered or disposed of by the same rules as waste that does not contain them. This is questionable considering the special characteristics of nanomaterials, with altered properties such as reactivity. Waste management rules must therefore be adapted to the new challenges while upholding a distinction between production waste and municipal waste.

Production waste containing nanomaterials comes from making and processing such materials and so can be separately collected at source. Measures to ensure precautionary management of production waste containing nanomaterials therefore include:

- *Classification as hazardous waste:* Given the huge knowledge gaps about the behaviour of nanomaterials in the waste stream and given their special characteristics, it is justified, on precautionary grounds, to assume by way of a rebuttable presumption of danger that production waste containing nanomaterials is hazardous waste. Classification as

hazardous waste triggers specific requirements to ensure careful management (such as requirements on reporting, treatment methods to be used, and separation from other types of waste).

- *Separate collection:* Producers and processors should be required to collect production waste containing nanomaterials separately, store it separately and subject it to suitable treatment.
- *Management of production waste containing nanomaterials:* Recycling, recovery and disposal of production waste containing nanomaterials by the same rules as for other types of waste is not recommended. There is therefore enormous need for research in this regard. The SRU is of the opinion that producers and processors have a duty to contribute in the search for solutions.
- *Landfilling:* The criteria for the acceptance of waste of each landfilling class must be appraised to identify any need for adaptation for production waste containing nanomaterials.

Municipal waste containing nanomaterials poses a special challenge as separate treatment would appear to be unfeasible. Current waste recycling, recovery and disposal rules should therefore be reviewed to make sure that they make adequate provision for the special characteristics of nanomaterials. The SRU proposes the following specific measures:

- *Classification as hazardous waste:* Municipal waste containing nanomaterials should only be classified as hazardous if the nanomaterials themselves are hazardous. What needs to be modified here is the classification system under the CLP Regulation.
- *Take-back schemes:* It is neither feasible nor helpful to generally distinguish between municipal waste that does and does not contain nanomaterials. It should be investigated whether separate collection should be required for specific types of waste containing nanomaterials, for example because of the quantities expected or of specific properties.

Regardless of the waste type (production waste or municipal waste), the SRU sees a particular need for research on the following regulatory issues:

- *Testing methods:* The testing methods to be developed for nanomaterials must be suited to the type of waste stream (for example exhaust air from waste treatment or flue gas from waste incineration).
- *Spreading of sewage sludge:* Research should be carried out into how nanomaterials behave in sewage sludge and whether specific prohibitions or thresholds are necessary as a result. This also creates a need for suitable parameters and methods for testing sewage sludge.
- *Recycling and recovery:* It should be investigated to what extent nanomaterials can be released in waste treatment processes (such as shredding, sorting, heating and

agglomeration). Research is also needed into how far nanomaterials can interfere with or prevent recycling and recovery.

- *Waste incineration:* It is necessary to determine to what extent incineration requirements are still appropriate when waste contains nanomaterials.
- *Landfilling:* Research must be carried out into whether landfill requirements need to be redrafted as landfilling of nanomaterials is likely.

7.2.3.3 Enhancing precautionary environmental and health protection

Powers to act on abstract concern

737. Under the precautionary principle, the state should fundamentally be able to take specific action based solely on an abstract concern. That concern should be narrowed down using easily applied criteria. With nanomaterials, it is therefore helpful to carry out a precautionary risk assessment using the criteria for nanomaterials and nanoproducts set out in section 7.2.2. In addition, however, the foundations should be laid for state action in specific cases based solely on the existence of an abstract concern. To achieve this, the SRU recommends gradually shifting the burden of proof onto the risk originator. A means of identifying the cause for concern needs to be built into substance and product authorisation procedures, and this can be done by creating a rebuttable presumption of danger. It is then up to the risk originator to rebut the state's presumption concerning specific cause-effect relationships and hence the cause for concern (see para. 2.3.4.2).

