Responsible Use of Nanotechnologies:

Report and recommendations of the German Federal Government's **NanoKommission** for 2008

Imprint

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Content

Foreword

Nanotechnologies are key technologies of strategic importance. Still relatively young, they are already enabling us to foster a new type of innovation culture that is committed to principles of sustainability and precaution. Worldwide, efforts are being made to learn from errors made in technology conflicts of recent decades, and to develop an integrated innovation strategy for nanotechnologies. Ideally, technology promotion should always go hand-in-hand with consideration of the potential hazards to people and to the environment, with scientific exploration of the possible ethical, legal, ecological and other consequences for society, and with public communication of the results of such studies. In addition, technology-development stakeholders in the areas of science, industry and society need to communicate effectively with one another.

The "NanoKommission" – a stakeholder commission on Nanotechnologies – was established by the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) at the end of 2006, in the framework of the Federal Government's High-Tech Strategy.

The NanoKommission's efforts are structured as dialogue between stakeholders: representatives of environmental and consumer organisations, unions, the science sector, industry and government (ministries, federal authorities), working in an ongoing process, discuss their various positions and assessments of specific issues in the area of nanotechnologies.

In such a dialogue process, priorities have to be set. The NanoKommission has concentrated its efforts on nanomaterials, and it has begun by setting the following aims:

1. Explore nanotechnologies' potential for contributing to sustainable development by reducing negative impacts on the environment, on human health and on our limited resources. To this end, the NanoKommission wishes to present relevant clear examples that can help shape an appropriate policy to support the development of nanotechnologies in Germany.
2. Work on the question of potential risks that nanomaterials can present for the environment and for human health. This effort especially involves identifying what findings concerning potential risks are already available and what additional research is needed in the short-to-medium time frames.
3. Develop recommendations regarding ways in which voluntary commitments could already contribute to responsible use of nanomaterials, even though too little is known about this area at present (principles paper). In addition, develop recommendations for preliminary classification of nanomaterials in accordance with their potential risks, in the interest of ensuring that innovation respects criteria for sustainability and precaution.

The NanoKommission has intensively followed relevant efforts in the OECD, in the European Union, and in major industrialised countries, and has taken account of such efforts in its own work. Furthermore, it has considered the important issue of communication, also drawing on the advice of experts in this regard. All in all, the German public, when compared to the publics of other countries in this regard, tends to view nanotechnologies in a positive light, although its demand for information about the subject is growing rapidly. Consumers clearly distinguish between desirable and less desirable applications. At present, hardly any acceptance problems are being encountered in connection with products with nanomaterials – with the exception of food products. The overall situation is considered sensitive, however. In a crisis of communication, the public might readily be reminded of experience gained in the debate on "risk technologies".

In retrospect, interaction of diverse experiences, information items, communication cultures and interests has played a central role in the NanoKommission's work. At the same time, the NanoKommission has profited from a clear willingness for open minded cooperation, a mutual learning process and – wherever possible – to reach consensus. This orientation is highlighted in the NanoKommission's present report.

As all stakeholders in this area are well aware, society's dialogue on nanotechnologies is not going to end in November 2008. The present report is intended as an inventory of relevant efforts to date. In addition, it presents recommendations for continuation of the stakeholder dialogue.

Wolf-Michael Catenhusen

Summary

The German NanoKommission has set itself the task of considering the potential benefits and risks of nanotechnologies, in keeping with the precautionary principle, and of promoting sustainable innovations. At a time when our knowledge is still insufficient, the NanoKommission is providing criteria for preliminary assessment of benefits and risks, as well as formulating basic principles for the responsible use of nanomaterials.

The NanoKommission was established by the Federal Government at the end of 2006, as a central, national body for dialogue, and it has developed into a key platform for the various stakeholders involved. In this framework, representatives of the areas of science, industry, environmental and consumer organisations, unions, ministries and authorities are working jointly on specific potential solutions. The German NanoKommission's work has focussed equally on the potential benefits and risks of nanomaterials, on related scientific and technological issues and on cross-cutting topics such as transparency and information provision.

The commission's work is being carried out in the context of strong industrial and state efforts to promote and expand research and development of sustainable nanotechnological applications.

Germany has a relatively long tradition of societal dialogue regarding nanotechnologies. Since 2003, various groups of society have been participating, in different formats, in the debate on the benefits and risks of nanotechnologies. The general public has already become aware of the topic of nanotechnology. One out of every two persons has a specific concept of what the term "nano" entails. A majority of those who understand what nanotechnologies are take a generally positive view of this new area, even if a large majority are raising critical questions related to health protection. Consumers are demanding additional information. Experts as well require additional information – in order to refine criteria for assessing the risks of nanomaterials and for establishing international standards.

The German NanoKommission (16 members) has been supported in its efforts by a total of three working groups (each of which comprises some 20 persons). Participants in the discussions in this framework have shown great openness and willingness to learn. At the same time, they have had to tackle the challenges of a) differentiating the specific issues involved and b) combining the participants' different areas of experience, and different interests, into a coherent whole. All of the working groups submitted written reports, and all such reports entered into the present final report.

For purposes of the present report, the working groups' contributions were shortened and summarised to some extent. The pertinent original documents, which provide greater scientific detail, are available (German language) in the Internet at: www.bmu.de/nanokommission

Potential health and environmental benefits

The NanoKommission has compiled a list of nanomaterials applications that support the United Nations' Millennium Development Goals and that can help enhance efficient use of resources and contribute to health protection. The report provides an overview of such examples, as well as in-depth discussion of selected products, in the interest of highlighting the potential benefits for the environment and human health. As of the completion of the NanoKommission's first work phase, an integrated examination of benefits and risks considering the entire life cycle has been carried out to a limited extent only. The examples focus on:

1. Large-format lithium-ion batteries can enhance energy efficiency. With nanomaterials, such batteries can become lighter, cheaper and more durable. As a result, they can become more suitable for use in electric and hybrid cars, as well as for storage of electricity generated from renewable energies such as wind, water and solar power.

2. OLEDs are a new lighting technology that is highly power-efficient. OLEDs can thus help reduce CO_2 emissions. Thanks to nanostructures, OLEDs use considerably less power than other types of lighting and yet provide extremely high light yields.

3. Carbon nanotubes can be added to plastics to produce materials with special properties – such as extra strength, tear-resistance or electrostatic neutrality – that can greatly enhance products. Such materials can be ideal, for example, for production of structural components for aircraft, automobiles and wind-turbine blades. In addition to enhancing products' properties, such materials enable manufacturers to reduce energy inputs and costs.

4. Nanoporous foams can enhance structural insulation for both renovations and new buildings. Such materials improve the effectiveness of insulation in reducing heating costs and energy consumption.

5. Protection and conservation of precious water resources: nanofilters are used in treatment of wastewater from production operations, municipalities and landfills. They can also play a key role in purification and treatment of drinking water. Additionally nanofilters can be used for water desalination and neutralisation of heavy metals. In such applications, nanomaterials make it possible to control separation and throughput with much greater precision than can be achieved in conventional processes.

Quality control issues

Quality control must play a central role in development of nanotechnologies, if such development is to be sustainable, both now and in the long term. The following questions served as initial guidelines for a differentiated description and an assessment of different approaches:

- What special function or property does a product acquire when produced with nanomaterials / nanotechnologies (advantages over conventional products)?
- What added value, or positive contribution, does use of nanomaterials / nanotechnologies provide in environmental protection?
- Current status of product development / of relevant applications? What customer demands / social concerns are being focussed on?
- Is it already possible to assess the safety, sustainability and recyclability of the products / materials involved?

Thus far, the dialogue process has not been able to answer the question of whether these aspects can be developed into an integrated scheme for overall review of the opportunities and potential inherent in nanotechnologies. Some stakeholders called for development of such a review scheme, a scheme that would make it possible to compare nanotechnology products to their conventional alternatives, in terms of overall ecological impacts and throughout products' entire life cycles.

Risk and safety research

Development of new processes and materials brings up safety issues – questions regarding safety for people and the environment. The NanoKommission recommends that risk and safety research be intensified. Working Group 2 developed a list of priorities for such research intensification.

The NanoKommission also proposes preliminary classification of nanomaterials into relevant categories. In each case, such preliminary assessment, a precautionary approach, would apply only until specific assessments in the area of health and environmental protection become available. Working Group 2 developed criteria indicating concern or no cause for concern to support this preliminary assessment. These criteria need to be refined in the next step.

The criteria are based on nanomaterials studies that have appeared to date and that give an indication of initial trends in assessment: Currently, scientists see the greatest potential risks in inhalation of nanomaterials. On the other hand, most experts agree that the human health risks, in connection with inhalation, are small when nanomaterials are bound – for example, within a matrix such as a hardened surface coating. Most experts consider the risks arising from absorption of nanomaterials through the skin (example of sunscreens) to pose less of a problem. Many dermatological studies have found that healthy human skin provides relatively good protection against this type of nanomaterials and is able to keep them from entering into the human body. Findings of current studies involving tests with damaged skin have not yet been published. Less is known about the possible impacts of absorption of nanomaterials via the gastrointestinal tract. The experts clearly agree that more data is required in this area. In addition, the potential environmental impacts of nanomaterials cannot yet be adequately assessed. For example, this reason, the NanoKommission recommends making this area a special research focus.

Group 1: Probably hazardous – concern level: high	
	Criteria: Exposure occurs; materials have high mobility, reactivity, persistence or toxicity of the materials
	A concept is required for measures to minimise exposure or to avoid certain applications
Group 2: Possibly hazardous – concern level: medium	
	Criteria: Exposure cannot be ruled out; materials have unknown agglomeration or deagglomeration behaviour; too little is known about materials' solubility and biodegradability; the possibilities for release of nanoparticles from matrices have not yet been explored
	A concept is required for measures to reduce exposure of humans and the environment
Group 3: Probably not hazardous – concern level: low	
	Criteria: Exposure can largely be ruled out; materials are soluble or biodegradable; materials are bound in matrices; materials form stable aggregates or agglomerates
	No measures in addition to those for "good work safety practice" (or "hygiene practice") are required

Case-by-case risk assessment approach

The studies published to date regarding the risk assessment of nanomaterials can provide only first indications. It is not yet possible to draw any general conclusions as to whether nanomaterials are basically hazardous or not. In light of the many types of materials and applications involved, nanomaterials must always be assessed on a case-by-case base, and such assessment must always weigh the potential benefits against the potential risks. No general pronouncements can be made about even certain substances or groups of substances. Working Group 2 presented preliminary assessments of the sample cases listed below. For purposes of the present report, these assessments are provided in abbreviated form.

1. Synthetic amorphous silica (SiO_2) in foods;
2. CNT in electrically conducting films (life-cycle consideration);
3. Photocatalytic titanium dioxide (TiO_2) for self-cleaning surfaces,
4. Silver nanospray for application on plants.

The aims of this effort were to differentiate the potential risks and to make them describable, and to identify and specify requirements for further research.

Guide for responsible use of nanomaterials

How can safe use of nanomaterials be assured? Working Group 3 of the German NanoKommission developed "Principles for responsible use of nanomaterials". This framework is designed to complement existing regulatory measures (REACH, industry-specific EU directives) that, while in principle applying to nanomaterials, may need to be adapted. The two contexts provide an umbrella under which the science and industry sectors can develop nanotechnologies in a responsible way.

The 5 basic principles include:

1. **Definition and disclosure of responsibility and management (good governance)**
2. **Transparency with regard to nanotechnology-relevant information, data and processes**
3. **Commitment to dialogues with stakeholders**
4. **Establishment of risk management structures**
5. **Responsibility within the value chain**

These principles have been formulated on the basis of the current scientific, regulatory and societal situation. The need for, and appropriateness of, these principles are to be reviewed in the next two years and then adjusted as necessary. A consultation process, covering necessary criteria, procedures for implementing and reviewing such criteria and procedures for checking compliance with criteria, will be agreed at an early stage in the NanoKommission's next work phase.

Recommendations

The NanoKommission has formulated the following recommendations for the policy-making, administrative, industrial and association sectors:

1. **Cross-departmental research on safety and risk assessment:**
   In this area, funding for research and development relative to specific measures in the areas of work safety, health protection and environmental protection should be significantly increased, and the results should be made available, in a suitably structured form, to society.

2. **Implementation of preliminary assessment criteria and of principles for responsible use of nanomaterials:**
   It is recommended that defined determination and measurement procedures be assigned to the three preliminary risk-assessment groups (categories). The criteria have to be weighted. Classification criteria and resulting measures should be linked.

The principles paper should be extended to cover other industrial sectors that use nanotechnologies or nanomaterials. The issue of whether voluntary commitment can suffice overall, or whether tighter legal structures must be created, must continue to be discussed. The NanoKommission recommends that a system to monitor the implementation should be developed and that the principles be reviewed every two years.

3. **Market transparency for consumers:**
Clear, understandable information about ingredients, functions and effects, and about product safety, needs to be provided and made freely accessible. New concepts for such information provision need to be developed.

4. **Continuation of the NanoKommission's work:**
The NanoKommission's next work phase should be intensively focussed on the following:

- Discussion of regulatory issues;
- Consideration of additional applications;
- Intensified use of life-cycle analyses;
- Broadening of the dialogue towards social and ethical issues;
- Further development of precaution-oriented procedures for risk assessment and evaluation;
- Intensified public communication of ongoing efforts and current findings;
- Intensified participation in the relevant international discussion;
- Stronger involvement on the part of industries applying nanotechnologies.

For its further work, the NanoKommission will require professional support in the form of an office and related resources. As necessary, the NanoKommission should also be able to draw on the support of an independent moderator.

The NanoKommission can look back on two intensive years of productive co-operation involving a broad range of different stakeholders. It welcomes the Federal Government's initiative for continuation of this work, in the interest of a sustainable development of nanotechnologies' potential as a field for useful innovation.

I. Principles governing the work of the German NanoKommission

As a cross-cutting technology, nanotechnologies find use in a range of industries and can develop their innovation potential in diverse ways. Knowing how to create new materials and processes and how to convert research findings into products rapidly and with sustained effect is becoming a key competitive factor worldwide. The German NanoKommission aims to promote the responsible use of nanotechnologies and adresses in a timely manner the important issues of potential benefits and risks in dialogue with stakeholder groups.

1. Preliminary definition

The term **'Nanotechnologies'** covers a set of technologies that enables the manipulation, study or exploitation of very small (typically less than 100 nanometers) structures and systems. Nanotechnologies contribute to the development of novel materials and nanosystems. With this terminology the German NanoKommission is in line with the definitions suggested by the OECD Working Party on Nanotechnology.

- Engineered materials in this size range which, primarily as a result of their altered surface area to volume ratio, develop new properties, different from the propierties of individual atoms, molecules and bulk matter and which can be used to create improved materials, devices and systems that exploit these new properties are called **'nanoscaled materials'**.

- **Nano-objects:** Materials with one, two or three external dimensions at the nanoscale (approximately 1 to 100 nm). Typical examples are nanoparticles, nanoplates, nanofibres, nanotubes, nanorods, nanowires and quantum dots. Nano-objects are often found in groups such as agglomerates or aggregates. According to ISO these are not limited in physical size or form[1].

These terms have been incorporated into the OECD's preliminary definition and are used in a similar way by the European Commission, the German Chemical Industry Association and the German Federal Institute for Occupational Safety and Health. The NanoKommission has adopted these preliminary definitions in its work. Regardless of this, environmental and consumer organisations have raised concerns about casting such definitions in too narrow terms.

