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Responsible Use of Nanotechnologies

Report and recommendations of the German NanoKommission 2011

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Text:	Dr. Antje Grobe, Risk Dialogue Foundation
Editor:	St a.D. Wolf-Michael Catenhusen, Chairman of the German Federal Government's NanoKommission
Expert consultants:	BMU, IG II 6
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Report and recommendations of the German Federal Government's NanoKommission 2011

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This report provides the results of the second working phase (2009-2011) of the German Government's NanoKommission.
The Federal Ministry for the Environment, Nature Conservation and Nuclear Safety does not necessarily agree with the content of the report.

Content

Foreword

For the past ten years now nanotechnologies have been hailed internationally as a fundamental innovation and key technology. Nanotechnologies are widely expected to generate a broad range of applications throughout society and bring innovations in terms of products, processes and materials for many sectors of the German economy, with positive impacts on economic growth and skilled employment, resource conservation and environmental performance. At the same time, it is recognised that there is an urgent need to close gaps in knowledge regarding the potential effects of nanomaterials and products manufactured using such materials on human health and on the environment. Potential hazards need to be identified in time and precautionary measures put in place. Nanotechnologies present a window of opportunity to develop a culture of innovation rooted in the precautionary principle. In the interests of both industry and consumers, we need a broad innovation strategy guided by the principle of sustainability.

The task assigned to the NanoKommission when it was set up by the German Federal Government was to foster responsible use of nanomaterials by facilitating effective communication between technology development stakeholders in the realms of science, industry and politics, and stakeholders in civil society. In an open process, representatives of environmental and consumer organisations, a women's association and a medical practitioners' organisation, trade unions, churches, academia, industry and government bodies (such as federal ministries and agencies as well as *Länder* ministries, on regional state level) discussed their positions and appraised the issues. The NanoKommission was able to base its work on an extensive network of dialogue on nanotechnologies in Germany.

This report presents the key activities and findings of the NanoKommission's second dialogue phase, covering the period 2009-2011. The number of nanoproducts on the market increased sharply during this period, but intensive exploratory work and debate on appropriate regulation of nanomaterials and nanoproducts also began to gather momentum, especially within the European Union. This has already produced some regulatory decisions, most notably the new Cosmetics Regulation. The NanoKommission concentrated on continuing and consolidating its work to harness the potential benefits of nanomaterials for sustainable development, environmental protection, resource conservation and human health, and for consumption clusters such as construction and housing, energy, mobility and communications.

In this context, a shared paradigm for "Sustainable Nanotechnologies – Green Nano" may provide useful guidance both for public research promotion and funding programmes and corporate product development strategies.

The NanoKommission also continued in its efforts to develop and test new methods of risk prevention and agreed on principles and assessment procedures enabling prompt preliminary classification of nanomaterials on the basis of their potential risks and benefits.

To that end, the NanoKommission launched an in-depth exploration of principles and options for action regarding regulation of nanomaterials and nanoproducts based on the precautionary principle. NanoKommission members found common ground in their assessment of a range of issues, but opinions were divided on priorities and preferences, reflecting the different experiences and expectations of the stakeholders. This outcome will in fact be particularly helpful for the debate and decision-making process on regulatory issues that will follow over the next few years.

It became clear in the course of the discussions in the NanoKommission Issue Groups that although the stakeholders agree on a number of fundamental issues, views on how this should translate into socio-political action vary considerably, especially concerning regulatory issues. This is reflected in the concluding recommendations of the NanoKommission.

Wolf-Michael Catenhusen

Chairman of the German Federal Government's NanoKommission

Summary

The NanoKommission was established by the German Federal Government in 2006 as a central national platform for dialogue. Its mandate was to foster exchange among the various stakeholder groups in society on the potential benefits and risks of nanotechnologies and thereby promote the responsible use of nanomaterials. The present report summarises the discussions and outcomes of the NanoKommission's second dialogue phase from 2009 to 2011. During this period the NanoKommission comprised eighteen permanent members representing a variety of stakeholder groups. The members' work was supported by four Issue Groups, each consisting of 20-25 members representing ministries and public authorities, research and industry, environmental, consumer and women's organisations, trade unions and churches. An additional Working Group comprising NanoKommission members, research scientists and representatives of government authorities was set up to address the concept of "Sustainable Nanotechnologies – Green Nano". All in all, more than a hundred experts involved in nanotechnologies took part in the lively and sometimes controversial NanoDialogue debates and contributed to the findings of this report.

German activities relating to nanotechnologies – the current picture

Some of the fundamental issues addressed by the NanoKommission are currently also being tackled at international level. Representatives of various ministries, industry bodies and environmental organisations, for example, are actively engaged in international consultation processes aimed at establishing a definition of nanomaterials (Section 1.1), and contribute to the Working Parties on nanotechnology of the Organisation for Economic Cooperation and Development (OECD). Beside characterising and assessing the risks of reference materials, the OECD Working Parties also pool international research on toxicological and ecotoxicological testing methods. Germany makes important contributions in both of these fields (Section 1.2).

The German Federal Government continues to invest in expanding research on nanotechnologies. In 2010, public funding for research from the federal purse was increased to around EUR 400 million for institutional research and project-based research. A variety of national research projects are currently under way, investigating issues relating to the safe and responsible use of nanomaterials and their effects on human health and the environment. About 6.2% of federal spending on government department projects goes to accompanying social and risk-related research (Section 1.3)