Risk management for chemicals

738. Chemicals legislation places strong emphasis on producer and importer responsibility and only provides for official risk management with substance of very high concern and with unacceptable risks. Intervention is therefore only generally permitted to avert dangers. With nanomaterials, however, not enough is yet known to meet the legal definition of danger. At most, nanomaterials can only be said to raise abstract concern for the purposes of applying the precautionary principle. However, chemicals legislation does not provide the legal basis to support official intervention for precautionary action. The SRU therefore advocates that authorities should be able to act when there is an abstract concern. Specifically this means the following:

- *Powers to require authorisation:* A blanket clause must be added to Article 57 of the REACH Regulation allowing substances to be made subject to approval when there is a mere *possibility* of severe effects on human health or the environment. Currently, authorisation is required where there is a *probability* of serious effects and a substance has properties of high concern.

– *Restriction:* So that individual, application-related action can be taken for precautionary risk control, either restriction criteria must be construed in line with the precautionary principle (see Article 1 (3) of the REACH Regulation) or circumstances triggering restrictions must be defined in a way that implements the precautionary principle.

To help authorities identify substances for which precautionary risk management is needed, the criteria yet to be developed on the basis of Article 44 of the REACH Regulation should be defined in such a way that substance evaluation is required for nanomaterials when there is an abstract concern.

Risk management for products

739. In most instances, product safety is guaranteed by producers' statutory product responsibility and by liability law. Certain products are already more strictly regulated, however, notably with an authorisation procedure for specific substances that products may contain. Nonetheless, this does not necessarily apply to all products that release substances and to which consumers are exposed. It would be helpful here to create powers for the state to act with regard to individual products, groups of products or types of use based on only an abstract concern. This would include powers to require authorisation, to issue prohibitions and restrictions, and to impose information and labelling obligations. Where there is no ex-ante regulation for the marketing and use of products in the form of an authorisation procedure, it should be ensured that there are at least powers to take precautionary action for products that are placed on the market. Rather than requiring proof that a product is hazardous, these powers should allow competent authorities to restrict production, marketing or use of a product even if concerns remain at an abstract level. The burden of proof in this case is still on the state but the standard of proof is lowered.

Market monitoring requirement

740. Long-term effects in particular may not emerge until substances or products are already on the market. To avoid being held liable later, producers are already required to monitor their products after placing them on the market. There is not, however, a means of requiring systematic investigation and notification of new findings. Producers should therefore be required to monitor the market so that any adverse effects are quickly detected and action taken as needed. A requirement of this kind could build upon the update obligation under Article 22 of the REACH Regulation.

7.2.4 Improving information and resource availability for authorities

Improving information availability for authorities

741. Authorities currently do not have enough information about the production and use of nanomaterials – neither on industrial facilities where nanomaterials are produced, nor on

(risk) characteristics of the nanomaterials made, nor about what products contain them. This information deficit exists because in most areas nanomaterials are not treated separately from their macro counterparts and there is a lack of instruments of law securing access to the information needed. If only for competitive reasons, companies are often reluctant to give out detailed information on the (risk) characteristics of nanomaterials or the use of nanomaterials in their products. The lack of access to information is all the more of a problem because detecting nanomaterials in products and in the environment is both technically difficult and expensive. In Germany the problem is compounded by major cutbacks on both staff and funding in the administrations of the sixteen German states.

742. The SRU considers this lack of information about the market to be incompatible with the precautionary principle. It is part and parcel of risk management that new scientific findings can give rise to a need to act at short notice. Awareness of the potential sources of risk is indispensable for a rapid and effective response by the competent authorities. Unlike toxicological questions that can only be answered by long-term research, poor availability of information to authorities about products and uses is easily remedied. The SRU therefore recommends as follows:

- *Products:* A *notification requirement* should be adopted as soon as possible for products that contain manufactured nanomaterials. The notification requirement should feed into a semi-public *product register*. Such a product register should ideally be established at EU level for maximum geographical reach and minimum obstruction to trade. Work should nonetheless continue on plans for a national register that can be set up at short notice in case the European register initiative launched by the Belgian EU Council Presidency is postponed or fails (Belgian Presidency of the Council of the European Union, 14th September 2010). Various aspects should be taken into account when developing the register: Overlaps should be avoided with other notification requirements and with the traceability system. The product register is intended first and foremost for authorities, but certain basic information should be made publicly available. For precautionary reasons, a broad definition of nanomaterials should be used for the notification requirement. In terms of particle size this means nanomaterials at a scale of up to 300 nm, with agglomerates and aggregates of primary particles being included without any size limit. Appraisal is needed to determine how far the scope should be restricted to specific products.
- *Substances:* Improving the information available to authorities on substances, their properties and their risks is an aim of registration under the REACH Regulation. For this to work for nanomaterials, they need to be registered separately.
- *Industrial facilities:* So that appropriate concentration limits can be set for facilities where nanomaterials are manufactured or processed or whose emissions contain nanoscale particles, authorities need to be notified when nanomaterials are manufactured. The

manufacture or use of nanomaterials must therefore be made subject to approval or at least notification.

Improving resource availability for authorities

743. Implementing and enforcing the various rules and regulations affecting nanomaterials and nanoproducts takes considerable specialist capabilities and resources – all the more so given the doubts that current scientific and technical implementation aids such as standards, technical manuals and concentration limits are suited to dealing with nanomaterials. At the same time, these are difficult to adapt as long as there are large knowledge gaps, notably about toxicology. The result in many areas is major uncertainty about how to interpret and apply specific rules.

The work of authorities is hindered by the fact that methods for detecting and analysing nanomaterials in products and the environment are not yet technically mature. Because of this, even if, say, modified industrial emission limits are adopted for specific nanomaterials, it is doubtful that the technology is there to monitor compliance. A similar problem is faced with products: as it is often difficult or impossible to detect nanomaterials in specific products (such as foods), authorities needing to monitor the market mostly have to rely on inspections of production facilities. Inspections tie up large amounts of resources, however, and can only be carried out if it is known which companies make and use nanomaterials. The recommendations given in this report for improving information on substances, products and installations (mainly the REACH Regulation, notification requirements and a product register) could provide the basis for better enforcement capabilities.

Even if authorities are provided with better information on the manufacture and use of nanomaterials, enforcement of chemicals, product and environmental law will still involve large uncertainties for the foreseeable future. It is therefore pivotal for competent authorities to have the staff and capabilities to properly implement the statutory requirements in each instance. However, this is not even the case in conventional environmental administration (SRU 2007). Key points of criticism include the weakening and abolition of the middle, subordinate administrative level (lower-level regional government) and cutbacks in resources and staff. Municipal-level authorities in particular (such as trade supervisory offices) come up against the limits of their human, professional and financial resources in dealing with the specific challenges of nanomaterials.

7.2.5 Continuing social dialogue

744. Efforts to promote cooperative and constructive expert dialogue on nanotechnology began relatively early in Germany. On balance, the SRU takes a positive view of the dialogue efforts engaged in so far in Germany and the rest of the EU. State actors and also parts of industry are aware how important it is to involve the public, and have launched useful initiatives to promote communication and dialogue.

745. The resulting events and discussion forums nonetheless reach only a small group of experts from business, research, government, environmental organisations and consumer organisations. Neither in Germany nor in the rest of Europe is there adequate, broad social debate on benefits, risks and development paths. Development, use and regulation of nanomaterials thus go on evolving without the broader public being sufficiently aware. The SRU considers this deficit to give some cause for concern: If experts are left to devise innovation and risk strategies on their own, then unforeseen public acceptance problems and polarisation of opinions are a possible future outcome.

746. Addressing this is not an easy task, however, given the heterogeneity of nanotechnology as a subject area and the difficulty of delineating it. Broad social dialogue cannot be brought into being on command. While concerns about nanotechnology risks remain vague and relate more to how little is known than to specific evidence of harm, public interest will probably stay limited. Attempts should nonetheless be made to further develop and if possible broaden the social dialogue that has already been initiated, under a strategy on the further development of nanotechnologies. It must be borne in mind in this connection that dialogue processes cannot replace political decision-making under the framework of established democratic structures. Such processes are indispensable, however, in sounding out what nanotechnology applications society finds desirable, acceptable, controversial or unacceptable.