The NanoKommission believes that any future definition should make clear that aggregates and agglomerates of over 100 nm are also nanostructured materials due to their internal structure. Here too its opinion is based on the precautionary principle, not only because a clear definition is needed, but also because the new properties of nanomaterials are attracting a great deal of attention. When systems larger than 100 nm display new properties, these

[1] For an explanation of terms see Technical Specification (ISO/TS27687:2008(E)) dated 15 August 2008

too warrant consideration in future work. Where applicable, the definition of nanostructured materials should include substances which exhibit specific nanoscale structures such as cavities.

The work of international bodies on establishing key definitions is considered by the NanoKommission as of vital importance for regulatory issues. The various industrial associations should adopt a uniform definition in order to avoid conflicting interpretations and to enable authorities, NGOs and the general public to come to a consistent assessment of the application of nanotechnologies and nanomaterials. Such a definition is also needed to enable more specific parameters to be set for support programmes and measures to minimise risk.

In this report the German NanoKommission refers to the preliminary definitions described while also making allowance for any later adjustments.

2. Germany is investing in nanotechnologies

Germany is an important centre in the field of nanotechnologies. Nearly half the European businesses involved in nanotechnologies are based in Germany. Since the 1990s the Federal Republic has specifically fostered this future technology as well as cooperation between science and business. At the same time it has invested in risk research projects and established interactive dialogue programmes. Since 1998 funding for project support programmes has been quadrupled, and in 2002 an initial nano strategy was presented. Germany provides € 438 million in public funding annually, making it Europe's leading provider. Of the €165 million in Federal Ministry of Education and Research (BMBF) project resources, € 6 million (3.6%) are earmarked specifically for risk research. In addition, the individual research efforts of the Federal Environment Agency, the Federal Institute for Risk Assessment and the Federal Institute for Occupational Safety and Health have led to a joint research strategy aimed at improving coordination. The industrial research sector has invested € 250 million in nanotechnologies and nanomaterials through joint projects with the public sector. As far as the number of patent applications is concerned, Germany is in 3rd place behind the USA and Japan. It is in 4th place with respect to scientific publications.

In 2006, in the context of its High-Tech Strategy, the Federal Government launched its overarching “Nano Initiative – Action Plan 2010” to cut across departmental boundaries and provide a single framework for action. Seven ministries are involved in the plan, which is headed by the Federal Ministry of Education and Research (BMBF): The Federal Ministries for the Environment, Nature Conservation and Nuclear Safety (BMU), Labour and Social Affairs (BMAS), Food, Agriculture and Consumer Protection (BMELV), Health (BMG), Economics and Technology (BMWi) and the Ministry of Defence (BMVg).
The aim is to

- fund cross-departmental, interdisciplinary research and development in the priority areas of electronics, automotive engineering, the chemical industry, the medical field, lighting technology and energy,

- explore potential risks to humans and the environment,
- fast-track the implementation of research outcomes for sustainable innovations and reduce obstacles to innovation,
- invest in training and knowledge transfer at an early stage,
- cooperate at an international level on the formulation of standards and norms, the identification of potential risks and the preparation of potential regulatory mechanisms, and
- discuss potential benefits and risks with the general public and various stakeholders.

3. Societal dialogue on issues of sustainability and safety

The particular characteristic of the nanotechnology debate in Germany is the relatively early involvement of various stakeholders in discussions on potential benefits on the one hand and potential risks on the other.

As far as potential benefits are concerned, the NanoKommission focused on areas of application which support the United Nations Millennium Goals and can contribute towards efficient resource management and health protection. **Surface technology** is one example of a consumer-related application that could relieve the burden on the environment. Nanostructured materials provide easy-to-clean, scratch-resistant coatings for motor vehicles, sanitary products, cladding and windows. It is hoped that the environment will benefit from products that are more durable and that reduce the need for harsh cleansers. In drive technology, low-friction coatings used in bearings have the potential to reduce fuel consumption.

It is also hoped that nanotechnologies will deliver considerable benefits with respect to **environmental technologies.** They are expected to stimulate significant developments in the field of **efficient generation and storage of energy.** For instance, photovoltaic systems can be manufactured more cost-effectively and operated at a greater level of efficiency. The electricity generated can be safely stored in large lithium-ion batteries containing nanomembranes. In this way energy supply could become more mobile, compact and decentralised. Such technology has the potential to substantially change the future of motor vehicles and electronic appliances. Other examples are nanomembranes and nanocoatings for **filter systems,** which open up new options for treating drinking water, purifying polluted water and specifically preventing contamination.

However, at the same time the development of new processes and materials is raising questions about **human and environmental safety.**

Current research is concentrating on the inhalation of free persistent nanoparticles, as various tests have indicated potential health risks. Scientists are currently examining different materials in terms of potential dose-response-relationships, in order to work out applicable exposure limits. At an international level there is a need for standardised test procedures and more research on measurement technology, so that reliable conclusions can be drawn regarding the exposure of humans and the environment. As a precautionary measure, such exposure should be minimised or avoided during the manufacture and use of nanomaterials until a risk evaluation, exposure limits and validated measurement methods have become available.

The industrial sector addressed the issues of occupational health and safety at an early stage, and initial guidelines exist for the safe use of nanomaterials in manufacturing. These deal mainly with avoiding inhalative exposure. If nanomaterials are bound in matrices, either in a liquid or, at a later stage, in a hardened surface coating, most experts are agreed that inhalation tends to pose only a low risk to human health.

Most **dermatological** studies indicate that healthy human skin provides relatively good protection against nanomaterials, preventing them from penetrating the body. This also applies to cosmetic applications, such as sunscreens. Studies on damaged skin have not yet been completed, and their findings are still pending.

Less is known about the possible impacts of absorption of nanomaterials through the **gastrointestinal tract.** Little reference material is available from the food industry. Comparable studies on animal feed are available for only a few selected materials such as nanostructured amorphous silica. The NanoKommission sees a need for further research here, emphasising the imperative for improved communication between industry, science and public authorities – particularly in view of the topic's considerable relevance to the general public.

It is not yet possible to adequately assess the potential impact of nanomaterials on the environment, but initial investigations suggest that this area warrants special attention. The NanoKommission recommends that research efforts should be substantially increased in this area and the precautionary principle taken especially seriously. One problem associated with conducting a risk analysis of nanomaterials in the environment lies in demonstrating that changes have been caused by the materials introduced or in distinguishing them from naturally-occurring substances. Moreover, insufficient information is available as yet to allow an accurate description of how nanomaterials suspended in liquids behave in the environment. At this stage, therefore, it is impossible to draw any definitive conclusions regarding potential risks.

4. Implications for the work of the NanoKommission

So, are nanomaterials hazardous or not? The above section on risk issues shows that the many different materials and applications make it impossible at present to give any generalised, straightforward answers to this question. For the moment the experts' position is that nanomaterials and the use of nanotechnology should be assessed on a case-by-case basis, weighing potential benefits against potential risks. Suitable procedures should also be introduced to minimise risk in keeping with the precautionary principle. But here, too, specific consideration should be given to the material concerned, its exact properties (see the findings of Working Group 2) and its specific.

From a scientific point of view it is currently impossible to draw any general conclusions. Yet straightforward answers are precisely what the public is demanding. Perhaps the real challenge lies in dealing with the inevitable **complexity** of the topic, communicating this at a societal level and ensuring that the different steps taken to assess the potential benefits and risks are rendered transparent. Benefits and hazards should be weighed up impartially by all the stakeholders and the results summed up in a joint evaluation. The risk evaluation and guidelines (e.g. for risk management and communication purposes) require internationally standardised criteria which researchers, business entities and public authorities can all use as a benchmark.

Within the NanoKommission various stakeholder groups are addressing the uncertainties and knowledge gaps that exist at this early stage of nanotechnology development. A two-tiered process is proposed. The established risk management procedures – will be preceded by a **preliminary assessment** to include a scientific hazard assessment, exposure assessment, risk evaluation and risk management measure for health and environmental protection. This preliminary assessment will draw on information available very early in the innovation process – in other words, on the established or relatively easily ascertainable characteristics of nanomaterials (particularly their physico-chemical properties). Working Group 2 has developed a table of criteria indicating concerns or no cause for concerns for the purposes of the preliminary risk assessment. The next step is to use this grading system as a basis for establishing appropriate measures in accordance with the precautionary principle. The practical relevance of such preliminary assessments and their corresponding measures, however, will decrease as more becomes known about impact mechanisms and exposures, thus enabling traditional methods of risk evaluation and risk management to take effect.

The NanoKommission has taken up the challenges entailed in the responsible use of nanotechnologies. It seeks to deal with the uncertainties, unanswered questions and knowledge gaps using tangible examples with a view to finding solutions. Current and subsequent dialogue would seem to depend crucially on conducting a broad debate at societal level around the following issues:

- How can and should nanotechnologies and nanomaterials contribute to the future development of the economy and society? What risks do they pose for people and the environment and can these be safely ruled out?

5. Development of Germany's dialogue landscape

Germany's NanoKommission forms part of a broadly supported national dialogue process. It may be that these early discussions are what distinguish the German nano debate from that in other countries. The work of the NanoKommission has benefited from previous dialogue initiatives:

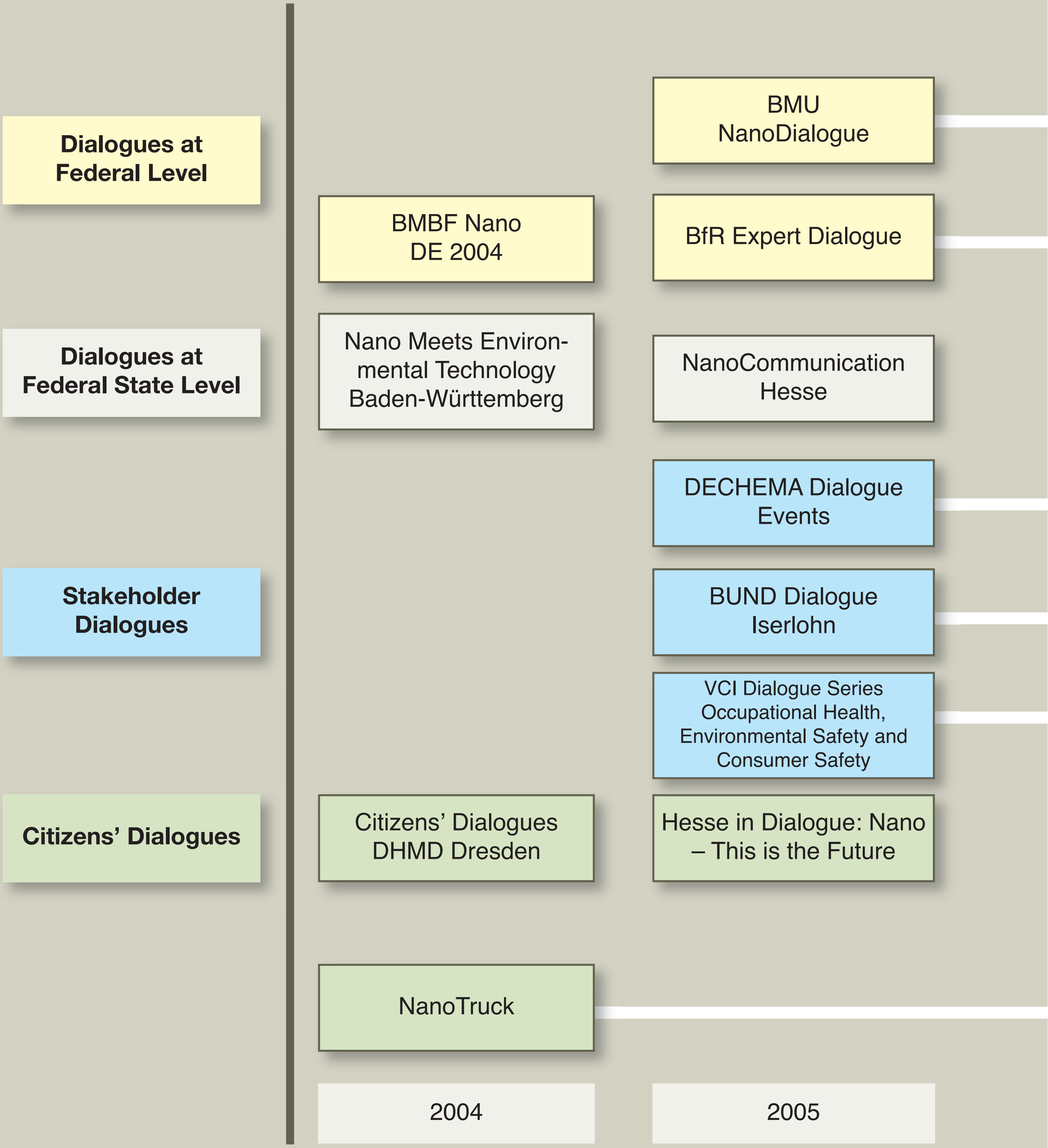
Socio-political debate on nanotechnology began in 2003 when the German Parliament's Office of Technology Assessment published its initial report. In spring 2004 the first “citizens’ dialogues” on nanotechnology took place at the German Hygiene Museum in Dresden (DHMD). In summer 2004 Parliament passed a resolution entitled “Entering the Nanocosmos – using potential benefits, assessing potential risks”. Major associations and scientific organisations such as the Chemical Industry Association (VCI), the Association of German Engineers (VDI) and the Society for Chemical Engineering and Biotechnology (DECHEMA) support the generation and transfer of knowledge on nanotechnology, and have implemented numerous events and research projects on new developments, risk research and risk management.

In 2005 the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU), the Federal Environment Agency (UBA) and the Federal Institute for Occupational Safety and Health organised a major international conference, providing a basis for the broad “NanoDialogue” project. Some 170 German experts in the fields of policy making and implementation, science, business, consumer and environmental organisations, unions and churches accepted the invitation to take part in the NanoDialogue, where they discussed potential benefits and risks along with issues of measurement technology and communication.

Since 2005 the VCI has been conducting an ongoing stakeholder dialogue on risk related questions (e.g. occupational safety). Here experts work on concrete measures for occupational health and safety and questions of measurement technology. Joint agreement has been reached between the stakeholders on guidelines to govern the responsible use of nanomaterials in the workplace and the dissemination of information along the supply chain. The VCI, together with the Federal Institute for Occupational Safety and Health, has carried out a business survey on the use of nanomaterials in the chemical industry. Dialogue is continuing, with a focus on the topics of environmental and consumer protection. During the same period the IKW (the German Cosmetic, Toiletry, Perfumery and Detergent Association) has been conducting its own stakeholder dialogue on the topic of “Nanotechnology and the Cosmetics Industry”.

The BUND, the German section of Friends of the Earth, has also been involved in the field of nanotechnology since 2005, holding annual conferences at the Evangelischen Akademie Iserlohn, a church-affiliated organisation. Various position papers and studies on nanotechnologies in the food and cosmetic industry have subsequently been published.

