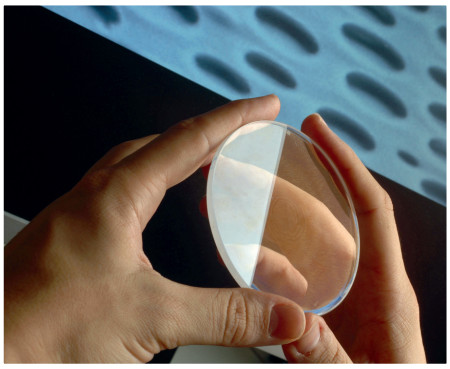
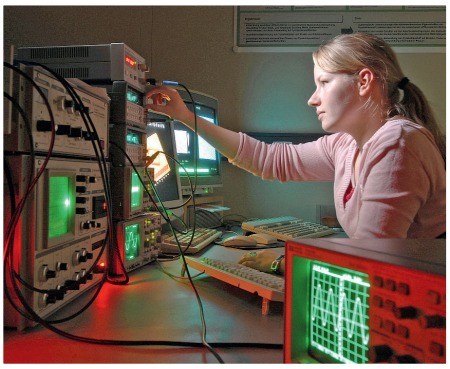
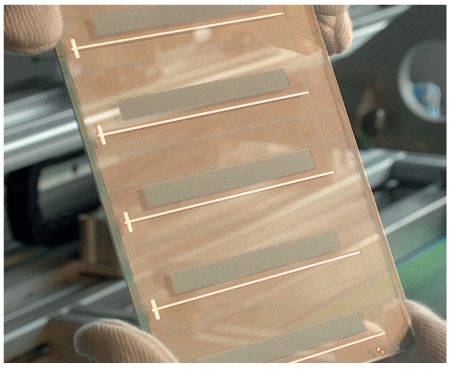
SRU German Advisory Council on the Environment

PRECAUTIONARY STRATEGIES FOR MANAGING NANOMATERIALS

Summary for policy makers

September 2011



The issue: The precautionary principle and nanomaterials

New technologies enrich our lives in many different ways and are valuable in the solution of pressing social problems. A country such as Germany also relies on innovation to stay globally competitive. Yet new technologies pose risks whose nature and scope only become known over time. Decisions on how to continue developing new technologies and where to restrict them are therefore often made in conditions of uncertainty.

In the past, commercial activities were not usually restricted on environmental or health grounds unless it was scientifically proven to a sufficient degree of probability that they caused harm. If, however, as is often the case with innovations, there is a lack of experiments and scientific findings to show that a substance, production process or product causes harm, then the sufficient degree of probability used in the conventional approach to averting danger as defined in law is not given. Following negative experience, it is now accepted that – subject to rigorous cost-benefit analysis – risks to human health and the environment should also be averted on a precautionary basis even if the science is inconclusive. This is the thinking behind the precautionary principle that is now broadly and firmly established in legislation as an extension of the state objective of environmental protection laid down in Article 20a of the German Basic Law, of the corresponding Community objective laid down in the second sentence of Article 191 (2) of the Treaty on the Functioning of the European Union, and of the international law principle of sustainable development (see Principle 15 of the Rio Declaration).

The precautionary principle notably applies where scientific evidence is inconclusive or is contested between experts but a preliminary and objective scientific risk assessment raises justified concern that a substance, production process or product may cause harm to human health or the environment. In risk prevention, this abstract concern (or reasonable suspicion) that harm may be caused is enough to legitimate state action. It allows earlier state intervention, before the danger threshold is reached.

To avoid exercising precaution for precaution's sake – which in any case would be legally questionable – it is first necessary to specify trigger criteria for precautionary intervention. This involves a two-stage process: a (science-based) risk assessment and normative risk evaluation. If there is then still any uncertainty about the cause for concern, the precautionary principle demands a reversal of the burden of proof to enable legislative action. It is then up to the risk originator to rebut the presumption of danger and hence the cause for concern.

When action is required to prevent risk, there are a wide range of available options. With an eye to the economic rights that open up opportunities for innovation, the choice of options should be informed by the abstract potential for causing concern, including the potential extent of any harm.

The introduction and use of nanomaterials is a topical example of a situation where the precautionary principle ought to play a key role, notably where knowledge of the dangers (in the legal sense) is largely absent. The precautionary principle requires the risks and opportunities of nanomaterials to be systematically identified and assessed. This prepares the ground for regulatory decisions that promote a technology's development while limiting the potential risks. By openly balancing opportunities and risks in this way, the precautionary principle can help build confidence in and public acceptance for the use of nanomaterials.