747. To this end, the SRU identifies a need to build on existing activities in various different areas. Such activities should follow a number of guiding principles:

- *Balance and transparency:* In Germany so far there has tended to be dichotomy between information campaigns emphasising benefits on the one hand and more balanced open-ended discursive processes on the other. The SRU recommends that the German government should develop a shared, consistent dialogue strategy that gives equal weight to the opportunities and risks and includes approaches for developing model frameworks. Given the uncertainty concerning potential risks, lasting confidence in policy and regulatory decisions can only be secured through transparency.
- *Focus on specific issues:* The debate on the heterogeneous family of technologies referred to as nanotechnology is already difficult today. With technological development expected to follow diverging strands, covering the subject area as a whole will become less and less feasible. Dialogue processes should therefore increasingly focus on specific sub-issues (such as recycling and waste, or the use of rare metals) and product areas (such as foods, or open-environment applications).
- *Extension:* Dialogue processes so far largely focus on specific risks to the environment and health. The debate on regulating nanomaterials has largely been held as a legal and technical discourse barely accessible to the lay public. While there is no question that discourse of this kind is important, broader debate should be conducted in parallel, for

example on how much precaution society demands and what products are considered to pose risks that are acceptable. With the onward development of nanotechnology in medical research, more attention should be paid to fundamental ethical and social issues. However it is important here to keep the focus on realistic scenarios for the technology and to draw a clear line between such scenarios and merely theoretical prospects.

– *Continuity and integration:* Rather than only occurring as part of projects with a fixed end date, public debate should be institutionalised. More firmly tethering technological development to social values and expectations is an ongoing task that the German government must address to a greater degree. A starting point might be greater institutionalisation of social science and interdisciplinary accompanying research that today tends to be carried out on a less coordinated basis. The SRU also recommends that the dialogue on model approaches for nanotechnology launched by the NanoKommission should be continued. Safety and the potential contribution of nanotechnology to environment protection and resource conservation should take a central place in this dialogue.

7.2.6 Securing transparency and freedom of choice for consumers

748. Regarding the question of how far consumers should be informed about the use of nanomaterials in products, it is a matter of comparing the advantages and disadvantages of different ways of providing information. On the one hand, consumers should fundamentally be given the option of consciously deciding for or against specific products. Many individuals demand precisely this freedom of choice (see section 6.3.4). On the other hand, there are downsides to product information that should also be carefully weighed. These include the possibility of consumers being misled if they cannot evaluate the information properly, administrative effort and expense for companies and authorities, and losses in the protection of producers' business interests.

749. The SRU's position is that consumers must be given freedom of choice if it cannot be ruled out with great confidence that a product has adverse effects. Putting this guiding principle into practice calls for a discerning but pragmatic approach. Product labelling is not viable in all instances, hence the SRU additionally advocates a product register open to the public. Specifically, the SRU proposes the following:

– *Labelling for nanoscale ingredients:* In areas where the law already requires ingredients to be stated on packaging with a CAS number, ingredient name, E-number or product name, an indication should be added showing which ingredients are nanoscale. This type of labelling should also be extended to products that make use of nanoscale ingredients to achieve specific properties (such as antibacterial properties) or release nanomaterials.

- *Information on use in specific cases:* If specific risks are attached to the use of nanoproducts, this should be brought to consumers' attention with provision of information on use.
- *Information on effects and risk profile:* The proposal of supplementing labelling with a simple indication that ingredients are nanoscale raises criticism that it gives consumers no idea of the risks associated with the nanomaterial. These risks depend on various factors such as size and coatings, however, which cannot be incorporated in easily understood labels. The SRU therefore considers that makers or vendors have a duty to provide consumers with more information. Options include product databases or websites with public information on potential environmental and health risks of nanomaterials (see section 6.3.4).
- *Nanoproduct register:* Even where products are not subject to labelling requirements, there may be concerns that give consumers a legitimate interest in being informed of nanoscale ingredients. For this purpose, parts of the nanoproduct register (see section 7.2.4) should be made publicly accessible.