Examples of German dialogue processes concerned with the potential benefits



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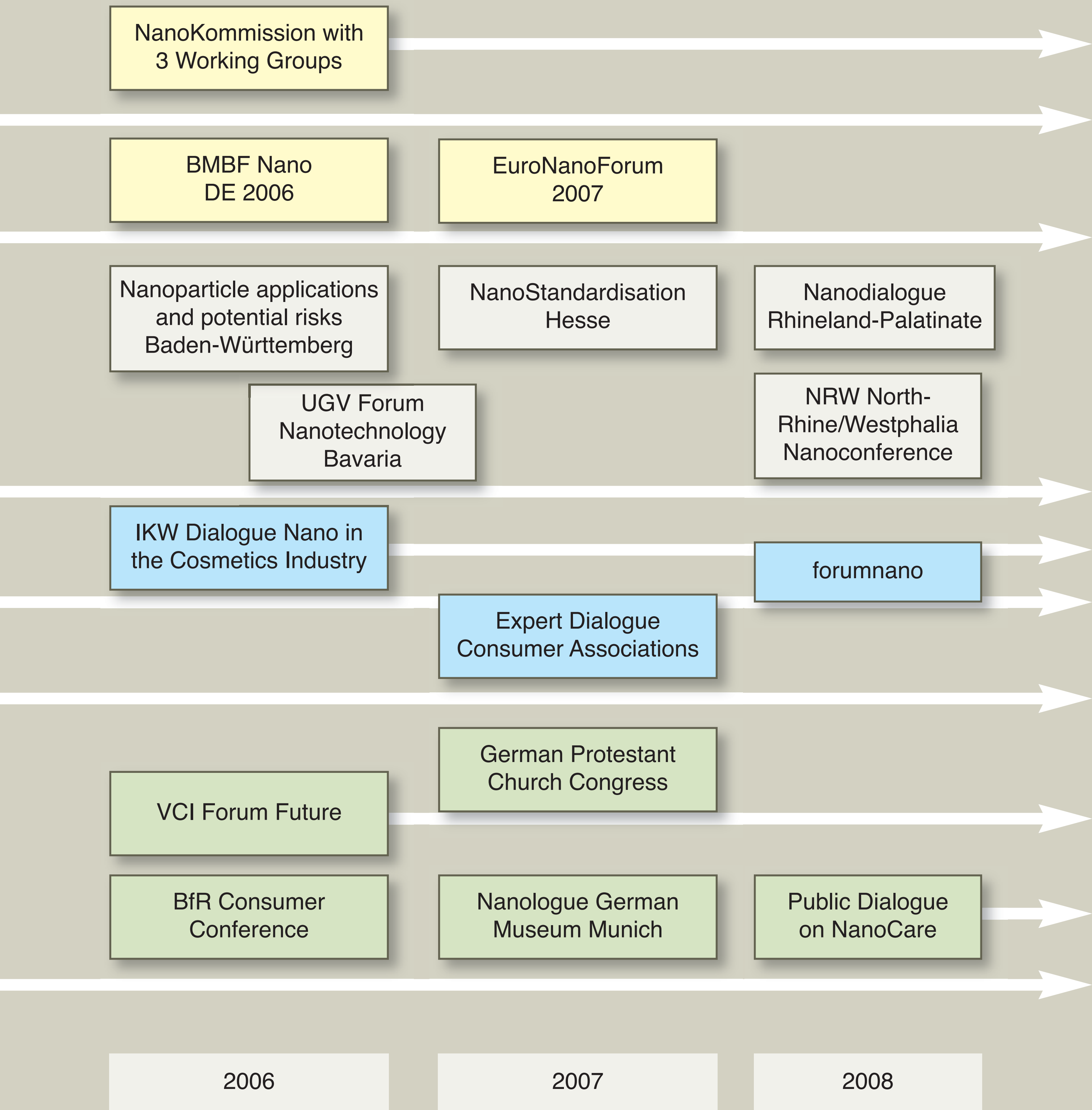


In 2006 the Federal Ministry of Education and Research (BMBF) launched the interdisciplinary research project 'NanoCare'. Representatives of science and industry have been working together on a risk evaluation of nanomaterials and on putting in place standardised test procedures. The project received € 7.6 million in funding from the Federal Ministry of Education and Research. The findings are introduced and discussed in dialogue events that involve citizen participation and are open to the wider public.

In the same year, three Federal Superior Authorities – the Institute for Occupational Safety and Health, the Institute for Risk Assessment (BfR) and the Federal Environment Agency – developed a joint research strategy on the health and environmental risks posed by nanomaterials. This strategy identified knowledge gaps and established a list of common priorities. In the course of a consultation process, various stakeholders had the opportunity to add to and evaluate the research strategy before it was finalised.

Also in 2006 the German Institute for Risk Assessment carried out an expert survey on nanotechnologies in the areas of food, cosmetics and consumer goods. Some 100 experts were asked about the potential risks in consumer-oriented fields, and they evaluated existing and future areas of application. The possible oversupply of vitamins (hypervitaminosis) caused by the use of nano-carrier systems in the food industry, the increasing use of silver in goods sold to consumers and the use of fullerenes in cosmetics were the subject of particularly close scrutiny. A consumer conference was held upon completion of the expert survey. The views of the citizens involved were varied and discerning. They stressed that their attitude was generally positive while at the same time making very clear their need for more information. Their main concern was the use of nanomaterials in food itself. In contrast, intelligent packaging met with definite interest, provided it is tested for safety.

In 2006 the Federal Environment Agency commissioned the Institute for Applied Ecology (Öko-Institut e.V.) and the Society for Institutional Analysis (SOFIA) research group at Darmstadt University to produce an expert report to examine – for the first time in the German context – whether the country's legal framework is adequate to cover nanotechnologies. Their report made several suggestions for more specific legislation and substantiated the need for action by German lawmakers. The VCI has also devoted several papers to the legal aspects of nanomaterials.

At Länder level (Saxony, Hesse, Baden-Württemberg, Bavaria, Rhineland-Palatinate, North-Rhine/Westphalia and Bremen) various support programmes and networks on nanotechnologies and nanomaterials have existed since 2005. The Länder have organised a variety of dialogue events on topics such as occupational safety, health protection, environmental protection and risk communication. The early involvement of Länder law enforcement agencies in the dialogues and the expansion of the knowledge base were considered to be vitally important.

In terms of communication with the general public, various event formats have been put to the test. The NanoTruck has been rolling through Germany since 2004, attracting general interest wherever it makes a stop; the truck's main clientele, though, are classes of schoolchildren who come to it to learn about nanotechnologies. The VCI's NanoBox programme provides materials for experiments and lesson-planning available to schools, to enable them to carry out their own experiments. Various internet-based knowledge portals specifically target groups of schoolchildren and students. Science museums, particularly the German Museum in Munich and the German Hygiene Museum in Dresden, have organised exhibitions and dialogue events on nanotechnologies, in which issues of risk have also been debated.

At the same time the work of the NanoKommission has prompted or reinforced dialogue among the various stakeholder groups. In 2007, for instance, the German Consumer Protection Association offered a lecture series on nanotechnologies for multipliers from consumer protection agencies, in which it gave an account of the NanoKommission's work. In May of the same year a major nanotechnology forum was held during the German Protestant Church Congress, and was attended by some 3000 people.

It is interesting that, in comparison with other countries, German people have a relatively positive attitude towards nanotechnologies. Their level of awareness of the field is about 50%. According to a representative survey carried out by the Federal Institute for Risk Assessment in 2007, 66% of those who had an idea of what nanotechnology is had a positive attitude towards it.

This level of approval was confirmed by a qualitative study commissioned by the German federation of consumer associations in 2008, according to which 64% of people were positive, 31% were not sure and only 5% were strongly opposed. The study also showed that those who had heard of nanotechnology knew on average of 5-6 different areas of application, and were far better informed than had hitherto been assumed. People are watching developments very closely in the media and the Internet and are differentiating clearly between desirable and less desirable aspects. The fact that 87% spontaneously mentioned the topic of health risks shows how great is the need for information on the functions and impacts of nanomaterials. “More information” is therefore one of consumers' key demands.

The initial conclusion is that the various dialogues have helped to increase the level of knowledge of both participating experts and the general public. They have also encouraged the early handling of crucial issues and helped to broach the issue of the responsible use of nanotechnologies. This is a vital principle of the work of the German NanoKommission. Its objective is to build on the conclusions drawn from the various dialogue processes and research projects while maintaining its focus on results as these are carried forward.

6. Structure and aims of the NanoKommission

The German NanoKommission was created in late 2006 as a key dialogue panel within the Federal Government's Nano-Initiative. It is an important platform for different stakeholders and advises participating ministries and their federal authorities on issues such as research and the evaluation of current developments. The work of the NanoKommission focuses equally on the potential benefits and risks, scientific and technological issues as well as transparency and information transfer. Its findings are available to the wider public, thus promoting dialogue about the future of nanotechnologies. The NanoKommission has taken on greater significance as the debate on the benefits and potential hazards has developed. Its aim is to facilitate constructive dialogue despite diverging interests.

Wolf-Michael Catenhusen, former State Secretary, is head of the German Government's NanoKommission, which consists of 16 appointed experts from different stakeholder groups. These include representatives from the fields of science and industry and their associations, representatives of environmental and consumer organisations, a union representative and government representatives at federal and Länder level.

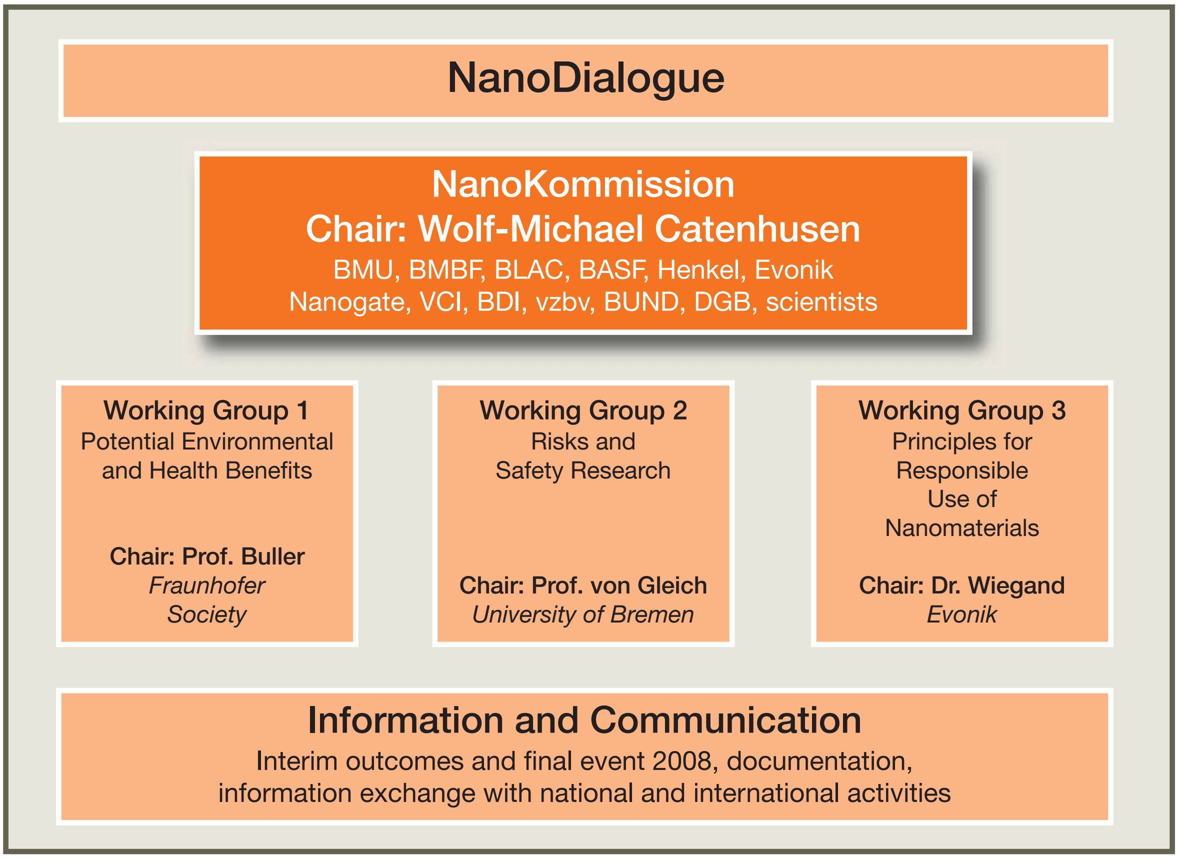
The NanoKommission jointly defined its priority issues and initially set itself three tasks, for which specific working groups were formed[2].

1. How can the use of nanomaterials contribute to sustainable economic and social development in Germany, especially in terms of environmental, health and consumer protection?

2. Where do we need interdisciplinary risk and safety research to clarify the potential impact of the use of nanoparticles on the environment and health?

3. Do we have to wait for the initial results from these two working groups or can we already do something to protect human health and the environment?

Figure 1: Structure of the NanoKommission 2006-2008



[2] The appendix includes a full list of members of the working groups and the NanoKommission.

Backed up by the Federal Environment Ministry, the NanoKommission supported the processes and meetings conducted by the working groups, which set their own objectives and developed work programmes within the context of the guidelines provided. To expand the debate, experts were invited to the working groups and the NanoKommission, and an event was organised to discuss interim results with interested parties.

The aim was to involve active representatives from the different stakeholder groups in the NanoKommission and in all the working groups. Key contributions by various NGOs (environmental and consumer organisations, unions and professional organisations) raised a number of important issues, which greatly helped to consolidate the outcomes. As a result of working together with societal stakeholders, business entities and their associations became more sensitive to socially-relevant risk issues. Strategies to promote the responsible use of nanomaterials were developed with respect to the transparency of risk management procedures, communication and a voluntary code of conduct. Scientists made their research outcomes available for discussion and were given suggestions for areas requiring further research. Policy makers and authorities at federal and Länder level gained a better insight into the current status of research and development, particularly in terms of risk topics.

The NanoKommission has also contributed to a more discerning societal debate in Germany. There has been little polarisation thus far – especially in the areas of application where dialogue took place early on, such as in the chemical and cosmetic industries. But it has also become clear that unanswered questions emerging from society need to be addressed transparently. Since 2008 even the food industry has signalled its readiness to enter into dialogue on the controversial issue of nanotechnology in food.

7. Embedding German dialogues in the international debate

The international Organisation for Economic Cooperation and Development (OECD) is focussing nanotechnologies together with 30 member countries, the EU-Commission and associated non-members such as Brazil, China, Singapore and Russia. Its meetings are attended by observers or experts sent by the International Standardisation Organisation (ISO), the World Health Organisation (WHO), the United Nations Environment Programme (UNEP) as well as the from industry, NGOs and unions. The professed aims of the OECD are to create sustainable economic growth and employment, raise living standards and maintain financial stability, to assist the economic development of other countries and to foster worldwide trade. Sustainability here means finding a balance between economic, social and environmental interests.

Two fields of activity have been established for the responsible use of nanotechnologies and nanomaterials:

- Firstly, established in 2006 the Working Party of Manufactured Nanomaterials, WPMN, which addresses the implications of nanomaterials for human health and the environment. The group is additionally focussing testing and assessment methods.

- Secondly, established in 2007, the Working Party on Nanotechnology, WPN, which deals both with setting up internationally compatible economic and technological data, information exchange and dialogue, and with global challenges such as obtaining clean drinking water.

Both Working Parties are supported by international working groups in which experts offer recommendations for guidelines governing the future use of nanotechnologies worldwide. The intensive preparatory work of the NanoDialogue, the NanoKommission and their Working Groups can make a contribution to this. Members of the NanoKommission will share their findings with the OECD and feed in their international experience to the German discourse.