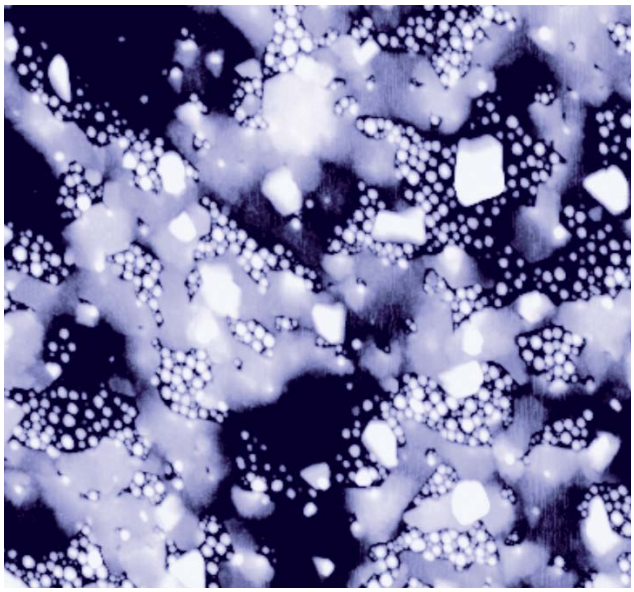


Figure 1: 10 nm-tall bismuth stacks on silicon

The broad network of stakeholder dialogues aimed at facilitating an exchange of knowledge and views in Germany provided another basis on which the NanoKommission has been able to build. In addition, several public information and dialogue events have been organised. The most recent Eurobarometer studies indicate that the German public is now relatively well informed regarding nanotechnologies. Of those surveyed, 46% thought the benefits outweighed the risks, while 29% believe the risks to be greater
(Section 1.4).

Investment in research and the knowledge generated by the dialogue process have boosted economic development. Some 950 German companies are currently engaged in developing or marketing nanotechnologies and nanomaterials at various stages of the value chain, and the trend is still on the rise. As a result, Germany remains at the forefront of this market in Europe. Small and medium-sized enterprises (SMEs) make up the majority of these companies (Section 1.5).

The work of the NanoKommission is aimed at fostering responsible use of nanomaterials in line with the precautionary principle, preventing risks and advancing sustainable innovation. It has produced:

- suggestions for improving implementation of the Five Principles for the responsible use of nanomaterials (see NanoKommission Report for 2008)
- a framework for guidelines for comparative benefit-risk assessment of nanoproducts
- criteria for preliminary assessment of risks posed by nanomaterials in terms of their impact on human health and the environment
- a statement on regulatory requirements
- recommendations for developing a shared paradigm for "Sustainable Nanotechnologies – Green Nano".

Each Issue Group also prepared extensive reports on its work, Excel spreadsheets and guidelines. These are available for download at www.bmu.de/nanokommission/. The results of their work are summarised in brief below.

Monitoring implementation of the Five Principles for the responsible use of nanomaterials

The remit of Issue Group 1 (Section 2.2) was to examine how the Five Principles for the responsible use of nanomaterials developed by the NanoKommission in 2008 were being implemented in practice. The group noted first that there was little awareness of the Five Principles, even within the sector itself. Measures to implement the principles were clearly falling short of expectations. Publications by both public authorities and industry stakeholders made no mention of applying the principles. This disappointing outcome was put down to inadequate communication on the one hand, but also to the fact that many enterprises already applied other voluntary Codes of Conduct or management standards. Such companies were deemed to be applying the principles implicitly. Implicit application of the principles might be equivalent to explicit application in terms of the level of protection provided. However, it denies stakeholders the possibility to reflect on and assess the processes and instruments used by enterprises and call for dialogue.

Despite the critical tone of the discussions in Issue Group 1, by the end of its deliberations some clear successes had been achieved: major German companies and industry organisations including BASF SE, German Statutory Accident Insurance (Deutsche Gesetzliche Unfallversicherung – DGUV), the German paint and printing ink industry association (Verband der Lack- und Druckfarbenindustrie – VdL) and the Federal Institute for Occupational Safety and Health (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin – BAuA) included explicit commitments to the NanoKommission Principles in their websites, position papers and guidelines.

Some Issue Group and NanoKommission members have proposed that the granting of public funding should be made conditional upon a binding commitment to apply the principles for the responsible use of nanomaterials. Other members, however, including representatives of some ministries and authorities and industry representatives, reject this idea.

Further recommendations of the group focus on obtaining a clear commitment to the principles from different stakeholders, publishing the principles on the internet in a form that is accessible and appropriate to target audiences, and the possibility of organising sector-specific awareness-raising events. In addition, checklist-style guidelines should be developed for the predominantly medium-sized companies in the user industries, illustrated with examples of good practice. With regard to monitoring implementation, the Issue Group reiterated and expanded the recommendations from the NanoKommission's first dialogue phase.

Approaches for preliminary, integrated benefit-risk assessment of nanomaterials and nanoproducts

For companies engaged in the process of innovation, preliminary assessment of the benefits and risks of new technological applications can be a helpful component of their strategic decision-making. Two Issue Groups elaborated an important framework as a first step towards an integrated approach enabling a meaningful assessment of benefits and risks even where there are gaps in the available data. The first Issue Group developed cross-sectoral criteria for screening benefit and risk aspects of products in their development phase. Five categories were explored: environment,

Summary

Figure 2: Folding arm awning with Swela Sunsilk Nano-Clean fabric

consumers, employees, society, and company. The Group also asked what key information was already available and what measures, if any, should be taken. The assessment criteria are organised in checklist form, reflect the various stages in a product's life cycle (production, use, disposal), and compare the properties of the nanoproduct in development with those of conventional products. The checklist is aimed particularly at companies involved in processing or disposal further down the supply chain (informed users) and is intended as a decision support tool, especially for small and medium-sized enterprises. The Group recommends developing the content of the assessment criteria further, drawing on scientific expertise to a greater extent. It also advocates developing the existing Excel spreadsheets with a view to converting them into a user-friendly, IT-supported tool.

In the innovation process, those who must ask themselves about potential risks associated with their materials are above all the manufacturers and producers of intermediates in the early stages of the product life cycle – especially in the case of products intended for consumer use and/or applications in the open environment which could result in exposure.

The second Group therefore explored in greater depth meaningful criteria for a preliminary risk assessment of nanomaterials, a task which it had already begun in the NanoKommission's first dialogue phase. In cases where a risk assessment required by law or comprehensive voluntary risk assessment is available, such assessment takes the place of any preliminary assessment based on the criteria presented here. Criteria such as exposure probability, physico-chemical properties, behaviour in the environment, toxicology and ecotoxicology were established on the basis of specific guiding questions. If information on a particular area is lacking, a note is made recording that there is a "data gap". The Group recommends setting up an advisory body at federal agency level to assist users to interpret the results and devise appropriate risk management measures.