The German Advisory Council on the Environment (SRU) is in favour of giving greater place to the precautionary principle in society, government, the law and administrative process as a guiding principle for dealing with the uncertainty inherent in new technologies. Exploring the example of nanotechnologies, and specifically nanomaterials, this report analyses to what extent the precautionary principle is already in use today, where there are deficits and gaps, and how these can be closed. The subject of nanotechnologies is especially well suited to an investigation of this kind because it acts as a lens focusing the various threads of social debate sur-

rounding the risks of new technologies. For their profoundly cross-cutting nature and scope for bringing about fundamental change in whole technological disciplines, nanotechnologies rank among the key technologies of the 21st century.

At the same time, the potential risks are heterogeneous and difficult to foresee. This has partly to do with the new properties of the materials themselves and partly with the diversity of their structures, products and applications.

Opportunities of nanomaterials

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 intermediate products in chemical industry production processes. There is no doubt that nanotechnologies will open up a vast range of new technological opportunities in the long term. There is reason to hope that in some areas these opportunities will not only be a source of profit economically, but will also deliver large social benefits, for example in medicine. The environmental opportunities of nanotechnologies are also widely emphasised. However, few such hopes have so far been translated into reality. The few life cycle assessments done to date show that nanotechnology applications do not always have a fundamentally smaller environmental footprint. In the longer term, decisive improvements are nonetheless expected in fields such as solar technology and energy storage.

Risks of nanomaterials

An important preliminary finding of risk research is that nanomaterials differ from their macro counterparts not just physically and chemically, but also in their behaviour and effects in living organisms and the environment. A problem aspect here is that nanomaterials both differ from conventional materials in ways that may be biologically significant and are also able to move about more easily than macro-structured solids in environmental media and organisms. Biological impacts are therefore another area where nanomaterials cannot be bracketed together with their conventional equivalents and should be treated instead as 'new' substances.

It is not possible to make general statements about the risks of nanomaterials. On current knowledge, some materials essentially raise no concern, while research on others shows significant potential risks. There is no scientific proof so far that nanomaterials – as they are made and used today – cause actual harm to the environment or human health. This cannot be taken as an all-clear, however, because for many nanomaterials there is a lack of standardised test methodologies for a full risk assessment and knowledge of their potential adverse effects is limited. A number of products and uses raise concern (as defined in the context of the precautionary principle). These include the use of nanomaterials in consumer sprays, growing sales of consumer products containing silver nanoparticles, and the production and use of carbon nanofibres and nanotubes with carcinogenic potential. Many more nanoproducts are expected to come onto the market in the next few years. There is a risk that the number of products which cause concern will grow accordingly. The concentrations of nanomaterials in manufacturing processes, products, waste water and solid waste is also very likely to increase.

Although properties of some nanomaterials are problematic, the challenge as seen in the light of current knowledge lies not so much in specific dangers of nanomaterials, but in risk research and regulation barely being able to keep up with the fast development of technology. A key aspect relates to

specific methodological difficulties in toxicity testing – for example in preparation and standardisation of materials to be tested. But an equally large problem is the sheer variability of the new materials. Small changes to a single material can produce dozens or even hundreds of variants that can each differ in effects and environmental behaviour.

Recommendations for a precautionary approach to nanomaterials

This report aims to secure consistent application of the precautionary principle to nanomaterials. This does not mean, however, that all potentially risky products and materials should be restricted or prohibited. The purpose of the precautionary principle is not to halt innovation, but to balance the opportunities and risks. The SRU proposes a wide range of measures to enable this balancing to take place when there is cause for concern. The main recommendations are summarised in the following.

Key recommendations for action:

— **Makers of nanomaterials should be placed under stricter obligation to file data on the risks of nanomaterials.**

— **Risk research should be made to account for a considerably larger portion of publicly funded nanotechnology research.**

— **Existing dialogue activities should be extended to a broad cross-section of society.**

— **For an overarching definition of nanomaterials, an upper size limit of 300 nm is recommended. A smaller size limit may be appropriate for specific regulatory purposes.**

— **In many areas of the law, there are nano-specific regulatory gaps that should be closed as soon as possible on the basis of the precautionary principle. In some areas, however, the report's analyses reveal deficits in application of the precautionary principle that also hold with regard to other substances and products. A number of recommendations therefore relate to a need for action going beyond the regulation of nanomaterials.**

— **To enhance market transparency, existing labelling obligations should be supplemented with an additional 'nano' indication. Products that release nanomaterials or make use of them to achieve specific properties (such as antibacterial properties) should also require mandatory labelling. For other nanoproducts, a notification requirement should be introduced that feeds into a semi-public product register.**