Project 1 has set up a data base on human health and environmental safety research. Project 2 of the WPMN is developing an internationally coordinated research strategy on health and environmental risks. Germany hold the chair in this project and the findings from the NanoDialogue have been contributed to this. In Project 3 the OECD experts are examining a set of 14 market-relevant nanomaterials for their impact on health and the environment. Germany can make a significant contribution here, particularly as some of the world's leading manufacturers of nanomaterials are based in this country. Germany is taking the lead sponsorship for titanium dioxide (together with France) and is co-sponsor for silver applications. Additional German contributions will be made on single-walled and multi-walled carbon nanotubes, cargon black, aluminium oxide and cerium oxide. Other nanomaterials have been selected by the OECD for testing, including fullerenes, iron particles, zinc oxide, silicon dioxide, polystyrol, dendrimers and nanoclays. Project group 4 of the WPMN is looking at adapting test procedures. Groups 5 and 6 are working on a voluntary schemes and regulatory programmes and issues of cooperative risk evaluation, groups 7 and 8 on nanotoxicology and exposure measurement.

The scientific and business sectors in Germany are actively engaged in researching the fields mentioned above and are involved in numerous national and international research projects. Additionally the study on the use of nanomaterials in the chemical industry conducted jointly by the Federal Institute for Occupational Safety and Health (BAuA) and the Chemical Industry Association in 2007 can support the work of the OECD.

At the European level, in 2004 the European Commission presented its strategy in a paper entitled "Towards a European strategy for nanotechnologies". In 2005 it adopted an action plan for an integrated, safe and responsible nanotechnology strategy for nanosciences and nanotechnologies, to ensure that environmental protection, health protection and safety form an integral part of all relevant European research projects. In 2008 the Commission presented a proposal for a "Code of Conduct" for responsible nanosciences and nanotechnologies research. This code, has not yet been debated within the NanoKommission. Working Group 3, however, has addressed similar issues in connection with industrial applications. In summer 2008 the European Union set up CASG Nano, an expert advisory group, to analyse how the REACH chemicals regulation applies to nanomaterials. Its work will be relevant for future NanoKommission discussions, too.

II. The NanoKommission's findings

The work of the German NanoKommission is guided by the precautionary principle. Following intense discussion, the three working groups were able to:

- identify the areas of application which, in the opinion of the stakeholders, may have positive potential for the environment,
- collate knowledge about potential risks and develop criteria for timely risk evaluation, and
- assemble a set of principles outlining appropriate measures to ensure the safe use of nanomaterials.

The three working groups were given a set of guidelines by the NanoKommission to govern their work. They set their own priorities and developed work schedules in line with this framework. The participating experts made their knowledge available to the NanoKommission in consultation with their own organisations. The findings are documented in the chapters that follow. They should be seen as representing the interim stage of a process that cannot be regarded as finished. Where applicable, any unanswered questions requiring future attention will be pointed out.

1 Findings of Working Group 1: Nanotechnologies – Potential Environmental And Health Benefits

Working Group 1 is comprised of some 20 experts from industry, research, environmental and consumer protection associations, as well as federal and Länder authorities, who met for the first time in 2007. The NanoKommission's assignment for Working Group 1 was to:

- identify examples of nano-products and processes – already available or currently being developed – which could have potential environmental and health benefits,
- develop comprehensible criteria to assess the potential benefits, and
- make recommendations for development priorities within Germany's High-Tech Strategy, focusing on protection of the environment and human health.

A large number of examples already available were collated in the initial phase of investigation. “Energy” and “environmental and resource protection” emerged as priority themes. The members of the working group set themselves the goal of gathering further research projects and examples of actual products from these fields and describing the (expected) reduced environmental pressures associated with them. It was hoped that a life cycle analysis could be carried out for selected examples, an idea that should generally be reflected in all the assessments.

Criteria were developed to define reduced environmental pressures, in both qualitative and quantitative terms:

- **Climate change mitigation** e.g. reduction in greenhouse gases
- **Energy efficiency** compared to existing products
- **Resource efficiency** e.g. reduction in amount of substances needed for the manufacture, use and consumption of new products, as well as potential to minimise waste and conserve raw materials
- **Substitution of environmentally hazardous substances** such as heavy metals, chlorine compounds or organic solvents with non-hazardous, environmentally-sound nanomaterials
- **Reduction of environmentally hazardous substances** through the use of nanotechnologies and nanomaterials e.g. thinner layers of material, easy-to-clean surface finishes which reduce the need for cleaning agents, filter technologies for water, soil and air
- **Increased safety** in the manufacture (process management) and application of a product through the use of nanotechnologies and nanomaterials.

These criteria describe potential innovations in keeping with sustainability, provided they do not prompt any new potential risks to human health or the environment. They outline a type of corridor of positive characteristics ('Go-Areas') which are very broadly accepted in Germany and, in the opinion of the stakeholders, warrant specific support.

The following summary of results contains a selection of the more extensive examples contained in the original documents of Working Group 1. The original document is available on the internet at http://www.bmu.de/nanokommission.

1.1 Nanotechnologies for the environment: an initial overview

The following table details nanoproducts currently under development in Germany which have major potential to reduce environmental pressures. The products listed are already commercially available, although in many cases they are not yet widely in use. Therefore, the extent to which their potential benefits can be fully realised is still unclear. In the opinion of the NanoKommission this list could be expanded to form a component of a comprehensive research and market review.

Type of product	Brief description	Status
	Energy storage	
Lithium–ion batte-ries	A ceramic membrane with nanocomposites provides greater safety in lithium-ion batteries. The batteries are lighter, lower-priced and more durable. They are suitable for electric vehicles and hybrids and can store alternative energies derived from wind, solar or hydropower.	Produkt auf dem Markt
Fuel cell technology	Various fuel cells are currently being developed. For example, nanostructured hydrogen reservoirs consist of synthetic metal-organic frameworks (nanocubes), making fuel cells portable. Other research projects are investigating nanocrystalline materials and ionic liquids. Hydrogen-powered fuel cells use special nanoporous membranes and nanostructured catalysts (platinum) to increase power density.	Prototypes
	Energy and resource efficiency	
Photovoltaics	Various nanomaterials are used in more recent photovoltaic cells. For instance, nanocrystals increase the otherwise relatively low efficiency factor of thin film solar cells. Nanoporous layers have an anti-reflective effect on silicon solar cells, and special techniques produce more effective structures. Nano-silver coating blanks out the portion of light unused by the photovoltaic system, preventing it from heating up the solar cell and reducing its efficiency. Dye-sensitised solar cells with nanocrystalline TiO_2 are also available on the market and contribute towards the efficient use of energy.	Product on the market
Thermal insulation	Silica aerogels in particular display very favourable properties for use as transparent thermal insulation for windows and building materials. Aerogels form a solid-state material, up to 95% of which consists of nanometer-sized pores. They are transparent, do not conduct heat and are also very light in weight.	Product on the market
Alternative manufacturing processes in the chemical industry	Nanomaterials used in various chemical processes can help to save energy and resources. Nanoscale powders make possible lower temperatures in production processes (e.g. sintering or soldering), nanocoatings save water, energy and chemicals. Nanoparticles used as a solvent make lower temperatures possible in polymer melts, e.g. in injection moulding.	Product on the market
Building materials, concrete	Optimising asphalt mixtures can make road surfaces more stable and durable. This application shows great promise in the context of specific climatic requirements. Concrete containing nanoparticles is ten times more stable and less susceptible to corrosive agents than standard concrete.	Product on the market

Type of product	Brief description	Status
	Energy and resource efficiency	
Lightweight construction materials	Automotive or aircraft parts made of nanotechnologically optimised synthetic materials can save weight and reduce fuel consumption. A minimal proportion of nanoparticles, usually 2%– 5%, can often improve the mechanical and thermal properties of synthetic materials by at least 50%. Thus they are increasingly able to compete with metallic materials.	Product on the market
Soluble bonded joint	Use of magnetic nanoparticles in bonded joints: particles are heated by a varying magnetic field. They are used both to harden polymer compounds and to destroy the bond. This process simplifies the re-use of product components.	Product on the market
	Environmental protection	
Nanoporous filters	Nanofilters are used to recycle waste water from manufacturing, residential areas and landfills. Drinking water can be refined and purified. Water desalination is also a possibility, as is neutralisation of heavy metals, dioxins and radionuclides. Efficiency of separation and throughput can be controlled far more accurately than by conventional processes.	Product on the market
Nano-based photocatalysts	Photocatalysts break down bacterial film and grime on surfaces and are used to disinfect swimming pools – without chlorination. Active oxygen and hydroxyl radicals disinfect the water. Photocatalysts can also prevent soiling on cladding, glazing, window frames and in construction materials (thus increasing durability and reducing the need for harsh cleansers). They are also used to purify contaminated air.	Product on the market
Easy-to-clean and self-cleaning coatings	Consumers are familiar with nanoscale surface coatings on cars, bathroom ceramics and shower cubicles, where they reduce the need for water and harsh cleansers. Nanomaterials in varnishes and paints increase the durability of exterior finishes, for instance.	Product on the market

1.2 Examples of energy storage, energy and resource efficiency and environmental protection

The following examples were contributed by business entities involved in Working Group 1. It was agreed that an initial quality assurance of the in-depth examples should be based on the following questions:

- What special function or property of the product is generated by using nanomaterials / nanotechnologies (advantages over existing products)?
- What added value or positive contribution to environmental protection results from the use of nanomaterials / nanotechnologies?
- Status of product development / application?
- Which customer demands / social concerns does it satisfy?
- Can an assessment of safety, sustainability and recyclability be carried out at this stage?

Wherever the stage of development allowed, the participants collated data and facts on the expected benefits. In the case of some products currently under development, estimates had to be made on the basis of plausible assumptions. A parallel research project being conducted at the University of Bremen (Steinfeldt, M. et al., 2008)[3] has made a very positive contribution here, in that the life cycle data available for selected examples had already been systematically collated and assessed.

During this work phase it was not yet possible to develop an agreed testing matrix for future activities. As Working Group 1 progressed a growing desire to make an integrative and systematic examination of individual examples became apparent, and this is suggested for the ongoing work of the NanoKommission and its working groups. However, in some cases explicit conclusions are drawn on safety issues, potential risks or disposal.

1.2.1 Energy storage

A new generation of more powerful yet safe, affordable and light-weight batteries can enable the more widespread use of renewable energies. The storage of alternative energies generated from wind, water and the sun will trigger a major upsurge of innovations aimed at sustainability. More efficient hybrid and electric drive technologies in motor vehicles show promise of success, whereas previous applications without nanomaterials proved unsuccessful. A study commissioned by the Federal Environment Agency estimates that hybrid-drive buses (used in local public transport services), combined with lithium-ion batteries, consume up to 25% less fuel than conventional city buses (Steinfeldt, M. et al., 2008). The BMBF has made € 60 million available in research funding over the next four years under the “Lithium-Ion Battery 2015” innovation alliance, in a bid to advance this technology. A consortium of German companies has also committed a total of € 360 million to this project.

Membranes are an essential component of lithium-ion batteries. These separators prevent overheating (danger of explosion). Nanoscale oxides and ceramic reinforcement are incorporated in the membrane, resulting in a thin and very heat-resistant membrane with excellent insulation properties. This considerably improves not only the safety but

[3] (Steinfeldt, M. et al., 2008): Steinfeldt, M., von Gleich, A., Petschow, U., Sprenger, R.: Entlastungseffekte für die Umwelt durch nanotechnologische Verfahren und Produkte, Bremen 2008

Example: High-performance portable energy supply – lithium-ion batteries	
Nanoform	Thin, porous composite membrane containing nanoscale oxide particles
Product	Membrane separator for li-ion batteries
Nano-based property = Advantage over existing products	High temperature stability due to use of oxide particles
Added value achieved	Battery safety due to stable temperature separation of the electrode chambers Potential fuel savings of up to 25% on hybrid vehicles with future lithium-ion batteries
Customer demand satisfied	Safety, mobility at low cost Possible application for storage and portable use of renewable energies
Product status	Commercially available products and new prototypes under development

also the durability of large-format lithium batteries. Conventional separators are adequate for smaller consumer applications such as mobile phones and laptops, but high thermal stability is essential in large-format batteries.

This application has been commercially available for some years now, and large-format lithium batteries are also going into mass production.

Quelle: Li-tec GmbH (Foto S. Döring)

Lithium batteries can be regarded as environmentally friendly as long as they replace lead or cadmium compounds and do not contain cobalt. There is also a functioning recycling system for lithium batteries which ensures that when they are handled appropriately, no (nano) materials can leak into the environment.

Other nanomaterials intended for use in lithium batteries are currently under development or already integrated. Nanoscale lithium iron phosphate, for example, increases the safety and efficiency of cells, while nano-silicon substantially improves the energy density of the batteries.

1.2.2 Energie- und Ressourceneffizienz

Lighting accounted for 2651 TWh of global electricity consumption in 2005. It is technically feasible that highly efficient lighting systems could save 30%–50% of this energy. According to estimates, this would reduce global CO_2 emissions by 450m tonnes. Incandescent light bulbs convert only 5% of used energy into light, but this figure increases to 25% in compact fluorescent lamps, and up to 50% in **organic light-emitting diodes (OLEDs).** OLEDs made of semi-conducting materials are surface-emitting diodes which operate without efficiency-reducing external reflectors. According to a report published in December 2006 by the US Department of Energy, OLEDs are predicted to be almost doubly energy-efficient compared to conventional luminescent substances with the same durability. Such lighting systems could widely replace traditional lamps in future and open the way towards entirely new applications. Apart from generating diffused light – which is much more pleasant for the user – they are substantially easier to recycle. Unlike fluorescent tubes, they contain no toxic mercury. Research continues into stable and efficient semi-conducting materials for the wafer-thin light emitting diodes. Under the German Government's OLED-initiative (including the OLED innovation alliance, which received € 100 million in BMBF support) materials and production processes are being developed for market launch, with the intention of producing fully phosphorescent light emitting diodes within the next 2 years.

(Foto: BASF AG)

Other research projects are concentrating on white LEDs using quantum dots which enable a quantum efficiency of up to 100%, i.e. minimal power consumption. Although the development of such high-performance LED modules is not yet complete, the first marketable products such as interior lighting and car headlights are already in use.

Example: Energy saving with OLEDs	
Nanoform	Thin, active layers
Product	OLED lighting systems
Nano-based property = Advantage over existing products	Nanostructures combine a very high light output with low power consumption
Added value achieved	Energy saving
Customer demand satisfied	Low costs, convenience
Product status	Commercially available products and new prototypes under development

Resources and energy sources must be used efficiently if the future development of our society is to be sustainable. Nanotechnologies can substantially help to achieve this objective. In the context of the "CNTs capture markets" innovation alliance, the BMBF is promoting the continued development of composite materials containing nanoparticles and nanofibres, in order to establish a national technology platform for a wide range of value chains.

Example: CNT product developments for lightweight construction materials	
Nanoform	Carbon nanotubes (CNT), general polymer-based, metal-based composite materials with nanofibres, nanoparticles, nanotubes as fillers. Composite materials based on polymers or metals (structural
Product	components for aviation, automotive engineering, wind turbine blades and sporting equipment)
Nano-based property = Advantage over existing products	Improved electrical or mechanical properties with low filler content The same electrical or mechanical parameters with reduced weight (material savings) through use of nanofillers
Added value achieved	Energy saving, resource/material-saving, reduction of CO_2 emissions (huge potential here), new properties and combinations of properties, higher efficiency, cost reduction
Customer demand satisfied	Lower costs, optimal combinations of properties, enhanced efficiency (e.g. when generating electricity from wind)
Product status	Products on the market

Carbon nanotubes (CNTs) are mechanically very resilient (many times more so than steel) and provide flexibility. Their controllable electrical and thermal conductivity give them the potential to substantially improve materials. In the field of light-weight construction, for instance, using only a small percentage of CNT-modified composite materials can achieve considerable weight savings compared to conventional composites. Also, these CNT nanocomposites often inhibit electric charging. In the automotive industry this property can reduce the number of process stages as well as weight (e.g. with electrostatic painting), thus reducing the overall consumption of energy and materials.