Figure 3: Device for measuring particle size distribution

Both Issue Groups thought it important that the ultimate aim should be to integrate the elements developed by them, but this was beyond the scope of the present work. Both groups also felt that closer coordination with the Swiss Precautionary Matrix for Synthetic Nanomaterials would be desirable, along with an exchange on initial experiences with its implementation. A detailed description of the Issue Groups and the guidelines they produced is given in Section 2.3.

Positions on the need for regulation

Concerning regulatory matters, another Issue Group was assigned the task of analysing the existing legislative provisions at European and national level, of identifying gaps and developing appropriate recommendations. As well as discussing fundamental issues relating

to definitions and to the precautionary principle, the stakeholders also debated the need for action in the following, often controversial, areas: the EU REACH Regulation (on the Registration, Evaluation, Authorisation and restriction of CHemicals), regulatory approaches in the field of occupational health and safety, the EU Cosmetics Regulation, various laws relating to foods, and the EU legislation on biocidal products and plant protection products. In addition, participants stated their positions on current policy issues such as the introduction of a product register and the labelling of consumer products. Sometimes the Group formulated recommendations on the basis of a shared position, while in certain areas additional demands expressed by some Issue Group members were noted. The report also contains tables presenting and contrasting the various opinions on specific regulatory areas. The full report of Issue Group 3 is some 70 pages long. Its key findings are summarised in Section 2.4 below.

Developing a shared paradigm for "Sustainable Nanotechnologies – Green Nano"

Early in the NanoKommission's second dialogue phase, environmental organisations put forward the issue of "Green Nano" and of developing a shared paradigm for sustainable technology design. The NanoKommission convened a small additional Working Group to set out key features for a shared paradigm and take the first steps towards developing design criteria.

Design principles include:

- Biomimetics: use of local resources and energy sources, self-organisation as a principle of manufacturing, where possible physiological manufacturing conditions (soluble materials, pH-neutral, low pressure and temperature),

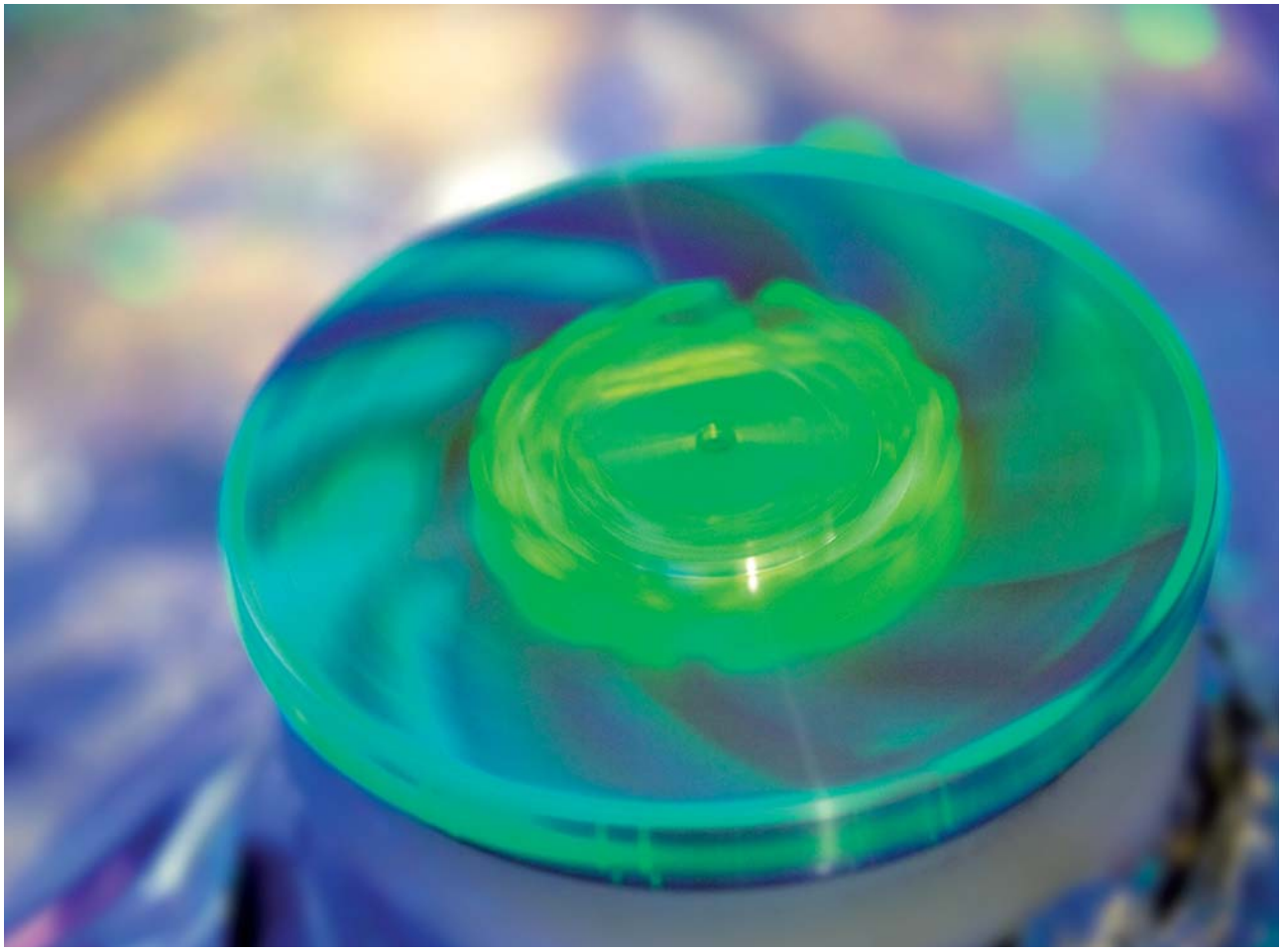


Figure 4: Photovoltaic technology based on organic materials

- Minimal risk: prevention and reduction of hazardous structures, morphologies, substances, functionalities and potential exposures,

- Energy and environmental technology: emissions reduction, environmental monitoring and remediation, and switching to renewable materials and energy sources, and

- Resource efficiency: preventing/minimising side reactions, wastes and emissions, low material intensity, energy efficiency throughout the life cycle, and recyclability.