7.2.7 Strengthening corporate responsibility

Enhancing responsibility among producers and users

750. Developers, products, importers and users owe considerable responsibility for ensuring that nanomaterials and products containing them do not pose environmental and health risks. This is especially the case in areas where limited knowledge, regulatory gaps, testing problems and dynamic technical progress make it hard for the state fully to discharge its protective obligations. In the SRU's assessment, there are companies which endeavour to meet this responsibility, but at the same time there are major uncertainties, deficits and impediments on the part of industry.

Developing a realistic, goal-oriented strategy for corporate responsibility makes it necessary to recognise the limits of voluntary instruments and initiatives. These can only succeed if companies have tangible incentives and the capacity to take part, do not face risks and competitive handicaps as a result, and there is a minimum degree of binding force.

In the SRU's opinion, voluntary initiatives to boost market transparency do not promise success due to various severe impediments (such as business secrecy and control of external communication). Initiatives are therefore more likely to be successful that target corporate responsibility in dealing with nanomaterials (such as manuals and best practice initiatives), improving and hence safeguarding corporate risk management.

The SRU recommends the following:

- Work should continue on the NanoKommission's Principles Paper and be supplemented with more specialist and sectoral initiatives. The main aim of these initiatives should be to

improve internal risk management and raise awareness for responsible management of nanomaterials, especially in small and medium-sized companies. Alongside the core thematic areas of occupational safety and health and environmental protection (primarily with regard to waste), this includes proactive risk communication and sensitisation to consumer expectations and preferences.

– In parallel, producer and user responsibility can be fostered by tightening liability law. Especially in areas where substance and product safety is not ensured by authorisation procedures, for example, it could be made easier to enforce liability when companies fail to comply with a code such as the Principles Paper. A presumption of fault could thus be supplemented with a liability-triggering presumption of causation as soon as it is established that a product has been used.

Ensuring information is passed on along the supply chain

751. Information on the nanoscale nature of substances must not be lost in the supply chain, including when substances are finally incorporated into a product. This is a precondition for ensuring individual producer and user responsibility with regard to nanomaterials.

– *Safety data sheets:* For substances and preparations, provisions stipulating safety data sheets ensure that information is passed on. Safety data sheets should be compiled for nanomaterials regardless of their hazard classification, with all information needed for application of the precautionary principle to nanomaterials. In particular, nanomaterials should be identified as such.

– *Product data sheets:* With regard to products, there is no provision for an instrument comparable with the safety data sheet. Requiring the compilation of safety data sheets would probably not be feasible, particularly for complex products such as computers. The SRU therefore proposes the introduction of product data sheets. These could be used to communicate, along the supply chain, information on the substances contained in a product together with information on use and disposal.

– *Traceability:* For foods, food contact materials and cosmetics, traceability is required so that action can be taken on a case by case basis. This makes it more likely for information to be passed on along the supply chain. To ensure that this takes place, foods should be labelled so that it is possible to identify the batch they originate from. If it is not possible to label a container or packaging, information should be passed on in an accompanying document. This should include information on nanoscale ingredients, unless communicated otherwise.

7.3 Looking beyond nanotechnology: How can policy, law and society be made more precautionary in managing risk?

752. Innovation and technological change are an engine of development in the market economy. Dynamic scientific, technical and economic progress opens up great opportunities but also has the side effect of creating new risks whose implications are often not immediately apparent.

This problem of unknowns is closely tied to the notion of risk. In many environmental policy areas, detailed impact and migration chains can only be predicted for pollutants to a very limited degree. Cumulative, synergistic and antagonistic effects make for a level of structural complexity – and here environmental releases of nanomaterials are very much a case in point – that makes it very hard to pin down causal links, and hence the source of any harm, in a way that meets legal standards of certainty. This complexity together with multicausality often makes it impossible to identify direct causation, attribution, responsibility and fault in the legal sense. These problems are often made worse still by long latencies between cause and effect; examples include damage to the ozone layer from CFCs and the climate impacts of carbon dioxide emissions. Another, related factor is the very limited predictability of primary and secondary impacts: Small causes can have large effects and adverse trends can persist when the primary cause is long gone. This can be further amplified as a result of ecosystems being exposed to unceasing change, with the outcome that disturbances can trigger trends that follow a power law or even an exponential curve.