Another field of application for CNTs is packaging. For instance, by adding a small percentage of CNTs, the thickness of film used to package electronic components can be reduced by 10%-20% compared to conventional film with the same conductivity and stability. The need for less material substantially reduces both energy consumption (by 17%) and CO^2 emissions (by approx. 20%) (see Steinfeldt, M. et al., 2008).

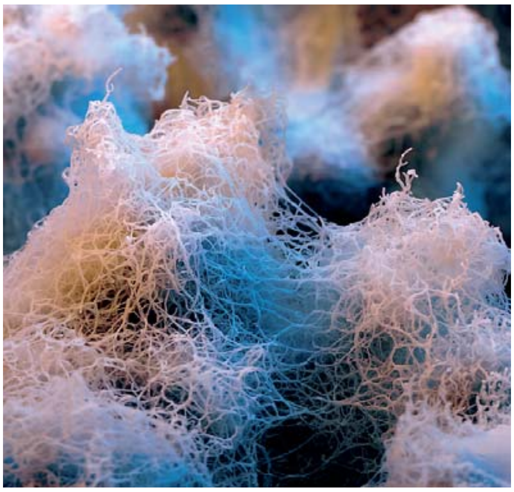
(Foto: Bayer MaterialScience)

Carbon nanotubes allow wind turbine blades to be made longer (and/or lighter with greater mechanical strength). Wind energy can be converted to electric power more efficiently.

In all the above applications the CNTs are bound within a matrix. Currently there are no indications that consumers or the environment could be exposed. Occupational health and safety measures already exist. In many cases – e.g. thermoplastic nanocomposites – the high quality materials can be recycled. Regarding risk assessment, please refer to the example of Working Group 2 (page 47).

The key to energy-efficient living is insulation. According to a study by Techem in Eschborn, German households consumed an average of some 15 litres of heating oil per square metre of living space per year in 2005/2006. People who live in old, unrenovated homes can easily use half as much again, or even double this amount. Polystyrene is still the most commonly used insulating material today, followed by materials such as Neopor® (expandable polystyrene) and extruded polystyrene. The latter have much better insulation properties than polystyrene. Polyurethane foam is currently the best polymer insulating material.

Example: Nanofoams as insulating material	
Nanoform	Foam with nanopores
Product	Thermal insulation with polymer nanofoams
Nano-based property = Advantage over existing products	Reduced thermal conduction, therefore improved insulation properties
Added value achieved	Energy savings, reduction of CO_2 emissions
Customer demand satisfied	Lower costs
Product status	Polymer nanofoams so far only at the prototype stage



(Foto: BASF AG)

Nanoporous foams with greatly-improved properties could prove to be an insulating material of the future. In polystyrene the dimensions of the pores are on the micrometre scale. Nanofoams, on the other hand, are synthetic foams with nanometre-scale pores. As the pores in nanofoams are smaller than the mean free path of the gas particles, air molecules inside the pores cannot collide. This makes such materials much poorer conductors of heat than polystyrene. As these are nanostructured materials (nanosized cavities filled with air) from which no nano-objects can be released, the issue of potential risk does not arise. However, to make nanofoams competitive, industrial-scale processes must be developed and manufacturing costs reduced. They do, however, show promise of making a substantial contribution to energy efficiency in the future.

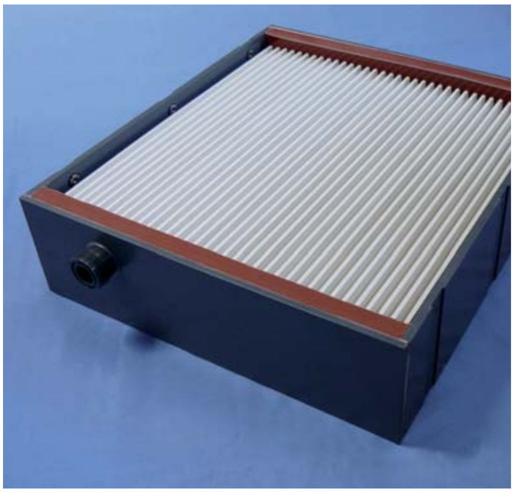
1.2.3 Environmental protection

Filtration systems for such applications as biological wastewater treatment and water purification are based on special ceramic membranes. The specific advantage here is that for the first time the properties of a plate membrane are combined with those of a ceramic membrane. A special production process provides the ceramic flat membranes with a durable, resistant nano-coating, while the active filter bed is situated on the outside – unique for ceramic membranes.

Example: Filtration systems for water treatment	
Nanoform	Membrane with nanopores
Product	Filter membrane for water purification
Nano-based property = Advantage over existing products	Improved filtration due to adjustable nanoporosity
Added value achieved	Clean water, resource savings
Customer demand satisfied	Health, hygiene
Product status	Products on the market

The system allows stable, high filtration rates and enables the construction of space saving high-output wastewater treatment plants, so-called membrane bioreactors (by reducing the membrane surface). The performance of existing wastewater treatment plants can be further enhanced. Purified wastewater can be reused safely (final effluent free of suspended solids and germs). The provision of high-quality drinking water or universal treatment of surface water becomes feasible.

Being resistant to a wide range of outside influences, a ceramic membrane is more durable than organic membranes. According to previous experience and materials expertise, its operating life is 15 to 20 years.



(Foto: ItN Nanovation AG)

1.3 NanoKommission assessment of Working Group 1 findings

During the spring 2008 event held for the interim appraisal, the NanoKommission assigned certain tasks to Working Group 1:

- Their examples should be comprehensible and consumer-relevant
- They should communicate knowledge on the function of nanotechnologies and nanomaterials
- The benefits to human health and the environment generated by nanotechnologies should be clearly conveyed and, if possible, quantified.
- The analysis of potential benefits should include important issues of sustainability, such as whether there is a risk of exposure of humans and the environment, and how potential risks should be handled.

The group addressed these tasks following the interim appraisal. Special thanks are due here to the participating businesses which made the data available. It is unfortunate that time was too short to discuss the examples with environmental organisations, consumer associations and authorities, as this could have added greater insight and clarity to the evaluation of potential risks. Dialogue on this subject should be intensified during the coming period, and the benefit and risk aspects should be integrated as soon as possible. Some businesses collated information on this subject in advance of the dialogue, while others are currently working on it. From the experience gained in joint dialogue the NanoKommission recommends that:

- Businesses should draw differentiated and, where possible, quantifiable conclusions about the **nano-specific benefits** of a product or application – particularly compared to previous solutions.

- At the same time they should be specific as to how **potential risks** will be prevented in the relevant context. This information should include statements about the material used, possible exposure of people and the environment throughout its life cycle, along with statements on test procedures and exposure measurements.
- An indication of the **reliability of the information,** e.g. reference to international standards or independent testing agencies, should be provided.
- **All partners in the value chain** are responsible for providing a comprehensive, detailed information strategy on benefits and risk management.
- New topics for the coming working period could be the fields of medicine and consumer products.
- Future discussions should be held on the development of an integrated testing matrix for an overall evaluation of potential benefits. This should allow the ecological footprint of a product over its entire life cycle to be compared with potential alternatives.

2 Findings of Working Group 2: Risks and Safety Research

2.1 Introduction

At its constitutive meeting held in March 2007, the NanoKommission gave Working Group 2 the following framework upon which to base its work:

- Overview of knowledge on the potential risks to human health and the environment posed by nanomaterials – including what is known about materials and exposure, references, an evaluation of knowledge, as well as an identification of knowledge gaps. This information should provide the basis for recommendations on how to approach a risk assessment.
- Suggestions for safety research priorities, starting from a deliberation of the research strategy provided by the Federal Regulatory Authorities BAuA, UBA and BfR, and including the BMBF's ongoing supportive measures.

The working group participants first pooled the various priority work areas they wished to address. These were:

- to gain new perspectives through the structure of the Working Group, and learn about the activities of the stakeholder groups
- to initiate specific research into risk assessment, and draw up a roadmap
- to draw up an evaluation strategy, ideas for an intelligent testing strategy, and integrated risk evaluation strategies

- to apply the precautionary principle, deal with incomplete facts and lack of knowledge, to consider each case individually
- to include national and international activities.

The working group first of all familiarised itself with the topic in brief presentations (Research Strategy of the Federal Regulatory Authorities, Debate on Defintions in International Bodies, Indications for Sensitive Areas of Application from the Perspective of the Federation of Consumer Organisations). Initial agreement on fundamental terms such as risk assessment / risk evaluation / risk management was also important. Ministries, the NanoKommission and the organisations of the participating stakeholders were all considered to be crucial target groups for the joint work activities.

The following priorities for the work schedule emerged:

1 Recommendations on research priorities: The Working Group 2 should help to prioritise research approaches and projects based on the research strategy provided by the Federal Regulatory Authorities, and thus also make suggestions to the OECD Working Party on Manufactured Nanoparticles.

2 List of criteria: The Working Group 2 should collate a set of physical, chemical and biological properties and functions of nanomaterials with specific reference to the environment, human health, occupational health and safety and consumer protection. On the one hand the criteria should allow for a better comparison of the findings of risk studies, which can and will help to raise the quality of scientific studies. On the other hand criteria indicating concern or no cause for concern were collated for a provisional assessment.

3 Addressing typical areas of application of nanomaterials: Working Group 2 should examine typical examples of selected fields of application of nanomaterials and undertake a provisional assessment.

2.2 Recommendations for research priorities

It is to be expected that as the use of nanomaterials increases, workers, consumers and the environment are more likely to come into contact with them. This raises issues of potential risk and unintentional impacts on human health and the environment.

The Working Group 2 actors are well aware that the development and use of nanomaterials involves knowledge gaps about potential risks to people and the environment. Therefore it is in the interests of all that these knowledge gaps be closed as soon as possible so that the safety and public acceptance of nanotechnological applications can be guaranteed. This requires urgent research to allow a sound assessment of the potential hazards. It is particularly important to clarify the toxicological and ecotoxicological risks, as well as issues of sustainability based on the entire life-cycle of a product. Data on exposure and its impact on people and the environment are also needed. This list of priorities was put together by the members of Working Group 2. Those involved were mainly scientists – especially toxicologists and ecotoxicologists from various institutes – along with interdisciplinary experts from the business sector and public authorities engaged in risk research, as well as environmental and consumer protection associations.

A. High priority

Characterisation and identification of nanomaterials

Characterisation of nanomaterials
- identification of relevant physical and chemical parameters
- reasons for relevant parameters
- specification of minimum requirements for a dataset for assessment purposes (to compare publications)
- method development and definition of suitable methods
- theory formation for the potential grouping of nanomaterials

Identification of the relevant nanomaterials with respect to exposure
- identification of nanomaterials which are manufactured and marketed (incl. production volumes, manufacturing methods, applications and usage) with special reference to potential exposure of humans or the environment
- method: surveys, voluntary and/or compulsory reporting procedures

Measurement methods and strategies

Measurement methods and strategies
- adaptation and development of measurement methods to verify and characterise nanomaterials
- development of measurement strategies (allowing for background contamination) in the workplace, the environment, organisms, products sold to consumers and food,
- development of standardised, well-defined reference nanomaterials (keywords: benchmarking, round robin tests, accreditet laboratories)

Exposure assessment and analysis

Exposure assessment / analysis of nanomaterials throughout their life cycle
- assessment and analysis of exposure throughout the life cycle of nanomaterials: manufacture (emissions / ambient loads), handling and use (in the workplace, consumer products, incl. food), disposal (waste)
- analysis of weak points: scenarios of the spread of nanomaterials in the environment (e.g. free, matrix-bound or coated particles) and assessment of expected concentration and deposits
- modelling and categorisation

Behaviour in the environment

Analysis of the behaviour of nanomaterials in the environment

- persistence and degradability
- agglomeration, sorption
- catalytic effect
- mobility, fate, long-range transport, interaction
- stability, exposure, metamorphosis
- accumulation through the food chain
- carrier function
- background contamination
- identification of relevant parameters for environmental behaviour, taking account of changing environmental conditions

Analysis of potential ecotoxicological impacts of nanomaterials

- subject to type, absorption, concentration, durability and fate in environmental media, as well as organisms (incl. systemic properties) etc. (with special regard to agglomeration formation, stability)
- absorption mechanisms for aquatic and terrestrial organisms

Toxicology and toxicokinetics

Analysis of potential toxicological impacts of nanomaterials

- subject to type, absorption, concentration, durability; identification of target organs and toxicological endpoints; inclusion of number of particles, concentration and surface concentration
- investigation of interaction between different nanomaterials
- impacts on tissue (e.g. alveoli, mucous membranes)

Toxicokinetics

- determination of the distribution, accumulation, persistence and elimination of nanomaterials within the human body (toxicokinetic profiles)
- investigation of relevant exposure routes (primarily oral, but also through the lungs and skin), distribution, accumulation, stability and agglomerate formation
- development of appropriate methods

Testing and evaluation strategies

Ecotoxicology

- research into the practicability of validated testing systems for nanomaterials by adjusting them to the particular requirements of nanoparticles, e.g. new parameters
- verification of the suitability, possible adaptation of standard ecotoxicological tests (with specific provision for solubility, etc.)
- development of new testing systems as a basis for assessment and regulation

Toxicology

- development of a risk-related, toxicological testing and evaluation strategy having regard to human and environmental exposure

Current risk evaluation of selected nanomaterials

Current risk evaluation
- outline of potential risks with present regulatory instruments covering exposure-prone nanomaterials (e.g. selection of silicon dioxide, titanium dioxide, zinc oxide, carbon black, aluminium oxide, iron oxide, silver, nanotubes and fullerenes etc.), including deficiency analysis and explanation of need for action
- appraisal of studies carried out (literature review) in terms of relevant endpoints; which methods have been used (including unvalidated methods), what significance do they have?

B. Medium priority

Toxicology
- investigation of skin penetration of nanoparticles from cosmetic products and consumer goods, protective measures in the workplace and their evaluation
- development and testing of technical, organisational and personal protective measures after exposure
- new and ongoing development of measurement methods in the workplace
- evaluation of personal protective equipment for handling nanomaterials and further development of the control banding approach for nanomaterials

Development and examination of possibilities for categorising nanomaterials with reference to expected behaviour / fate, exposure and hazard to humans and the environment; development of theoretical principles of such categorisations.

2.3 Criteria on the comparability of studies

2.3.1 Information on the characterisation of nanomaterials for biological experimentse

When setting the research priority list, Working Group 2 discussed the difficulties of comparing study findings. Many internationally available studies cannot easily be compared at present, as test materials and processes are inconsistent and, depending on the research design chosen, generate different results. Consistent test parameters are therefore essential for a risk evaluation of nanomaterials. The following list of parameters does not claim to be complete. It does, however, aim to establish some important prerequisites needed to verify and guarantee the value of studies on the biological impact of nanomaterials. Due to the diversity of nanomaterials, it is the responsibility of those carrying out the study to add to or alter the parameters appropriately. The list is intended to lay the foundation for:

- investigations to be repeated and findings refined, and thus to provide the evidence necessary to validate a testing system.

- findings from different studies to be compared and fundamental links between material properties and adverse effects identified.