— **Extensive changes are necessary in chemicals legislation (REACH): Nanomaterials should be consistently treated as if they were substances in their own right and registered with dossiers of their own. A core data set should have to be submitted for them that ensures observation or a preliminary risk estimation, according to their size. Quantity thresholds must be reduced for nanomaterials and the standard information requirements need to be supplemented. Authorisation should be based more closely on the precautionary principle. It should also be possible to restrict or prohibit nanomaterials merely on the basis of an abstract concern.**

— **In product legislation, it must be ensured in existing authorisation procedures that nanomaterials are always approved separately. For weakly regulated products, the foundations should be laid for powers to intervene on the basis of the precautionary principle.**

— **In environmental law, there is a considerable need for research and assessment. Operators of industrial facilities should be obliged to minimise emissions of nanomaterials for which there is an abstract concern.**

1. Intensification of risk research

For the technology to go on developing along responsible lines, it is necessary to close the currently widening gap between technological advancement and knowledge of risk. The following should be done to achieve this goal:

Manufacturers of nanomaterials should be placed under stricter obligation to file data on risks of nanomaterials. Existing European chemicals legislation provides a good framework for this purpose but must be modified for nanomaterials (see below).

Risk research should be made to account for a significantly larger portion of publicly funded nanotechnology research.

Where scientific risk assessment is not possible due to a lack of data, a preliminary risk assessment should be performed on the basis of specific criteria indicating concern or no concern. This makes it possible to balance risks and opportunities in conditions of uncertainty. The SRU proposes criteria and a decision tree as a basis for determining potential concern specific to nanomaterials.

2. Promotion of social dialogue

On balance, the SRU takes a positive view of the dialogue efforts engaged in so far in Germany and at EU level. However, the institutions and dialogue forums established to date have only reached a relatively small group of experts. As a result, development, use and regulation of nanomaterials continues to advance generally out of the broader public eye. The SRU therefore sees a need to extend existing dialogue activities to a broader cross-section of society. Care should be given in doing so to ensure that all communication processes operate transparently, address risks and opportunities in equal measure, highlight important details, and include non-experts such as consumers and the interested public. In particular, the SRU advocates mandating existing institutions to continue the social dialogue on nanotechnology and further institutionalising accompanying social sciences research.

3. Legal framework for the regulation of nanomaterials

While they have characteristics that set them apart, the nanomaterials manufactured today are basically chemical substances that are already subject to comprehensive regulation (notably under REACH). They are also used in products that are regulated in their own right. Any specific rules for nanomaterials should therefore build on existing law. However, because so many different policy areas are affected (chemicals, waste, pollution control, food, cosmetics, etc.), modifying numerous individual laws involves a loss of transparency for the public. For systematic reasons, legislation should be adopted laying down certain ground rules on a cross-sectoral basis for the management of nanomaterials. The SRU therefore proposes combining the various sector-specific modifications in a single piece of legislation so that certain cross-sectoral stipulations can be covered at a general level. This general section of the proposed legislation, preferably to be enacted at European level, should first and foremost provide an overarching definition, require the application of the precautionary principle and establish powers for individual action invoking that principle. For an overarching definition of nanomaterials intended to serve as a framework for government and regulation, the SRU recommends an upper size limit of 300 nm. This upper size limit should relate solely to primary particles. Agglomerations and aggregates of primary particles should be covered by the definition without any size limit. The definition can be made narrower for specific regulatory purposes as appropriate, for example to exclude certain materials not posing any risk.

4. Closing nano-specific regulatory gaps

Nanomaterials are not normally dealt with separately in prevailing law. For example, nanoscale titanium dioxide is treated exactly the same in law as conventional titanium dioxide consisting of larger particles. This raises problems because the nanoscale form of a material can pose different risks than the conventional equivalent. Existing legal limits may prove too lax, for example, if a nanomaterial is more reactive than the convention-

al material that the limits were originally set for. Risk estimation for nanomaterials normally calls for additional tests and data that need to be made a separate requirement. Nano-specific regulatory gaps of this kind should be closed as quickly as possible. Alongside revision of technical implementation documents, this also requires changes to various areas of the law.

The analyses in this report generally show that there are not only specific regulatory gaps with regard to nanomaterials, but also broad deficits in application of the precautionary principle in various areas of chemicals, environmental and product legislation that also apply for other substances and products. Some of the legislative changes proposed in this report may therefore also serve as a model for regulation of other substances and products.

5. Labelling and product register

For precautionary reasons, the SRU considers it necessary to create greater transparency regarding the use of nanomaterials in products. On the one hand, authorities must be able to obtain an overview of the market, not least so that they can respond quickly if indications of specific dangers become known. On the other hand, consumers should generally be allowed free choice. Among other things, the SRU therefore advocates the following:

For products (such as foods) whose ingredients already have to be listed on packaging, labelling should be supplemented with an additional 'nano' indication. A new labelling requirement should only be introduced for products that make use of nanoscale ingredients to achieve specific properties (such as antibacterial properties) or that release nanomaterials.