With conventional technologies, professional experience means that risks are fairly well defined and contained, whereas some ‘new’ technology risks remain undefined in many ways (Lau 1991, p. 249 ff.; Grimm 1991, p. 417). This relates both to who is affected and to the nature, scope and ultimate timing of any harm. A paradoxical situation results, either due to the unintended collective, additive effects of individual actions (as with carbon dioxide emissions from transport, industry and housing, or pollution from industrial, farming and consumer products), or due to the systematic separation, in functionally differentiated societies, between risk source and locus of impact.

On the other hand, the scientific and research capabilities for investigating the environment in all its complexity and multicausality remain limited. As this special report has shown very clearly with reference to nanomaterials, in many areas there are gaps in both data and research. Initiatives to monitor and describe the environment also tend to target different media and lack coordination. In addition, there are wide-ranging difficulties with regard to analysis and detection. These are often made uncertain by the instability of many pollutants and incomplete knowledge about substance life cycles, making the subject of environment policy intervention a moving target. This is compounded by inadequacies in testing methods and assessment. Testing methods either suffer a degree of inaccuracy that increases

towards the detection threshold or fail from the outset because it is not possible to model specific factors such as multiple pollutant loads or indeed to capture the real situation at all. Because of this, a degree of simplification is necessary in the context of thresholds and concentration limits, and safety margins must be used to apply a typology allowing for the biological differences between people. This imposes limits on how far the multicausal effects of environmental pressures in the biosystem can be taken into account (Böhm 1996, p. 20 ff. and 129 ff.). Risk estimation and assessment also rely on existing knowledge and so are necessarily provisional and subject to later revision. Familiar everyday materials can suddenly prove harmful, as happened with asbestos, or different, perhaps new, assessment methods can reveal a need for broader legal safeguards. Finally, many environmental impacts are irreversible, or can only be reversed over timescales beyond the reach of practical policy (Ritter 1992, p. 642 f.).

The notion of the risk society coined in the social sciences proposes that the continued survival of society today is under threat from internally generated risks. Risks are an outcome of decisions – or to be more accurate, an uncertain and unconsidered side-effect of decisions – accepted consciously or unconsciously, avoidably or unavoidably in deliberate pursuit of a given purpose (Beck 1986, p. 35 ff. and 300 ff.; adopted for legal science among others by Di Fabio 1994, p. 53 ff.; Calliess 2001, p. 158 ff.). At the same time, it is a feature of the risk society that dangers can no longer be attributed to outside causes. In the complex system of our highly differentiated, technologically advanced industrialised society, which brings forth highly specialised actors working on a distributed basis in science, industry, government and the law, pinpointing individual causes and responsibilities becomes almost impossible. Nuclear, GMO and chemical megarisks cannot be contained within a specific place, time or society. They are neither calculable nor compensable and thus far exceed the capabilities of conventional risk management. Unlike conventional technological risks, which were isolated, individual and specific, these ‘new risks’ are global, collective and diffuse. This makes attribution to individual decisions almost impossible. After a phase when society believed in technological mastery, the ubiquitous threat of new risks heralds a return to uncertainty and insecurity.

Personal responsibility and ultimately collective harm present a paradox. Because the new risks cannot be attributed to a specific source, it is harder to pin down responsibility in law. Individual compensation is no longer feasible – including through insurance – yet collective compensation arrangements prove difficult (Reiter 1998). In situations like this where responsibility can no longer be individually assigned, the state also faces new expectations regarding public safety and is expected to take precautions to protect from and prevent harm (see e.g. BGHZ 102, 350 ff. on liability for the unprecedented forest decline beginning in the late 1970s and the German Constitutional Court decision of 24 November 2010 on ‘green’ genetic engineering, at 137). At the same time, circumstances seem beyond the expertise of state institutions, which often defer to professional scientific and technical knowledge. Put

provocatively, references in legislation to ‘best available technology’ serve as a kind of enabling act that lets government, parliament and the judiciary hand over command to technical specialists and engineers. More and more, uncertainty and uncontrollability undermine trust in the technical feasibility of mastering outcomes, and state institutions risk seeing their credibility eroded as a result. By the same token, however, citizens themselves place near-limitless trust in technology and its proponents, for example when travelling by air, rail or car.