The aim of establishing guiding principles of this sort is to foster socially viable innovations by setting priorities in line with the principle of sustainability and the precautionary principle early on in the research and development process. This could help to resolve uncertainties regarding potential benefits and risks, and provide an early indication of viable paths of innovation. The Working Group has outlined an initial framework for guiding principles, and recommends that these should be developed further in dialogue with the various stakeholders. It is proposed that this should be supported by a research project.

Additional recommendations of the NanoKommission

The NanoKommission formulated a number of recommendations to the Federal Government and various stakeholders. These are summarised below:

Recommendations on research into risks and accompanying social research:

➔ Significantly increase funding for research in this field.

➔ Close the research gaps in the field of life-cycle management and prioritise research on consumer applications and the environmental impacts of nanomaterials.

➔ Evaluate cross-departmental and multi-stakeholder research carried out in Germany on the safety of nanotechnologies. Publish a combined list from government departments and industry on a central website. Feed this data into international databases (e.g. OECD).

Recommendations on regulation:

➔ Update and amend REACH and its Annexes and the European Chemicals Agency (ECHA) Guidance documents in a timely manner. Priority should be given to:

- Introduction of a definition of nanotechnologies and nanomaterials
- Adjustment of requirements on provision of data on substances at the nanoscale
- Further review and, where appropriate, adjustment of the OECD testing methods and strategies
- Requirements and specifications concerning the incorporation of nano-specific information in Safety Data Sheets
- Adjustment of transitional deadlines for the registration of substances at the nanoscale
- Review of the tonnage thresholds for a nano-specific assessment programme and chemical safety reports based on it.

➔ Review current European legislation on biocidal products and plant protection products to establish whether current guidelines on testing adequately take into account the specific properties of nanomaterials, or whether they need to be amended.

➔ The NanoKommission underscores the recommendations for further work to establish generic thresholds for occupational health and safety. It proposes that German contributions in this field be presented rapidly in the international arena.

Within the NanoKommission and its Issue Groups there were considerable differences of opinion on the definition of nanomaterials, on labelling and establishing nano-specific testing procedures as a prerequisite for registration, as well as on substance authorisation and product approval and the issue of a product register. On these points, therefore, no joint recommendations have been made.

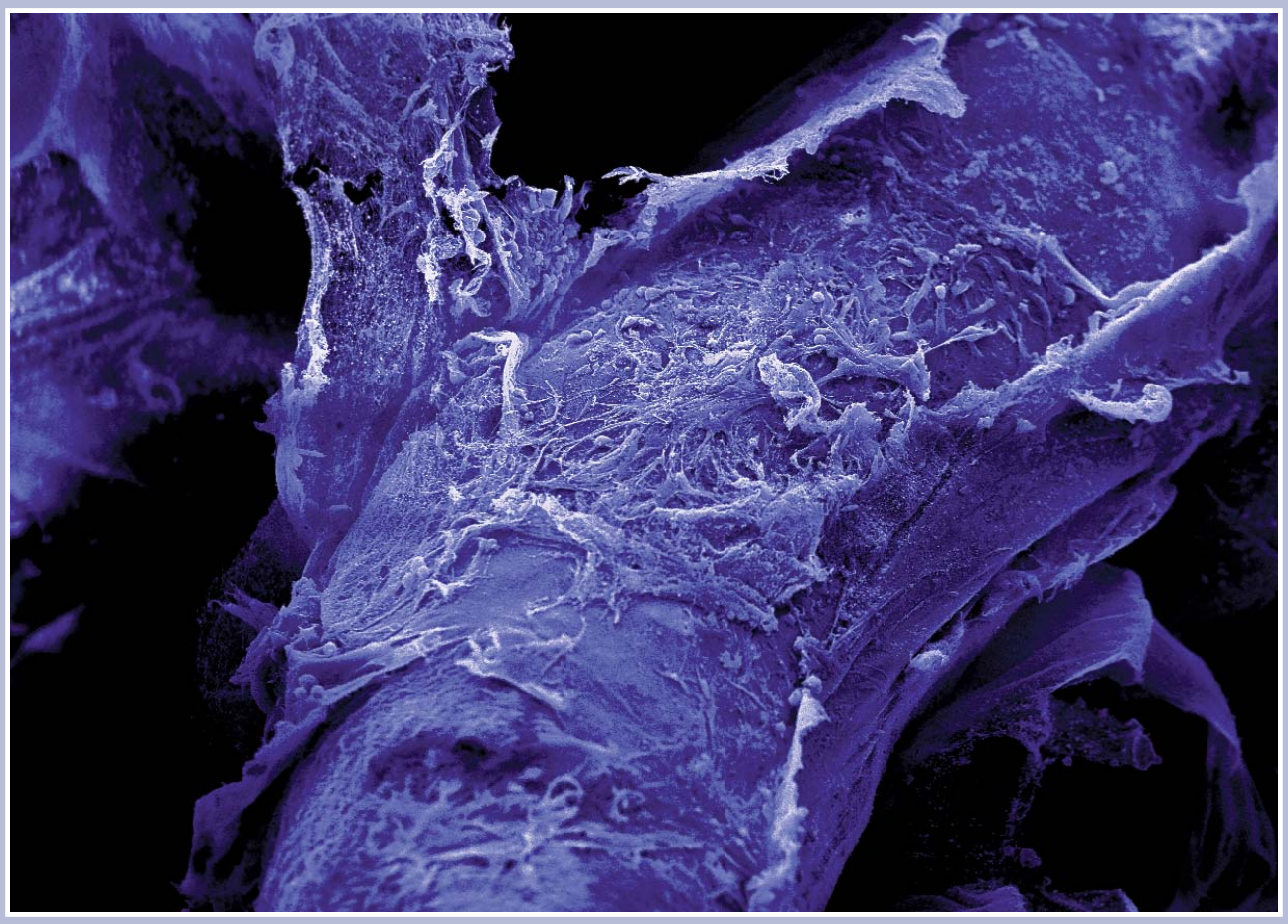


Figure 5: Scanning electron microscopy image of a coating material for implants (hydroxyapatite granule with stem cells)

Recommendations on preliminary, integrated benefit-risk assessment of nanotechnologies and nanomaterials

- Integrate and continue to develop the basic findings of both Issue Groups within a further research and consultation project involving stakeholders.