It is important to clearly characterise the test sample not only before the experiment but also under the test conditions. Only then can the findings be interpreted appropriately. Undetected changes to characteristic parameters (e.g. during the sample preparation) can lead to the original material properties being incorrectly linked to effects observed during the experiment.

For study comparison purposes the minimum nanomaterial characteristics needed are:

- chemical composition, purity, impurities
- particle size and particle size distribution
- specific surface
- morphology (crystalline phase, form)
- surface chemistry / coating
- extent of agglomeration / aggregation and/or particle size distribution under test conditions depending on requirement (e.g. medium with or without protein)
- water solubility (with special focus on metastable particles)
- for ecotoxicological issues only: octanol-water partition coefficient

The measurement method should be specified for all procedures. Under ideal conditions all relevant information should be included, and should be weighted (depending on need for the test) for future studies.

2.3.2. Requirements for exposure measurements in air, water and soil

The following list contains the parameters which are relevant for an exposure assessment. In the event of a clearly specified source, for example, in workplaces in industry, the specific properties of the material can be described more precisely. In this case the list of minimum requirements for biological experiments on exposure measurement can be consulted.

Where there is no specified source for a nanoscale material it is difficult to give a characterisation of the original substance. With increasing distance (and time) of the release, processes occur that can change the specific properties originally given.

For an exposure evaluation it is important to first identify nanostructured product materials in the air, water and soil. Aspects which are particularly relevant for identification are:

- structural size of material/particle size,
- chemical composition,
- persistent, morphological structures; crystalline phases

Only when these nanostructured materials in the air, water and soil have been identified can the physico-chemical parameters be described in more detail. Parameters which involve the mobility and spread of nanoscale materials in the environment should also be taken into account. These parameters influence exposure pathways and possible environmental fate. They include:

- hydrophilic properties,
- size/structure,
- dust-producing behaviour, agglomerate stability.

2.4. Criteria indicating concern or no cause for concern

It is clear to the members of Working Group 2 "Risk and Safety Research" that implementing the principal research tasks will take some time. In view of the dynamic market launch of nanomaterials, ways and means of allowing an initial assessment of nanomaterials should be provided at this stage. Potential hazards should be detected early on with the aid of comprehensible criteria, making a **preliminary assessment** possible.

In its considerations, the NanoKommission's Working Group 2 draws on available materials testing and evaluation systems such as those existing under applicable EU law. To what extent these systems are appropriate for nanomaterials, whether they should be modified, or whether new testing strategies should be found is not within the scope of Working Group 2's work. These topics are currently being dealt with by international bodies.

Measures based on the precautionary principle may be appropriate if no adequate scientific findings are available on the potential effects of nanomaterials with respect to safety, the environment and human health (European Commission 2000).

As a result, criteria can now be introduced as 'Concern-Criteria' indicating problematic nanomaterials and their applications on the one hand, and as 'No cause for concern-Criteria' indicating applications likely to result in lesser hazards on the other hand.

- **Relevant to 'No cause for concern-Criteria'** are indications that the nanomaterials in the respective application are either firmly bound in matrices, or that they rapidly lose their potentially problematic nano-properties, e.g. through good solubility or rapid degradability.

- **Relevant to 'Concern-Criteria'** are indications of an expected high level of exposure (to the point of irretrievability), potential problematic effects and also problems with providing evidence for and the tracing of released nanomaterials.

The list of criteria indicating concern or no cause for concern below is the result of intense discussion between the stakeholders from the business sector, federal and Länder authorities, environmental and consumer associations and the scientific sector. This list reflects current knowledge and the experience of the participants and does not claim to be complete. The criteria should be understood as references to expected (lesser or greater) hazards. The criteria will become less relevant to risk management as knowledge increases on the effects and expected exposure.

The criteria indicating concern or no cause for concern should be taken into account within a framework of risk management. It would be desirable for them to be integrated into the “Recommendations for practical implementation” worked on by Working Group 3.

The group views the criteria as a relevant tool for an initial assessment of nanomaterials. For example when exposure occurs, a high level of reactivity, mobility and persistence of nanomaterials indicates a need for action in consideration of the precautionary principle, while nanomaterials which are firmly bound in matrices throughout their life cycle are less likely to be released and become a threat to people and the environment.

When implementing the criteria it is crucial to note that they are only indicators of potential risks. It would be too simplistic to automatically match the presence of a criterion with a consequential risk management measure. Using the indicators and deriving conclusions from them require technical, careful monitoring.

The list represents an initial step for a systematic **preliminary assessment** of nanomaterials in the future and should be consulted for measures according to the precautionary principle. In keeping with the responsible use of nanomaterials, and bearing in mind the knowledge gaps about potential impacts and exposure previously mentioned, such measures should form an elementary component of risk management. This is particularly important because we are in a relatively early phase of technology development. Of course, the overarching aim is still to make a prompt assessment of the nanomaterial in question based on scientific risk analyses.

"No cause for concern-Criteria"

Loss of nano-properties as a result of:

- Good solubility (in water, body fluids ...), if this causes the loss of nano-properties
- Rapid degradability (biological, photocatalytic ...) in non-toxic degradation products
- Fixed, permanent bonding in matrices (stability of matrix, type of bond, end-of-life behaviour)
- Presence of firmly bound aggregates (determined by conditions of production)
- Agglomeration behaviour: formation of stable, large agglomerates, (e.g. size, stability ...)
- Nanostructured modifications on surfaces, and nanostructures that do not release particles and are not reactive (e.g. nanopores, lotus effect ...)

Concern-Criteria

Indications of expected high level of exposure:

- Production volume and/or quantity used for the field of application (probability of exposure)
- High level of mobility in nanoform
  - in organisms (alveolar macrophage mobility, persistence in water, fat and body fluids, transport through cell membranes, blood-brain barrier, placenta, consideration of the special case of drug delivery systems)
  - in the environment (long-range transport, persistence in water and fat, solubility in fat and water, bioavailability, dustiness)
  - mobilisation potential ("piggyback", infiltration, sorption, complex formation)

- Targeted release (e.g. groundwater remediation, agricultural applications, consumer-oriented applications, interior applications...)
- Persistence of nano-properties
- Bioaccumulation

Indications of potentially problematic effects:

- High level of reactivity (catalytic / chemical / biological)
- Problematic morphology (stable, long tubes or fibres, aspect ratio, fullerenes, crystal structure, porosity)
- Indications of problematic interactions (e.g. piggyback)
- Indications of problematic transformations (ageing, changes to surface properties, porosity) or metabolites (e.g. changes to or loss of coating)

Indications of risk management problems:

- poor verifiability
- unclear fate

2.5 Initial risk assessment for typical areas of application

Working Group 2 decided to carry out an initial assessment of potential risks using selected examples to help them further refine the risk debate and specify research needs. The working group took its lead in this from the judgment expressed by the scientific community that a risk assessment of nanomaterials currently requires examination on a case-by-case basis.

When choosing examples, the members debated and weighed up various features, such as proximity to consumers, potential support from participating companies, life cycle considerations and (environmental) exposure. They eventually decided to look at the following materials:

- synthetic amorphus silica (SiO_2) in food,
- photocatalytic titanium dioxide (TiO_2) for self-cleaning surfaces,
- carbon nanotubes (CNTs) in electrically conductive films (life cycle analysis),
- also, following the interim appraisal: silver nanospray for use on plants.

The four examples were prepared by small interdisciplinary teams of experts and then debated by the working group. An opinion statement was prepared for each of them, containing an initial high-level scientific assessment of potential risks and a more detailed differentiation of them. The in-depth texts produced by Working Group 2 (German language) can be found online at: **www.bmu.de/nanokommission**

2.5.1 Synthetic amorphous silica (SiO_2) in food

Synthetic amorphous silica (SiO_2) is approved as an anti-caking agent in foods such as tomato powder, table salt and spices (E551). When approval was given, however, the particle size distribution of the substance was not specifically taken into account. There have been several indications that silicon dioxide is also being used or is to be used in nanoparticle form in food. Various in-vitro studies have indicated that the nanoform of this substance is potentially toxic.

Are SiO_2 nanoparticles being added to food?

This question triggered concerns that consumers are ingesting or could ingest silicon dioxide nanoparticles by eating food containing this additive (E551), without sufficient evidence that such food is safe. This prompted calls to take seriously the high potential for exposure as a 'Concern-Criteria' and to pursue indications of possible toxicity using the example of commercially available synthetic amorphus silica in food.

Manufacturing processes generate larger agglomerates

A sub-group of Working Group 2 investigated the manufacturing processes of products that have been approved. It was stated that flame hydrolysis produces nanostructured agglomerates in the 1–250 µm size range, the wet chemical process about 500–600 µm and the gel process – depending on the type of mill used – in the 1 µm size range. The manufacturers say that the SiO_2 in food manufactured by the above processes is about 2–12 µm in size, and that the processes used cannot produce synthetic amorphus silica in the form of free nanoparticles. Accordingly, although the approved products contain nanostructured materials, they do not contain nanoparticles.

Toxicity tests

Food additives in the EU are subject to an approval process which includes a health assessment of the substances. In this context the commercial forms of nanostructured, synthetic amorphous silicon dioxide in use since the 1960s have passed various toxicity tests with no worrying results (ECETOC). It has also been proven that amorphous silica is dissolved by enzymes in the human organism and then eliminated. The working group did not find any studies that gave cause for concern by showing adverse health effects from the SiO_2 which, according to information from manufacturers, is customarily used. It should be noted here that small amounts of SiO_2 in nanoparticle form can also be present in the products investigated. According to the information available, the form of the materials used in food has not changed thus far.

If synthetic amorphous silica were to be produced using new processes which differ markedly from those used previously and lead to a substantial change in specification (including particle size), new studies on the behaviour of the nanomaterial will be required to prove that it is harmless to health.

Environmental organisations recommend further testing to analyse the extent to which nanoscale SiO_2 does in fact agglomerate, how many primary particles then still exist, and what their properties and effects are. They also recommend that the safety assessment be updated.

2.5.2 Photocatalytic titanium dioxide (TiO_2) for self-cleaning surfaces and air purification

After medical applications, self-cleaning surfaces are the nanoproducts most familiar to consumers. Nanoscale titanium dioxide (TiO_2) is used on some products (e.g. glass, tiles or paving stones and cladding paints). In sunshine this forms hydroxyl radicals and oxygen radicals which break down organic contamination or airborne pollutants into CO_2 and water. Inorganic contamination or airborne pollutants can also be broken down. The nanomaterials are not free but are bound in a matrix.

Long-term stability and efficiency subjected to critical analysis

The Working Group 2 report on titanium dioxide addressed long-term stability. Some research outcomes suggest that titanium dioxide can leach out of wall paints, potentially releasing nanoparticles into the environment. For this reason it is important that long-term studies investigate both efficiency and potential leaching. The authors of Working Group 2 also noted critically that a photocatalytic reaction can produce undesirable intermediate products. In this event it becomes difficult to weigh up the benefits (e.g. reduction of typical hazardous substances in new vehicles due to specially developed photocatalysts) against the risks (formation of formaldehyde, acetaldehyde and benzaldehyde as intermediate products).

Statements about potential hazards

As products with a photocatalytic surface can be used both indoors (e.g. on furniture, wallpaper, curtains) and outdoors (e.g. cladding paint), the potential hazards should be considered separately for interior and exterior use. Working Group 2 identified the formation of undesirable intermediate products as crucial in terms of human toxicology and ecotoxicology. One study shows that formaldehyde may arise as an intermediate product and its concentration in enclosed spaces can reach 24% of the MWC value (maximum permissible workplace concentration at which human health is not compromised). With respect to exterior use, it was shown that the conversion of nitric oxide produces nitrate as an intermediate product. The measured nitrate value, however, was considerably below the EC standard. Due to a lack of data, it was not possible to assess whether deterioration of the materials could increase exposure of humans and the environment to released TiO_2 nanoparticles.

Time will tell

In summary, Working Group 2 noted that the length of time that a contaminant and the photocatalyst are in contact determines whether the undesirable intermediate products are generated. Further tests are also required on the products in question in order to prove for the long term that no nanomaterials are released. Overall, the data available was considered inadequate for carrying out a definitive risk evaluation.

2.5.3 CNTs in electrically conductive films (life cycle analysis)

As insoluble (persistent) materials, carbon nanotubes (CNTs) are generally seen in a negative light as far as preliminary evaluation is concerned. The findings of various studies indicate that some CNTs can have negative effects on humans and the environment. Inhalation in particular is seen as problematic. Working Group 2's case study investigated whether risks to humans and the environment can occur when CNTs are bound in a synthetic material and, if so, in which phases of the product's life cycle. An actual generic product was selected, namely, the film used in the packaging of components susceptible to electrical discharge, which has been made both antistatic and more tear-resistant by the addition of multi-walled CNTs (MWCNTs).

Consideration of exposure over the entire life cycle

The analysis included a description of the most common production process, in which work is carried out in fully-enclosed reactors to rule out the risk of explosion triggered by the entry of oxygen. Only when the material is added to the synthetic compound or to the extruder can MWCNTs be released into the atmosphere, unless the correct precautionary measures have been taken (extraction, filters). In this way it is possible to protect workers from exposure to airborne MWCNTs to the maximum extent feasible. Spilled materials can be soaked up easily, so that they are unlikely to enter the soil. To avoid contact with the skin, appropriate protective measures (gloves, protective clothing) should be taken. As soon as the MWCNTs are bound in polymers, accidental release through dissolution appears to be largely ruled out. Water is only used for cooling purposes after the MWCNTs have been bound in the synthetic material, the cycle nevertheless remains closed (separate disposal). However, this assessment did not take potential system malfunctions into consideration.

The finished polymer / MWCNT compound is supplied to the customer in pelletised form, for processing into a film. The general opinion, including that of external experts, is that CNTs are highly unlikely to rub off the pellets or the finished film. Offcuts, punching waste or used film can be recycled or incinerated by conventional means. In principle it can be assumed that the CNTs will be incinerated. It is not yet known whether the CNTs behave differently from microscale carbon in the waste incineration plant.

Environmental and health effects

Currently it can be assumed that hardly any engineered CNTs are present in the environment. Their increasing production and use, however, could raise levels of environmental exposure in future. Analysis of various studies on the behaviour of CNTs in the environment (ecotoxicity) and health effects (toxicity) has clearly shown that the observed effects greatly depend on the type of CNT used, making it virtually impossible to make any generalisations. Nor have the dose-effect relationships yet been clarified. Current findings from testing different forms of CNT on animals indicate that only specific types of CNT have an adverse effect on health (e.g. similar to acute exposure to asbestos fibres). In principle, therefore, one option would be to minimise the hazard by producing differently-structured CNTs ("design for safety").

Where other manufacturing processes are chosen (arc process / laser ablation process), it would once again be necessary to conduct a case-by-case study over the entire life cycle.

Over all, the BUND considers that assessment of CNTs is fraught with difficulties, and urges the strict application of the precautionary principle.

2.5.4 *Silver nanospray to promote plant growth*

Silver nanospray is marketed as a plant care product that promotes the growth of plants and vegetables (for spraying or watering both indoors and outdoors). At the same time the nanosilver contained in it is supposed to have a bactericidal, fungicidal and algicidal effect. Its effect on various species of fungi was demonstrated in a study.

The application was of special interest to the Working Group 2 because in this case the exposure of the environment to nanomaterials is intentional. Also, the method of application made it impossible to rule out potential human exposure through the respiratory system.