In managing technology-related risks, all this places pivotal importance on society’s awareness and acceptance of risk. This is because underlying social attitudes to potential risks, brought into play through state institutions and increasingly through the media, are reflected in how the risk-constituting factors are addressed in legislation.

- Risk awareness: Before any decision is made on whether or not to accept a risk, there must first come a realisation that a set of circumstances can possibly lead to harm. The initial tasks are therefore ones of scientific risk analysis, assessment and communication. This is complicated however by the fact that risk perceptions differ not only between experts and the lay public, but also within the general population (Pildes and Sunstein 1995) and even within the professional community. That is, risks are not perceived consistently by society. People are more likely to find something if they are looking for it or are sensitised to it in the first place. Society thus exercises a certain selectiveness in perceiving risk (Di Fabio 1994) and, through policy makers and state institutions, this selectiveness can find its way into law. It may merely comprise conscious recognition that something is unknown (Jonas 1979).
- Risk acceptance: Technology-related risks are partly a matter of social definition and are not solely technical in nature. For example, traffic noise and the noise of a waterfall may produce identical instrumental readings but this does not mean they have an identical chance of being found acceptable. Risk acceptance is heavily dependent on subjective factors: Risks taken voluntarily are – quite rationally – more eagerly accepted than risks that are enforced upon the population; (supposedly) individually controllable risks are more readily accepted than risks that cannot be influenced; natural risks are felt to pose less of a danger than anthropogenic risks; high-profile risks currently in the news trigger greater unease than everyday lurking threats; complicated, hard to understand and new technologies are mostly considered riskier than familiar technologies. Nor is risk acceptance constant, because it changes in parallel with social trends. For reasons to do with cultural history, for example, alcohol and tobacco consumption, despite the high individual and social risks, is largely accepted and fairly weakly regulated. In other areas, growing prosperity has brought about a shift in focus onto the spillover effects of industrial society. For a long time, smoke-billowing factory chimneys were emblematic of prosperity, high standards of living and progress; now they epitomise pollution (Berg 1996).

In this light, risk management is shown to be not only a matter of avoiding risks that are scientifically identifiable. Over and above that, it indirectly involves the question as to the social, geographical and temporal distribution of risks and their consequences and of the distribution of costs of risk avoidance. The approach taken to risks, and particularly their definition, therefore becomes partly a problem of risk ‘equity’. This is made clear by the fact that how risks are defined decides the size of the population affected – for example via the setting of thresholds – the nature and size of the group creating the risks, the costs of risks, and notably the costs of avoiding them, the opportunities and rewards of accepting risks (Kloepfer 1998), and individual risk management options (Lau, 1991). But because the definition and delineation of risks is so beset with problems in this way – and hence also difficult to communicate – public debate surrounding risks can result in alarms being raised both too readily and too slowly.

This makes it necessary to subject risk management to rationalisation. One means of rationalising social processes is regulation. At the same time, with the democratic legislature serving as intermediary, the law is also what legitimates the shaping of social processes by policy makers, the balancing of the interests of freedom and protection, and hence the attainment of the risk equity mentioned previously. In this context, the precautionary principle – which in the course of this special report has been shown by the example of nanomaterials to be capable of practical application when dealing with new technologies in general – takes on (and is also constitutionally assigned) a central guiding role in policy making. To begin with, the precautionary principle formulates a general requirement directed at the legislature that, once made law, shapes how risks are addressed. In particular, the legislature must stipulate in the light of the precautionary principle how unknowns and the related uncertainty are dealt with, as from what point risks are no longer to be accepted, and when restrictions can and must be imposed on civil liberties. However, dealing with risks also exacts a tribute from the law. This is because the law, too, cannot entirely overcome the underlying reality of uncertainty or lack of knowledge. It is, however, the task of the law, and hence first of all a responsibility of lawmakers, to decide where to strike the balance between freedom and protection and between risks and opportunities, and in particular what action the executive is permitted to take in light of the precautionary principle in order to counter risk in fulfilment of its protective mandate. While this responsibility cannot be taken as meaning that decisions always have to prove right in hindsight, it is there to ensure that available ex ante knowledge and means of judgement are actually put to use. It is therefore the task of policy makers to legislate the management of risks under the precautionary principle in such a way that risks which appear reasonable are made acceptable to individuals. Politically legitimated processes must also be in place to guarantee effective remedial action if this reasonableness threshold is breached. Channelling the development of new technologies along precautionary lines in this way and thus also upholding the overarching principle of sustainability is essential in order to secure the confidence in technical progress that a