- Step up practical testing of the guidelines with involvement of future users from industry and small and medium-sized enterprises (SMEs), and close cooperation with the developers of the Swiss Precautionary Matrix.

Recommendations on developing principles for "Sustainable Nanotechnologies – Green Nano"

- Stimulate multi-stakeholder dialogue to develop principles and review design criteria.

Recommendations on continuing dialogue in future

- The NanoKommission recommends that the Federal Government should continue the dialogue process on nanotechnology in an appropriate manner, with continued participation of the stakeholders involved to date.

- Establish a central website on the activities of the Federal Government and its departments in the field of nanotechnologies.

The presentation of this second report concludes the activities of the NanoKommission for the Federal Government. The NanoKommission thanks all those who have taken part for their engagement and contributions.

1 GERMAN ACTIVITIES RELATING TO NANOTECHNOLOGIES – THE CURRENT PICTURE

1.1 Preliminary definition of nanomaterials

As yet, the question of what is meant precisely by nanotechnologies and nanomaterials has not been answered conclusively at international level. The NanoKommission and its Issue Groups had to deal with this uncertainty and decided to base their deliberations on the preliminary definition established in the previous dialogue phase.

According to this definition, **nanomaterials** refers to engineered materials in the size range typically smaller than 100 nanometres (1 nm=10^{-9}m) which, primarily as a result of their altered surface-area-to-volume ratio, develop new properties. In the course of NanoKommission discussions, environmental and consumer organisations expressed concerns about this size range, which in their view is defined too narrowly. By the time the NanoKommission was concluding its work, agreement on a definition had still not materialised, so the second dialogue phase also relies on the draft prepared in 2008 by the International Organization for Standardization (ISO Technical Committee 229):

- **Nano-objects:** Materials with one, two or three external dimensions at the nanoscale (approximately 1 to 100 nm). Typical examples are nanoparticles, nanofibres and nanoplates. Nanofibres include electrically conducting fibres (nanowires), nanotubes, and nanorods. Nano-objects are often found in groups.

- **Nanostructured materials** have an internal structure at the nanoscale and generally occur in compound systems of nano-objects. Typical examples are aggregates and agglomerates. According to ISO these are not limited in their physical size or form. [1]

This definition is regarded as a temporary solution. Intense debate is currently under way to establish a definition at the level of the European Union[2] within its advisory committees (Joint Research Centre,[3] Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)[4]), and at international level within ISO and the Organisation for Economic Cooperation and Development (OECD). The European Commission has concluded its consultation on a proposed definition. As of this writing (December 2010) it is not yet clear, however, when a decision of the Commission may be expected.

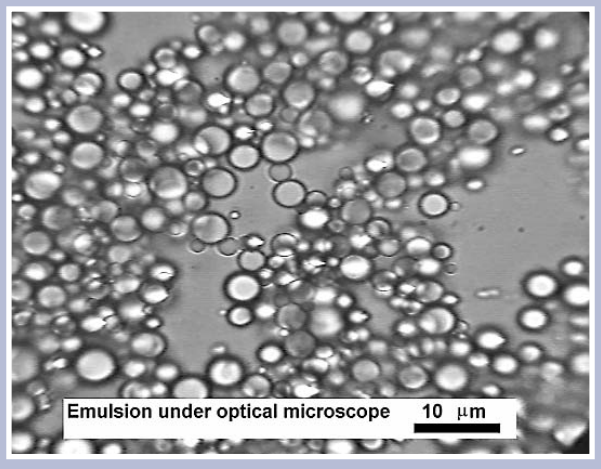


Figure 6: Emulsion droplets

1 For an explanation of the terms used see also Technical Specification (ISO/TS27687:2008(E)) of 15 August 2008
2 See European Commission 2010: Commission Recommendation on the definition of the term "nanomaterial", available at: http://ec.europa.eu/environment/consultations/pdf/recommendation_nano.pdf
3 See Joint Research Centre 2010: Considerations on a Definition of Nanomaterial for Regulatory Purposes, available at: http://ec.europa.eu/dgs/jrc/downloads/jrc_reference_report_201007_nanomaterials.pdf
4 See SCENIHR 2010: Scientific Basis for the Definition of the Term "Nanomaterial", available at: http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_030.pdf

In the NanoKommission's second dialogue phase the absence of a definition gave rise to problems as regards making specific recommendations. The Issue Groups found that a clear definition of which materials should be considered nanomaterials is a key prerequisite for all other deliberations and appraisals. The NanoKommission therefore welcomes international efforts to establish uniform nomenclature and standardised terms relating to nanotechnology.

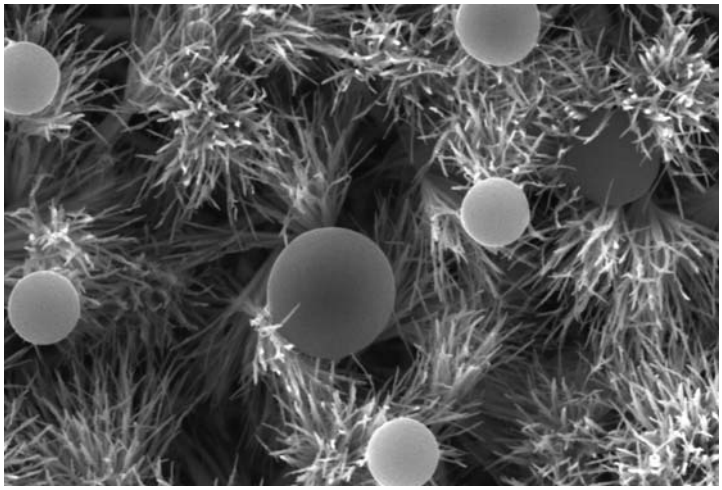


Figure 7: Nanostructured titanium dioxide

1.2 International context

In its work on the "Green Nano" principles, on criteria for preliminary risk assessment of nanomaterials, and on guidelines for assessing potential benefits and risks of nanoproducts, the NanoKommission focused on the early stages of the innovation process. The tools discussed are intended to provide orientation in situations where the data needed for a full risk assessment remain incomplete. Many of the issues relating to subsequent risk assessment of nanomaterials during the innovation process are also currently being addressed by the OECD. The NanoKommission received regular updates regarding progress with work on these issues within the OECD. In addition, members of OECD Steering Groups took part in some of the NanoKommission's Issue Groups.

The Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) chairs the German delegation to the OECD Working Party on Manufactured Nanomaterials (WPMN). This delegation comprises representatives of the federal authorities and of research institutes that have expertise in research relating to the safety of nanomaterials. German industry representatives are involved in the international industry delegation of BIAC (the Business and Industry Advisory Committee to the OECD). The centrepiece of the WPMN is its Sponsorship Programme for the Testing of Manufactured Nanomaterials, in which substance dossiers are being prepared on 13 representative nanomaterials. As part of this programme, Germany has taken on responsibility for gathering data on nanoscaled titanium dioxide (TiO_2) and contributing key data to the dossier on nanosilver. It will also provide data on zinc and aluminium oxides, cerium oxide, and carbon nanotubes (CNTs). This work is being coordinated by the Federal Environment Agency (UBA). OECD test guidelines for nanomaterials will be adjusted in the light of the findings of this testing programme. In the WPMN Working Groups, accompanying social research has already produced results, for example an international database of research projects that address issues of safety (http://webnet.oecd.org/NanoMaterials). The individual Working Groups have already delivered and published their preliminary findings.[5]

Alongside the work being done at OECD level, the activities of the European Union (EU) in the field of research promotion and regulation are also of considerable interest to the NanoKommission. A new EU Action Plan is expected to be approved in 2011 setting out EU strategies for the period up to 2015. In preparation for this, the EU conducted a consultation phase during winter 2009/2010 with all Member States, with national stakeholder groups in the Member States and associations and organisations at EU-level.[6]

EU activities intensified during the NanoKommission's second dialogue phase from 2009-2011, in particular those relating to regulation. In April 2009 the European Parliament decided that existing regulation on nanotechnologies was inadequate and needed to be reviewed. The European Parliament called upon the Commission to conduct a comprehensive risk assessment of nanotechnologies and to establish a binding

5 See: www.oecd.org/env/nanosafety

6 Public Consultation of the European Commission "Towards a Strategic Nanotechnology Action Plan (SNAP) 2010-2015", available at: http://ec.europa.eu/research/consultations/snap/consultation_en.htm

legal framework. Referring to various research findings indicating the toxic effects of some nanomaterials, Parliament called for clear legislation to enable sound risk management. The European Parliament favours introducing nanoproduct labelling and a corresponding nanoproduct register. It also called upon the European Commission to compile an inventory of nanomaterials and their uses by 2011.[7]

In November 2009, the recast Regulation (EC) 1223/2009 on cosmetic products (EU Cosmetics Regulation) was promulgated[8] and will enter into effect in 2013. In future, under the new Regulation, the use of nanomaterials must be notified to the European Commission and indicated on product labelling in the list of ingredients by adding the suffix "(nano)". Additional safety data on the use of these substances must also be provided. In the case of substances intended to be used as colorants, preservatives and UV filters, an authorisation procedure applies. The European Commission is reviewing whether further measures are needed, e.g. additional data on safety of nanomaterials contained in products, or regulatory measures. The definition of nanomaterials used in the Cosmetics Regulation is based on the position of the Scientific Committee on Consumer Products (SCCP). The legislator reserves the right to amend the legislation in the light of any changes to the definition.

The European Parliament is currently debating a new draft Regulation to replace Regulation (EC) 258/97 concerning novel foods (Novel Food Regulation). Here too, compulsory labelling is expected to be introduced. Consultations on the new Biocides Regulation[9] and on the recast of the RoHS Directive (Restriction of Hazardous Substances) have yet to be concluded. Specific provisions relating to nanomaterials are under discussion for both Regulations. Also under discussion is mandatory registration under REACH to ensure traceability of nanomaterials. This idea was considered and called for at a conference held during the Belgian Presidency of the Council of the European Union.

The many and varied activities of the EU on regulation sparked considerable demand for information and discussion among the NanoKommission stakeholders. In its second dialogue phase, the NanoKommission therefore set up a special Issue Group specifically tasked with conducting dialogue on issues relating to regulation. The Issue Group presented its analysis of the current state of debate in Europe and resulting consequences and recommendations for the Federal Government in a 70-page report (downloadable from www.bmu.de/nanokommission). A summary of this work on regulation can be found in Section 2.4 below, and the recommendations of the NanoKommission to the Federal Government are given at the end of this report.

1.3 Research activities

The ongoing process of initiating research on risks and accompanying social research, and of assessing research findings in dialogue between various stakeholders groups, is especially important for the work of the NanoKommission. A number of unresolved questions from the NanoKommission's first dialogue phase in 2006-2008 were picked up, for example, by the studies on nanosilver, on carcinogenicity, and on a nanoproduct register, as set out in the next section. In addition, this period saw the conclusion of a number of major research projects relating to key innovations and research on risks.

Investment in nanotechnologies at federal level

Since the last report of the NanoKommission in 2008, Federal Government funding for research and development of nanotechnologies rose from EUR 339 million to around EUR 400 million in 2010.[10] Of this, a total of around EUR 370 million is provided by the German Federal Ministry of Education and Research (BMBF) for institutional and project-based research on nanotechnologies. Other government departments such as the Federal Ministry for Economics and Technology (BMWi), the Federal Ministry of Defence (BMVg), the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU), the Federal Ministry of Labour and Social Affairs (BMAS), the Federal

7 Report available to download at: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+REPORT+A6-2009-0255+0+DOC+PDF+V0//EN

8 Report available to download at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:EN:PDF

9 Cf. Biocidal Products Directive 98/8/EC, and the German Biocidal Products Act (Federal Law Gazette I No 105/2000)

10 All figures for 2010 refer to planned expenditures at the time this report was finalised in December 2010.

Ministry of Food, Agriculture and Consumer Protection (BMELV), and the Federal Ministry of Transport, Building and Urban Development (BMVBS) together contribute the remaining EUR 30 million. According to an OECD study, this puts Germany in third place worldwide behind the USA and Japan for investment in absolute terms.