Approval issues

Substances containing nanosilver are listed as plant tonics by the Federal Office of Consumer Protection and Food Safety. According to the German Plant Protection Act (PflSchG), **plant tonics** are substances specifically designed to improve plant resistance to harmful organisms, to protect plants against damage and to keep cut flowers fresh. This does not apply to cultivated plants (e.g. fruit and vegetables).

According to the Act, **pesticides** are substances that are intended to protect plants or living parts of plants and plant products from harmful organisms. Pesticides have a direct effect on harmful organisms and are subject to different approval requirements.

Plant tonics may only be marketed if they have no harmful effects on human or animal health, groundwater or the ecosystem. Listing is subject to monitoring by the Federal Environment Agency (UBA), the Institute for Risk Assessment (BfR) and the Julius Kühn Institute (JKI).

Due to the nanosilver spray's assumed impact on harmful organisms, which is similar to that of a pesticide, Working Group 2 recommends a critical review of the risk evaluation. It also made a preliminary risk assessment based on the information provided by the manufacturer and available literature.

Effects of nanosilver on humans and the environment

Working Group 2 compiled a list of research findings which have shown nanosilver to have an adverse effect on the growth of aquatic organisms. So far no results are available from tests carried out on sediment organisms and soil organisms.

In toxicological tests on rats, however, even a markedly increased exposure (13 times the workplace limit) showed no lasting impact on organs. Even though this result left some questions unanswered in methodological terms, other studies of oral and inhalative absorption have given no indication of organ damage, genotoxicity or reproductive toxicity. However, depending on the dose administered, the nanosilver was seen to have spread to different organs.

Risk cannot be assessed reliably

Working Group 2 points out in its paper that no definitive statements can be made concerning the risk evaluation of pesticides containing nanosilver.

An environmental risk evaluation is also unfeasible at this time as too little data is available. The effects on aquatic organisms described above should be taken seriously, particularly as there is a growing trend to use nanosilver in everyday objects, leading potentially to a cumulative burden on the environment. Even if, as in the present case, the amount of nanosilver entering the environment in pesticides can be regarded as small, the impact of nanoparticle use on the environment is unknown and for this reason must be taken seriously. Working Group 2 takes a very critical view of product residues being emptied into the wastewater system. In terms of precautionary environmental protection, here too the minimisation principle should apply and the introduction of nanosilver into the environment be avoided.

2.6 NanoKommission assessment of Working Group 2 findings

Working Group 2's task included gathering available knowledge and specifically investigating future research needs. Although many research projects have been initiated, knowledge gaps still remain. It is debatable as to whether the used testing procedures followed enable us to say anything about the actual dose-effect relationships that occur in the course of day-to-day manufacturing or when humans and the environment are exposed to the finished product. The more precisely the materials can be characterised throughout their entire life cycle, the more reliable the statements that can be made about potential risks.

To sum up the Working Group 2 report, the NanoKommission recommends the following:

- Manufacturers and users should increasingly make specific materials available for testing by independent scientists. This would reduce the degree of uncertainty surrounding the use of engineered test materials. Realistic test procedures should also jointly be devised which simulate realistic exposure to the materials concerned and reflect normal usage.

- The NanoKommission dealt in considerable detail with the issue of categories and the use of criteria for concern or no cause for concern when assessing nanomaterials. It recommends that businesses estimate the risks involved in the manufacture and use of the relevant nanomaterials as accurately as possible. The 'Concern-Criteria' and 'No cause for Concern-Criteria' determined by Working Group 2 should act as a guide for preliminary assessments. They should be rendered operational and weighted during the second phase of the NanoDialogue. Legal obligations arising from the statutory provisions of REACH or labour protection laws and other legal provisions remain unaffected. Businesses are responsible for dealing with any data deficiencies.

It is suggested that, based on the 'Concern-Criteria' and 'No cause for Concern-Criteria' nanomaterials be tentatively ranked in the following three categories, until such time as risk evaluations for health and environmental protection become available.

Group 1: Probably hazardous – concern level high	
	A strategy is required for measures aimed at minimising exposure or avoiding certain applications
Group 2: Possibly hazardous – concern level medium	
	A strategy is required for measures aimed at reducing exposure
Group 3: Probably not hazardous – concern level low	
	No procedures are required over and above “good work safety practice” (or “hygiene practice”)

Further recommendations:

- If too little information is available to allow a preliminary ranking in one of the above categories, the material should be entered under category Group 1.

- The category system should also be used by businesses for communication along the supply chain, i.e. materials used should be ranked in accordance with these groups and corresponding risk management measures should be communicated. The provisions relating to safety data sheets must be complied with.

- The list of criteria used to assess nanomaterials should be subject to a prompt critical review and revised if necessary. The criteria should also be weighted and/or prioritised for the evaluation.

- Further steps need to be taken in rendering the category system operational. In other words, specific uniform testing and measurement procedures must be established and findings must be standardised for classification in groups.

- During the initial work phase it was not possible to forge a link between the work of Working Group 2 and that of Working Group 3 described below. A systematic linking of both approaches would be desirable for the coming phase.

The German NanoKommission recommends the use of this 'three category system', including the 'Concern-Criteria' and 'No cause for Concern-Criteria', as a preliminary point of reference for businesses and risk-evaluating authorities. Further development and ongoing review should follow in accordance with the status of research.

3. Findings of Working Group 3: Principles for Responsible Use of Nanomaterials

3.1 General conditions

The following section on "Principles for responsible use of nanomaterials – a contribution to the sustainable development of nanotechnologies" was drawn up in the context of the NanoDialogue initiated by the German Government. It formulates a set of principles intended to create a practical framework for responsible use of nanomaterials, particularly during the period when efforts are being made to close knowledge gaps and provide a scientific foundation for the advancement of existing legal provisions. This framework should complement existing mechanisms (REACH , sector-specific EU directives) which apply to nanomaterials in principle, but which may need adaptation. Together these form the umbrella under which science and business can develop nanotechnologies in a responsible way.

The first section of this paper describes the general conditions governing the formulation and application of principles. The principles themselves are contained in the second section of the paper.

Objective: The objective of the principles is to guarantee the greatest possible protection of human and environmental health and also to take the principle of sustainability into account. This requires the formulation of recommendations for the use of nanomaterials based on the precautionary principle (in accordance with the EU memorandum of February 2000).

Form: The principles form the framework for responsible use of nanomaterials. Sector-specific guidelines should be formulated to provide guidance on practical implementation. Industrial associations and other actors are called upon to develop these guidelines. The occupational health and safety guidelines developed jointly by VCI and BAuA may serve as an example.

The "Recommendations for practical implementation" constitute an integral part of this principles paper, offering assistance in drawing up sector-specific guidelines. They are included in the Appendix and are also available online (German language) atwww.bmu.de/nanokommission. For the coming NanoKommission work phase, Working Group 3 has suggested supplementing the recommendations with measures focused on environmental and consumer protection.

Period of validity: The principles have been formulated on the basis of the current scientific, regulatory and societal situation. Every two years a review should be undertaken to assess whether they are still appropriate or indeed necessary, and they should be adapted if required. A process stipulating the criteria and procedures needed for such a review should be agreed as soon as possible during the coming phase of the NanoDialogue.

Scope: The principles are aimed mainly at businesses, but also address other stakeholders. They are intended to cover the fields of research and development, the manufacture and transportation of nanomaterials, their processing into other products, including private use and recycling or disposal of these products. They relate initially to first generation nanomaterials, so-called passive nanostructures. Principles for the responsible use of next-generation nanomaterials such as active nanostructures, evolutionary nanosystems and molecular nanosystems still require development. They should also take account of ethical and social issues.

The principles presented were devised at national level as part of the work carried out by the NanoKommission's Working Group 3. All over Europe and the rest of the world parallel initiatives such as the Responsible Nano Code exist, which have the same objective of defining the framework for a responsible and sustainable development of nanotechnologies. All stakeholders are invited to contribute their suggestions to the European / worldwide debate. Efforts should be made to achieve harmonisation worldwide, provided this is compatible with the high level of protection to which the NanoDialogue is committed.

Obligations and review: Societal acceptance of this political tool will depend on certain conditions. These include an external review of the implementation of the principles, a defined set of obligations to which organisations commit when they adopt the principles, and repercussions for organisations failing to comply with them. Without these measures the principles will not deliver the necessary transparency. The joint task of producing a catalogue of measures must be dealt with as a matter of priority during the next phase of the NanoKommission. As soon as this catalogue is available it will take effect as one component of the principles.

Unresolved issues: The principles summarise those issues on which agreement was reached in the course of dialogue. Demands on which the group did not reach a consensus were formulated and questions for further exploration during the coming work phase of the dialogue were noted. These include practical proposals on measures for monitoring implementation of the principles, as well as clarification of issues pertaining to binding commitments. Such issues may be addressed, for example, through:

- Events to monitor implementation, at which issues surrounding the binding nature of commitments may be discussed.
- System for monitoring the extent of adoption of the principles:
  - Registration of businesses that are applying the principles. Possible forms: voluntary reporting system, verification by a neutral institution, certification of sustainability reports by an independent institution, documentation on BMU webpage.
  - Key issues to be explored: who is authorised to assess implementation? What criteria are applied – up to now, greater margins have deliberately been permitted to accommodate national and application-specific differences.
- Practical proposals for a process for adapting and updating the principles paper.
- Linking the criteria for reduced concern and added concern developed during the NanoDialogue to the principles in order to identify critical and extremely critical applications, as well as appropriate measures in each case, including management of data gaps.
- Specific guidelines for information transfer and transparency.

Points on which no consensus was reached in the dialogue:

- Notification of the uses of nanomaterial to a federal authority for a public database
- Mandatory public access to all the nanotechnology-related information, data and processes, as referred to under principle 2, and at least to all data relevant to safety
- Extension beyond the preliminary OECD definition to include materials that are smaller than 300 nm in at least one dimension and give rise to nano-specific effects
- No production or marketing of extremely critical nanomaterials and products.

3.2 Five basic principles for the responsible use of nanomaterials

Principle 1: Definition and disclosure of responsibility and management (good governance)

Responsible corporate management means implementing laws and introducing and implementing voluntary measures aimed at protecting human and environmental health. This objective of safety should be achieved by means of a comprehensible, transparent and verifiable management system. Such a management system should apply to all areas relating to the use of nanomaterials that are significant to the organisation, including supply chain management, occupational health and safety, product safety, consumer protection and disposal.

Elements of the management system should include:

- Formulation of a corporate policy
- Definition of programmes and objectives, including a schedule
- Stipulation of responsibilities
- Monitoring of implementation
- Regular adjustment in line with current knowledge

Responsibilities and management processes should be disclosed. This could take the form of regular reporting (e.g. company reports), ongoing updates (e.g. Internet) based on specific indicators or descriptive accounts.

Principle 2: Transparency with regard to nanotechnology-related information, data and processes

The organisation should ensure that transparency exists in relation to nanotechnology-related information, data and processes. This includes regular public reporting on the implementation of all the five principles mentioned here. The requirements of data transparency must at least comply with REACH requirements and include public access to information on human and environmental safety as regulated by REACH.

The information and mechanisms about which transparency is required also include:

- Nanomaterials used and their products

- Relevant information for a safety assessment over the entire life cycle, such as physico-chemical properties (incl. nano-specific information), toxicity, environmentally hazardous properties, exposure, consideration of any potential inadvertent release, test methods and measuring systems used as well as results of risk evaluation
- Implemented and recommended measures for safe use

This information should be made available using media channels geared to specific target groups (e.g. helplines, reporting, website, brochures, conventions, databases, on products, etc). Access to the information should be made as straightforward as possible. If information on safety is not available, reasons for this should be stated.

Recipients could include workers, works councils, customers, consumer organisations, unions, other civil society organisations, shareholders, governments or public authorities, insurance companies as well as international organisations and consumers.

Consumer expectations as regards being given information about products that contain nanomaterials should be taken into account. Consumer information should aim, among other things, to provide consumers with advice on how to handle products safely (safety) and enable them to make informed choices about what to buy (information and freedom of choice). For example, consumer information could include product labelling, detailed information provided along with product, databases, etc. To protect consumers against deception, only those products containing nanomaterials or manufactured using nanotechnologies should be marked "nano".

Principle 3: Commitment to dialogues with stakeholders

Commitment to dialogue means entering open into exchange with interested stakeholders on key nanotechnology-relevant issues. The organisation should initiate the dialogue and continue each dialogue process on a regular basis. Examples of forms of dialogue include meetings with stakeholders, discussion forums, consultations (hearings), as well as responding to queries from consumers and civil society groups.

Dialogues that have the same objectives should be integrated.

The principle of commitment to dialogue extends to stakeholders both inside and outside the organisation.

Such stakeholders could include employees, the works council, businesses, customers, consumer organisations, unions, environmental associations, other civil society organisations, shareholders, the general public, governments or government authorities as well as international organisations and consumers. The organisation should also evaluate the findings and outcomes of the dialogue together with the stakeholders involved, at a point in time to be jointly agreed. The evaluation results should serve to optimise future dialogue processes.

Principle 4: Establishment of risk management structures

Each organisation should set up a risk management system based on the precautionary principle to ensure a high level of protection for end-users, employees and the environment.

This requires thorough evaluation of the risks to human and environmental health and safety related to the manufacture or use of nanomaterials, so that a decision can be made on whether an application can go ahead at the present time, or to allow risks to be eliminated or minimised with appropriate management processes. This should be done not only with a view to the organisation itself but also to end users and partners, particularly along the supply chain.

A careful check should be made on a case-by-case basis to ascertain whether the methods and procedures used to identify and assess the hazards posed by conventional materials made up of larger particles are also suitable for identifying and assessing the hazardous properties of nanomaterials and associated risks. Until scientifically-based knowledge is available, the potential hazard of a certain nanomaterial cannot be ruled out. In such cases the precautionary principle (in accordance with EU memorandum dated February 2000) must be applied.

Currently unavoidable knowledge gaps should be documented and provided for in ongoing risk management procedures. The organisation should participate in safety research as far as it is able to do so.

Risks that may potentially occur outside the organisation itself should be communicated clearly.

Until uniform global standards for testing nanomaterials are available (OECD guidelines/tests) reasons should be given as to why the spectrum of methods applied is considered adequate.

Principle 5: Responsibility within the value chain

All partners along the value chain share responsibility for ensuring the safe use of nanomaterials. Responsibilities must be clearly allocated, and a flow of information along the entire chain must be established – in both directions – in keeping with REACH.

Raw material manufacturers should supply the key basic data needed for a toxicological and ecotoxicological assessment of the nanomaterials and their intended applications. Processors for their part should provide feedback to the raw material manufacturers about their actual use of the raw materials and intended areas of application.

The safety data sheet is of vital importance to the chemical industry supplying the raw materials, ensuring the transparent flow of information on occupational health and safety and environmental protection along the value chain. The details contained in the safety data sheet should relate to the nanomaterial in question.

Additionally or in the later stages of the value chain the use of other methods of communication should be considered in order to establish a transparent exchange of information about the nanomaterials. These methods could be technological fact sheets with data on particular technical aspects of the nanomaterials, scientific publications or conferences/forums to disseminate the findings from safety research, the Internet (also for general information on the safe use and positioning of companies on the subject of nanotechnologies), direct dialogue with customers or specific training courses on the topic of risk evaluation and occupational health and safety.

The processors will inform the raw material manufacturers in advance, along the lines of REACH, about planned new applications for the nanomaterials or their secondary products. In this way it will become clear at an early stage whether the raw materials are suitable for the new application, whether the current risk management measures will still apply or whether – subject to agreement – they need to be adapted.