democratic society needs. State institutions are therefore called upon to guide this process with timely action based upon the precautionary principle. If the impression arises that the state is not adequately delivering on its protective obligations, the result is uncertainty that can lead to irretrievable loss of social trust in a new technology and thus in the opportunities it holds. At least in a democratic society, this can quickly mean the end of a new technology.

To avoid such loss of trust, policy makers and society must improve their ability to reach nuanced and rational decisions about risk, founded on science-based decision criteria while taking legitimate social value judgements into account. Risk research in the social sciences has developed the concept of 'risk literacy' in this context (Petts et al. 2003; Risikokommission 2003, Renn et al. 2005; Ruddat et al. 2007). This means the "ability, based on knowledge of the factually proven consequences of risk-bringing events or activities, the remaining uncertainties and other relevant risk factors, to undertake a personal assessment of the risks which corresponds to one's own criteria or to the ethical criteria deemed appropriate for society" (Risikokommission 2003). Although this concept was primarily developed with a view to citizens and their individual decisions about risk, it can also be applied to society's management of collective risks. The development of a social risk culture along risk judgement sovereignty lines is a lengthy process that must take in a broad spectrum of social actors. A precondition is that policy makers, authorities and industry regain citizens' lost trust.

This report has shown ways in which the precautionary principle can successfully be applied to nanomaterials in practice and the changes that need to be made in order to make this possible. In the SRU's opinion, key findings are transferable in principle to other technologies and risk areas. These include new fields of technology (such as synthetic biology), and also risks that have been known about for some time but are still subject to great uncertainty (such as environmental and health effects of endocrine disruptors). The following general principles can be recorded for the precautionary management of risks beyond nanotechnology:

- Implementation of the precautionary principle is effected in practice through the cycle of risk assessment, evaluation and management: through risk research capacities and priorities, through criteria for the evaluation of risks in conditions of uncertainty, through decision processes, through the state's scope for action to minimise risk, and through risk communication.
- A precondition for responsible development of technologies is an appropriate balance between innovation-related and risk-related research. The gap between knowledge relating to technological development and knowledge about potential health and environmental impacts must be kept as small as possible.
- On the one hand, it is unavoidable in a modern, innovation-driven industrialised society that risk decisions have to be made despite knowledge gaps that make full scientific

assessment of the potential impacts impossible. Drawing on the knowledge base from dealing with established technologies, approaches for a preliminary risk assessment can generally be developed at an early stage, and these should be used and elaborated on continuously. On the other hand, however, the precautionary principle with the notion of reversal of the burden of proof (the rebuttable presumption of danger) derived in this special report can support a legislative decision on risk prohibiting (provisionally, until proof of safety) the market launch of a new technology or a new product or process based on it in the interests of health and environmental protection.

- Certain areas of chemicals, product and environmental legislation that currently place too great an emphasis on the legal concept of danger should be put on a more precautionary basis so that action can be taken to minimise risk when there is only an abstract concern that non-negligible adverse effects on human health or the environment are to be expected. This applies not just for chemicals, but also for those products currently subject to weak regulation.
- In a society well versed in dealing with risk, one-sided communication strategies that are ostensibly designed to build confidence and give reassurance can be counterproductive if they communicate a putative sense of safety. Risk communication can only survive when incidents and communication crises shake the population’s confidence if the risks and uncertainties are communicated just as systematically as the opportunities. Other important confidence-building measures include providing consumers and competent authorities with information about when and where they come into contact with a new technology, and giving authorities capacity to monitor the risks.

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