Institutional support and donors

Around EUR 178 million of the BMBF funding goes to the major research institutes funded by the federal and Länder governments. The German Research Foundation (Deutsche Forschungsgemeinschaft – DFG), the Helmholtz Association of German Research Centres (Helmholtz-Gemeinschaft Deutscher Forschungszentren – HGF), the Leibniz Association (Leibniz Gemeinschaft – WGL), the Max Planck Society (Max-Planck-Gesellschaft – MPG) and the applied research organisation Fraunhofer (Fraunhofer-Gesellschaft – FhG) are all engaged in intensive research into nanotechnologies with a focus on materials and technology development, measuring technologies and safety. In addition, there are private foundations such as the Volkswagen Foundation, Caesar, the Friedrich Ebert Foundation, which is associated with Germany's Social Democratic Party (SPD), and the trade union-affiliated Hans Böckler Foundation; these all provide resources out of their own budgets for nanotechnology research or projects involving dialogue with the public.

Länder

At the Länder level approximately another EUR 59 million (BMBF 2009) in funding is provided out of Länder ministry budgets. These resources are invested primarily in supporting medium-sized enterprises and promoting local knowledge transfer. In recent years a key priority of investment efforts has been to develop knowledge within the relevant enforcement authorities. The NanoKommission has taken this into account by increasing the number of representatives drafted into the Issue Groups from the Länder.

The activities of the Federal Government departments are coordinated by an inter-departmental working group on nanotechnology and are also integrated into various joint federal and Länder bodies.

Accompanying social and risk-related research

In the last NanoKommission Report for 2008 the stakeholders called for a significant increase in funding for cross-departmental research into risks and accompanying social research. According to the report, funding for research and development of specific measures relating to occupational health and safety and protection of health and of the environment should be increased and the results made available, in suitably structured form, to society at large (NanoKommission 2008:10).

Figure 8: Scanning electron microscope as an imaging system

Since 2009, annual expenditure on accompanying social and risk-related research by the Federal Government of Germany has stood at around EUR 14 million. This expenditure primarily represents the specific project funding of the BMBF, the BMU, the BMAS and the BMELV together with the federal agencies accountable to them. The Federal Environment Agency (UBA), the Federal Institute for Occupational Safety and Health (BAuA), the Federal Institute for Risk Assessment (BfR) and the Federal Institute for Materials Research and Testing (BAM) also make an important contribution to research on nanotechnologies in Germany, especially with regard to issues concerning safety and environmental impact. Other federal institutions also play an important role, such as the Max Rubner Institute, the Robert Koch Institute, the Johann Heinrich von Thünen Institute and the Julius Kühn Institute, as does the German Statutory Accident Insurance (Deutsche Gesetzliche Unfallversicherung – DGUV). Together, these bodies

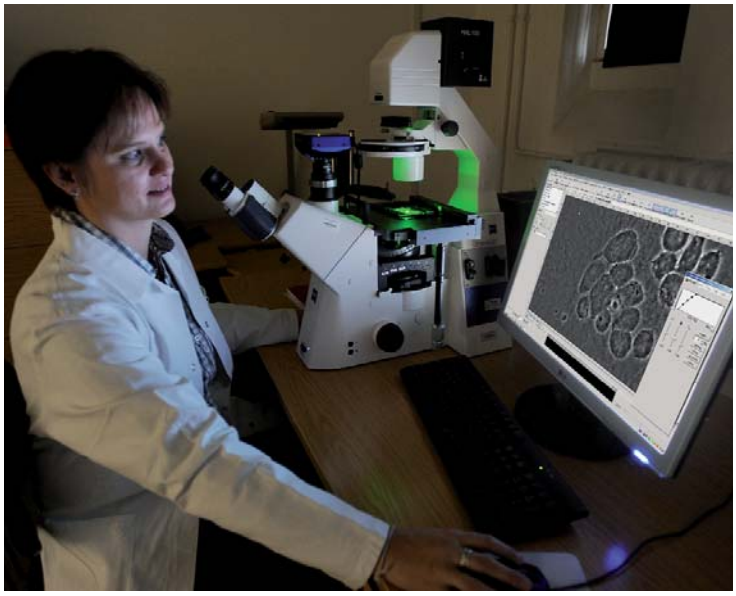


Figure 9: Using fluorescence microscopy to analyse cells treated with nanoparticles

carry out a multitude of activities relating to the development of measuring techniques and to assessment of nanomaterials. Risk-related research accounts for around 6.2 per cent of the total EUR 230 million in federal resources spent on research (government department projects).[11] The research associations provide additional research funding.

Accompanying social and risk-related research projects

In 2007 a joint strategy for research on risk and safety was established by the Federal Institute for Risk Assessment (BFR), the Federal Environment Agency (UBA) and the Federal Institute for Occupational Safety and Health (BAuA). This research strategy is currently under review to take account of prevailing gaps in the research. Areas where action is needed will be set out in the Federal Government's Action Plan. Austria approved an Action Plan on Nanotechnology as the outcome of a stakeholder dialogue process in December 2009, following Switzerland, which did so in 2008. The USA, with its National Nanotechnology Initiative, and the UK both have cross-departmental, national strategies for nanotechnologies, debated by stakeholders and in parliament. As already mentioned above, efforts are under way at the OECD level to develop worldwide databases of research on risks and accompanying social research and to improve transparency in this field.[12]

In German-speaking countries, there are web pages providing an overview of risk research and accompanying social research within the framework of the DaNa Project (http://www.nanopartikel.info/cms) and via the information platform www.nano-sicherheit.de. Below we present a summary of selected research projects conducted during this NanoKommission dialogue phase which also influenced its dialogue.