The organisation's policy with respect to nanomaterials, including the principles for responsible use, will be rendered transparent to their partners with the aim that they too should adopt a corresponding approach.

3.3 Outlook for Working Group 3: Next steps in the dialogue

- The dialogue should be extended to include social and ethical issues with special reference to – but not limited to – first generation nanomaterials. Discussion should take place on sensible applications and the question of informed consumer choice. Consideration should be given to the question of whether other stakeholders should be involved.

- The “Recommendations for practical implementation” currently focus on occupational health and safety. During the next stage they should be expanded to include measures related to the fields of environmental and consumer protection.

- To make information intelligible, proposals should be devised to target specific groups. This requires communication among all the participating stakeholders.

- With regard to monitoring implementation, it was suggested that an event be held by BMU in autumn 2009 (review of initial implementation phase of the principles paper) or alternatively that regular events be held on the status of implementation. Furthermore, the business sector should develop and present a suitable implementation strategy for 2008-2020. For instance, it is currently still unclear how successful implementation in a wide range of industrial sectors can be guaranteed and rendered transparent.

3.4 NanoKommission assessment of the findings of Working Group 3

Some risks may – quite independently of research – be lessened or even avoided by means of appropriate precautionary measures. The current focus here is on occupational health and safety through appropriate manufacturing conditions and protective measures. The German NanoKommission welcomes the suggested principles on the responsible use of nanomaterials and the recommendations of Working Group 2 and Working Group 3 to temporarily abandon applications where too many knowledge gaps exist until robust findings are available.

- The NanoKommission recommends that business entities – manufacturers and users – implement the principles paper for responsible use of nanomaterials in their businesses by 2010.

- Following the recommendations of the working group, VCI's offer to provide – preferably in cooperation with other major sectors – an intermediate report on the status of implementation in late 2009 / early 2010, plus any need for amendments, should be accepted. Policy-makers and NGOs should also closely monitor implementation and provide quality assurance e.g. in a review event.

- The NanoKommission notes that Working Group 3 did not deal in detail with issues of reporting procedures or labelling during this work period.

Further recommendations of the NanoKommission:

- The NanoKommission assumes that in future the use of nano-products and applications, including those aimed at consumers, will become more widespread. It considers that one important factor in societal acceptance is far-reaching **transparency** about nanomaterials in products and applications and the provision of specific information.

- Manufacturers and users should be aware that when they use nanotechnologies and nanomaterials, they not only have a new **marketing tool** in their hands, but that by deciding to communicate openly, they are also helping to shape the image of a promising technology. The important thing here is to set **quality standards governing both use and communication.**

- A crisis situation relating to communication or incorrect use cannot be entirely ruled out. Authorities at least should in future have a **basic minimum of information** at their fingertips so that they are in a position to act and communicate appropriately. They should be aware of what nanomaterials are being used where, and by whom. Suitable **methods of ascertaining and collating information** must be found in the interests of both market transparency and confidentiality.

- The NanoKommission notes that the Federal Government has at its disposal the legal instruments it needs to comply with its obligation to take precautionary action with respect to nanomaterials, but these may need to be broadened or adapted. Because nanomaterials have such a wide range of applications a considerable number of **regulations and directives** are relevant. REACH provides an essential basis fundament for the regulation of nanomaterials. First of all the annexes – and later the wording of the statute itself – will need careful reconsideration, in the framework of an appeal, to see whether adjustments are required. The objective must be to produce robust safety dossiers for nanomaterials. Drawing on the work of the CASG Nano at European Commission level, the NanoKommission recommends that future work should focus on requirements for robust and transparent dossiers pertaining to nanomaterials.

Environmental organisations consider it necessary to treat nanomaterials separately as 'new substances' in line with the European legislation, and they want to see the threshold quantities for REACH registration of nanomaterials abolished or markedly lowered. In contrast, industry representatives on the NanoKommission point out that it would make no sense to treat nanomaterials as 'new substances'; they say this would lead to a situation in which less information would be required for registering nanomaterials, and that in many cases the exemption rules for substances in research and development would apply.

The authorities remarked that in future new requirements will be set for testing and assessment methods, based particularly on the work of the OECD bodies. This knowledge should be integrated into EU regulations (e.g. Test Methods Regulation and Technical Guidelines). Such issues will be the subject of discussions at national and EU level. New findings should also be included in phase 2 of the NanoKommission.

III. German NanoKommission recommendations and outlook

1. *Cross-departmental research on safety and risk assessment*

A crucial step in reducing risk is to increase knowledge – in particular, knowledge about the potentially harmful effects of nanomaterials on humans and the environment, and about where and how nanomaterials can be released. The NanoKommission welcomes the fact that the Federal Government has intensified its efforts in this field of research (NanoCare, NanoNatur, etc.) during the past few years, and is participating in the OECD's test programme which aims to close significant knowledge gaps regarding the potential risks of 'common nanomaterials' and to adapt measurement methods by 2010.

In order to systematically close the knowledge gaps as soon as possible the NanoKommission recommends, over and above the report by Working Group 2:

- that the Federal Government should enhance interagency cooperation on safety and risk research with an emphasis on occupational health, and on health, environmental and consumer protection.
- The resources required for this should be substantially increased. The private sector should also intensify its research efforts in the field of risk research.
- Such research should be conducted in dialogue with the stakeholders.
- Research findings should be structured and made accessible to society at large.

In many cases the safe handling of nanomaterials demands that **protective measures** be put in place to avoid potential hazards to people in the workplace, and to nature and the environment. For this reason the NanoKommission sees the need to identify and describe in greater detail than previously the measures already being applied in operational practice. In particular, it seems sensible for companies and federal institutions such as BAuA, UBA and BfR to be involved in identifying proven practices and making them accessible to public scrutiny.

In its coming phase the NanoKommission will prepare an interim appraisal of the research efforts of the various federal ministries and the private sector, as well as recommendations for protective measures.

2. Implementation of preliminary assessment criteria and of principles for responsible use of nanomaterials

During the course of its work the NanoKommission has achieved consensus in some crucial areas about what precisely constitutes a sensible approach during a transition period characterised by inadequate knowledge.

The NanoKommission recommends:

- Approaches aimed at making a preliminary risk assessment and grading materials into the three categories of low, medium or high concern should be further refined. Firstly, the categories need to be assigned designation and measurement processes which will help to determine the extent of their applicability. Moreover, the individual criteria for substantiated reduced or added concern are not equally relevant. This means that, secondly, the criteria must be weighted. Thirdly and finally, rules must be developed to determine how the applicability or non-applicability of the differently-weighted criteria can provide an indication of the necessity for certain measures of precautionary risk management. The NanoKommission considers it important to continue this work.

With respect to applying the preliminary risk evaluation and the principles paper the NanoKommission recommends:

- **Expansion to other sectors**, so that the principles paper not only applies to businesses producing nanomaterials, but also inspires commitment in the companies and business sectors that use nanomaterials.

This approach builds on the **voluntary commitment** of companies and business sectors. Some stakeholders doubt the effectiveness of such methods, and would prefer to see a **legal obligation** to apply the principles. Notwithstanding of these differences the NanoKommission recommends:

- that in 2010, within the remit of the NanoKommission, the state of implementation of the principles should be monitored on the basis of industry sector reports; this is in order to give the general public an idea of how far the principles have been implemented as part of company practice and to provide a quality assurance of the process;

- that the monitoring criteria, the form of the report and issues of structure, quality assurance and control should be established at the start of the coming work phase in the context of the NanoKommission;

- that the names of those companies and business sectors that have committed to apply the principles should be published;

- that the principles paper should be reviewed after 2 years in the light of increased knowledge.

3. Market transparency for consumers

The NanoKommission assumes that the number of nano-products and applications – currently estimated to be at least 800 – will continue to increase. It is aware that a new culture of innovation in the field of nanotechnologies demands optimum transparency towards consumers by providing information about nanomaterials in products and applications. It recommends:

- The creation of an independent form of market overview for consumers in terms of available nanoproducts, so that information relevant to consumers and new scientific knowledge are collated and presented in an understandable way. Information on contents, function, impact and safety should be grouped together. Consumer and environmental associations should be involved in this. The NanoKommission will support the implementation of this strategy.

- New ways of communicating findings in an appropriate way to both the general public as well as various expert stakeholders must be developed.

4. Continuation of the NanoDialogue and the NanoKommision's work

The members of the NanoKommission assume that societal discourse on the potential benefits and risks of nanotechnologies will continue in Germany. They recommend that the work of the NanoKommission be continued for at least another two years.

The following summarises the NanoKommission's initial suggestions on potential topics and comments on improving working methods, based on the experience it has gained during the course of its work to date. These suggestions, however, in no way anticipate the open discussions about future work and the way that work is to be structured that will necessarily take place with the actors to be involved.

Possible topics:

- Discussion of proposals on regulatory mechanisms.

- Improvements in consumer information.

- Expansion of product areas, e.g. to food and cosmetics, as well as next-generation nanomaterials. Certain stakeholders endorse expansion to the field of medicine.

- Enhancement of the comprehensive, life cycle-oriented consideration of nanomaterials and their products from the perspective of their impacts on work safety and on health and environmental protection.
- Opening out the dialogue to include the social and, where necessary, ethical implications of the development and application of nanomaterials, and including other relevant stakeholders appropriate to this context.
- Development of procedures to assess, evaluate and manage risk as a precursor to regulation.

Recommendations on working methods:

- Improved communication of the ongoing activities and findings of the NanoKommission to the wider public.
- Involvement in international debate on the regulation of first-generation nanomaterials and initiation of a corresponding debate for further generations, including more broadly-defined nanotechnologies.
- Greater involvement of the private sector from the field of nanomaterial users.
- The ongoing work requires professional support from office staff, for which corresponding resources will be needed. The NanoKommission working groups should be able to draw on the support of independent facilitators if required.

IV. Appendix

Recommendation on practical guidelines for implementing the principles paper

The NanoKommission welcomes the initiative to make a strategy for the implementation of the principles an integral part of any agreements. It was decided to continue work on the practical guidelines for implementation during the coming phase. The present appendix is extracted from a consultation paper introduced to Working Group 3 which identifies thematic priority areas.

1. Protection goals
Guidelines should accord equal consideration to all three protection targets

- health,
- environment and
- sustainability

and – where possible – examine them together (horizontal integration). The protection targets should be pursued over the entire life cycle and include both occupational health and safety and consumer protection.

2. Communication along the value chain

When making recommendations concerning communication, the entire value chain should be taken into account. This includes research and development, production, commercial and private usage as well as disposal or recycling. One important priority is a set of practical guidelines to govern communications with upstream and downstream businesses along the supply chain (vertical integration). The ongoing work can build on an existing guide to communications along the supply chain which was developed by VCI in the course of a stakeholder dialogue.

3. Methodological design

The approach described in practical guidelines should comply with the requirements of a process of continuous improvement. The following elements could be included:

- identification and documentation of knowledge and lack of knowledge (physico-chemical, (eco)toxic properties and exposure)

- formulation and implementation of measures, with documentation (incl. reasons)
- additionally in the case of lack of knowledge: documentation of identified need for research or reasons why abandonment of relevant research appears justified
- verification of the efficiency of measures taken, with documentation of review outcomes.

The process of hazard assessment described in TRGS 400 of the Committee on Hazardous Substances (AGS), and the process described in the NanoRiskFramework of Environmental Defense and DuPont were named as examples.

4. Protective measures (for occupational health and safety)

Practical guidelines should include recommendations for protective measures. In general terms the applicability of the recommendations should always be verified on a case-by-case basis. Furthermore, the recommended measures concerning environmental and consumer protection should be discussed. This applies in particular to the order of precedence of the protective measures and compliance with the minimisation principle (for free nanomaterials in particular).

- Substitution
- Technical measures
- Organisational measures
- Personal protective clothing and equipment

It should be pointed out with regard to testing the efficiency of measures that determining exposure should form an integral part of the review. Moreover, measurements or assessments of exposure should be documented in such a way that they can also be used as a basis for exposure records of employees.

With respect to employees who work with or may potentially be exposed to nanomaterials, it should be pointed out that occupational health screening should be provided. Further, these employees should be provided with specific coaching on the activities concerned.

5. Transparency and involvement of stakeholders

Internal and external stakeholders should be taken into account and involved in the application of the communications strategies. The implementation guides should specify how such involvement can be guaranteed. With respect to employees, the relevant provisions of the Works Constitution Act should be taken into account.

Examples of good practice could be an important element in guides to practical implementation.

Structure of the German NanoKommission and Working Groups

NanoKommission:

Chair:	
Wolf-Michael Catenhusen	**Former State Secretary**
Prof. Dr. Ulrich Buller	Fraunhofer Gesellschaft
Prof. Dr. Helmut Horn (to 31.05.2008) Patricia Cameron (from 01.06. 2008)	BUND
Michael Jung	Nanogate AG
Dr. Martin Kayser	BASF AG
Dr. Holger Krawinkel	Federation of German Consumer Organisations
Dr. Uwe Lahl	Federal Ministry for the Environment, Conservation and Reactor Safety
Dr. Klaus Mittelbach	Federation of German Industries (BDI) – to June 2008 –
Dr. Thomas Müller-Kirschbaum	Henkel KGaA
Dr. Hanns Pauli	Confederation of German Trade Unions (DGB)
Dr. Gerd Romanowski	Chemical Industry Association e.V. (VCI)
Dr. Wolfgang Stöffler	Federal Ministry of Education and Research
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Dr. Hans-Jürgen Wiegand	Evonik Industries AG
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Dr. Kerstin Hund-Rinke	Fraunhofer Institute for Molecular Biology and Applied Ecology (IME)
Oliver Kalusch	Federal Association of Citizens' Environmental Protection Initiatives
Prof. Dr. Wilfried Kühling	BUND
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Dr. Markus Pridöhl	Evonik Industries AG
Marianne Rappolder	Federal Environment Agency
Dr. Eberhard Schrader	Henkel KGaA
Dr. Petra Wolff	BMBF
Prof. Dr. Harald Krug	EMPA (Swiss Federal Authorities for Materials Testing and Research)
Dr. Thomas Kuhlbusch	Institute of Energy and Environmental Technology IUTA
Dr. Bruno Orthen	Federal Institute for Occupational Safety and Health
Dieter Strupp	Environment Ministry of Lower Saxony
Dr. Karin Wiench	BASF AG

Working Group 3:

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Patricia Cameron	BUND
Dr. Reinhard Ditz	Merck KGaA
Dr. Dietmar Eichstädt	Verband der deutschen Lackindustrie e.V. (Association of the German Paint Industry)
Gabriela Fleischer	Consumer Council at the German Standards Institute
Dr. Frank Groß	Nano-X GmbH
Dr. Reinhard Jung	Clariant Produkte (Deutschland) GmbH
Dr. Harry Keidel	Ministry of the Environment and Forestry Rhineland-Palatinate
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Dr. rer. nat. Andreas Leson	Fraunhofer Institute for Material and Beam Technology (IWS)
Dr. Barbara-Christine Richter	Bayer Material Science AG
Dr. Norbert Schröter	Deutsche Bauchemie e.V. (German Industry Association for Construction Chemicals)
Dr. Heiner Wahl	Federal Ministry of Labour and Social Affairs
Dr. Sieglinde Stähle	German Federation of Food Law and Food Science (since 2008)
Dr. Torsten Wolf	Federal Institute for Occupational Safety and Health
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