For products that contain synthetic nanomaterials but are not subject to labelling requirements, a notification requirement should be introduced. The notification requirement should feed into a semi-public product register.

If specific risks are attached to the use of nanoproducts, the fact should be brought to consumers' attention with provision of information on use.

6. Need for reform in chemicals legislation

Nanomaterials should be consistently treated as if they were substances in their own right to ensure that they are registered, tested, assessed, labelled and treated separately. Nanomaterials should also be defined and made a focus of specific legal obligations.

In REACH, nanomaterials should have to be registered with dossiers of their own. The transition periods for existing substances and the exceptions formulated for specific substances should not apply for nanomaterials. Quantity thresholds must be reduced for nanomaterials. The standard information requirements for registration must also be modified and supplemented. The SRU additionally advocates the introduction of a core data set that varies in scope according to the size of a nanomaterial. A core data set should still have to be submitted if a nanomaterial is produced in quantities of less than one tonne per year. For all nanomaterials where a preliminary risk estimation reveals grounds for suspicion, a comprehensive chemical safety report should be mandatory.

It is also necessary to create, within REACH, a legal basis for intervention in accordance with the precautionary principle.

The powers to require authorisation under REACH should be formulated so that the mere possibility of a severe effect on human health or the environment can justify an authorisation requirement. This should include a rebuttable presumption of danger in accordance with the precautionary principle, with the burden of proof on the applicant.

It should be possible to prohibit or restrict nanomaterials as soon as an abstract concern is identified.

7. Need for reform in product legislation

Some areas of product legislation already have regulatory regimes based on the precautionary principle. Here it is only a matter of ensuring that the special characteristics of nanomaterials are taken into account. In general, this means existing authorisation procedures (such as for foods, food contact materials and cosmetics) must be adapted so that authorisation for nanomaterials has to be applied for separately. Such authorisation should be granted, firstly, only if use of the nanomaterial is proven to be safe. Pending risk evaluation methods and related test standards, one option would be to grant provisional approval subject to subsequent testing. Secondly, authorisation should only be granted if methods exist for detecting the nanomaterial in a product.

For products that have been subject to weaker regulation to date, the foundations should be laid for authorities to take action (such as powers to require authorisation or to impose restrictions and labelling requirements) if there is 'merely' an abstract concern. These powers could be included in the cross-sectoral legislation proposed by the SRU (see above).

8. Need for reform in environmental law

A basic problem in protecting the environment from nanomaterials is patchy knowledge about their environmental release, behaviour and impacts. This means there is not enough of a scientific basis for decision-making in order to set limits at sub-statutory level. The SRU therefore expects that decisions will continue to be made on a case-by-case basis in many areas for some time to come.

It can be assumed that only a small number of synthetic nanomaterials so far enter the environment to a greater extent. This volume is expected to increase, however. There is therefore an urgent need to ensure that nanomaterials enter the environment in the smallest possible quantities. The SRU identifies the current priorities in this connection as follows:

Legislation governing industrial facilities: Use of insoluble or barely soluble nanomaterials should be made subject to powers to require approval under pollution law. Thought should also be given to establishing a notification requirement for all production and use of nanomaterials. The German Major Accidents Ordinance (Störfallverordnung) should be applied to facilities that make or process nanomaterials for which there is cause for concern.

Protection of environmental media: Speedy appraisal is needed to decide where prohibitions, quality standards or emission limits can be imposed for individual nanomaterials or identifiable groups of nanomaterials. The current state of the art needs to be delineated and suitable testing methods developed. To ease the burden of proof, emissions of nanomaterials for which an abstract concern is identified should have to be limited as far as possible. Authorities should be provided with guidelines for formulating requirements on a case-by-case basis, and need to be given broad information rights for the purpose.

Waste: There is considerable need for research here, for example on the development of suitable testing methods and on nanomaterial behaviour and release in waste recycling and recovery, incineration and landfilling. For precautionary reasons, pending more precise knowledge of the behaviour of nanomaterials in the waste stream, at least production waste containing nanomaterials should be classified as hazardous waste. For certain waste containing nanomaterials, thought should be given to establishing take-back schemes to prevent such materials from being disposed of as part of municipal waste.

Precaution beyond nanotechnology

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.

The confidence in technical progress that a democratic society needs can only be ensured if the ongoing development of technologies is guided by the precautionary principle and account is also given to principles of sustainability.

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