2009, for example, saw the conclusion of three major BMBF-funded risk research projects (**NanoCare, INOS** and **TRACER**). NanoCare characterised eleven nanomaterials and conducted a variety of toxicological studies in vitro and in vivo, as well as research on exposure to nanomaterials in the workplace. In addition, five public dialogue exercises were carried out. INOS developed methods for assessing nanomaterials in vitro, while the TRACER project addressed issues relating to biocompatibility and cytotoxicity of carbon nanofibres. The results of all three research projects have been collated into a database, processed and made accessible to the wider public.

Since 2009, the BMBF has had projects under way within its research support programme NanoNature, which focuses on research into the impact of nanotechnologies on the environment. Potential applications for environmental technologies are also being investigated alongside research into issues relating to exposure, distribution and persistence of nanomaterials. A key activity in this regard is research on measurement technologies and methods. The NanoNature projects are: Fe-NANOSIT, NADINE, NanoFlow, NanoKiesel, NanoMembrane, NanoPharm, NanoPurification, NanoSan, Nano-SCR, NanoTrack und NAPASAN.[13]

CarboSafe[14] with a budget of EUR 2 million, is a project of the interdisciplinary group Innovation Alliance Carbon Nanotubes (Inno.CNT). Research is focused on

11 See Federal Ministry of Education and Research (BMBF) (2010): Minor interpellation by Bundestag members René Röspel, Iris Gleicke and others and the parliamentary group of the SPD on the "Current state and outlook for nanotechnologies"
12 See http://webnet.oecd.org/NanoMaterials/Pagelet/Front/Default.aspx?
13 For more detailed information see: http://www.nanopartikel.info/cms
14 For more detailed information on CarboSafe see: http://www.cnt-initiative.de/download/CNT_CarboSafe.pdf

developing an online system for analysing carbon nanotubes (CNTs), static and portable measuring technologies, a measuring system and on characterising CNTs (CarboSafe 2010). Most of the research effort in this area is being carried out by industry.

The Report of the NanoKommission for 2008 also raised the issue of nanosilver. Several of the higher federal authorities addressed this issue. In November 2008 the Federal Environment Agency published a study on the assessment of total environmental exposure to silver ions from biocidal products (Beurteilung der Gesamtumweltexposition von Silberionen aus Biozid-Produkten).[15] In December 2009 the BfR published an opinion criticising the use of nanosilver in foods and products intended for everyday use.[16] In the context of the NanoNature programme mentioned above, a project entitled UMSICHT is currently investigating the environmental behaviour and fate of silver nanoparticles in textiles.

Some of the findings of the research projects on risks of nanomaterials were included in the work of the Issue Group examining assessment of the benefits and risks of nanomaterials. The NanoKommission itself took an explicit stance on the following studies:

In January 2010, a **Report of the Federal Environment Agency (UBA)** published in autumn 2009 entitled "Nanotechnology for Humans and the Environment – fostering opportunities and reducing risks" (Nanotechnik für Mensch und Umwelt – Chancen fördern und Risiken mindern) [17] was hotly debated in the NanoKommission. In keeping with the precautionary principle, UBA recommended minimising or avoiding the use of products that could release nanomaterials until an exhaustive risk assessment has been conducted and grounds for concern ruled out. Criticism by stakeholders was levelled particularly at the public relations work accompanying the report.

As a result of the last **Report of the NanoKommission**, the Federal Environment Agency (UBA) and the Federal Institute for Risk Assessment (BfR) produced a **study on potential cancer risks** arising from nanomaterials. Following a critical appraisal of the available data, the study found that there was insufficient information for making a general assessment of the carcinogenic potential of nanomaterials. According to the study, potential risks can only be assessed at present on a case-by-case basis in relation to specific substances. The fact that a number of studies have produced contradictory findings was also perceived as a problem. While some studies pointed to nano-specific tumorigenic potential, in other research no carcinogenic effects were observed. The researchers put this down to inadequate characterisation of test materials, differences in design of research experiments, the use of different animal models and species and/or differences in the dose administered (UBA/BFR 2010: 1). The report highlighted the need for more research in this area and recommended efforts to develop and refine standardised methods of testing. In terms of regulation, the scientists at UBA and BfR considered it imperative to create a separate category for substances in the nanoform.

Both the methodology and the findings of the study were criticised by some members of the NanoKommission. Debate centred on the question of the extent to which animal experiments at extremely high doses are meaningful. It was not possible to reach a common position on the study's findings. The UBA/BfR carcinogenicity study and scientific feedback from the German Chemical Industry Association (VCI) and the BfR are available as downloads from (www.bmu.de/nanokommission/).[18]

Another publication that provoked some controversy was a study on the **legal feasibility of a nanoproduct register**,[19] produced by the Institute for Applied Ecology (Öko-Institut e.V.) for the Federal Environment Ministry (BMU) in 2010. In this study the authors examine possible options for a nanoproduct register at European Union (EU) level and for Germany, and make recommendations on the issue of mandatory product registration. In other EU countries, such as France and the

15 The UBA study "Beurteilung der Gesamtumweltexposition von Silberionen aus Biozid-Produkten" is available [in German] to download at: http://www.umweltdaten.de/publikationen/fpdf-l/3673.pdf

16 See BfR 2009: "BfR rät von Nanosilber in Lebensmitteln und Produkten des täglichen Bedarfs ab" (BfR advises against the use of nanosilver in foods and products intended for everyday use), Opinion No 024/2010 of the BfR, 28 December 2009, available [in German] at: http://www.bfr.bund.de/cm/216/bfr_raet_von_nanosilber_in_lebensmitteln_und_produkten_des_taeglichen_bedarfs_ab.pdf

17 The UBA study "Nanotechnik für Mensch und Umwelt – Chancen fördern und Risiken mindern" is available [in German] for download at http://www.umweltdaten.de/publikationen/fpdf-l/3765.pdf

18 The UBA study on carcinogenicity is available [in German] at: http://www.umweltbundesamt.de/technik-verfahrensicherheit/publikationen/index.htm

19 Study available [in German] for download at: http://www.bmu.de/files/pdfs/allgemein/application/pdf/bericht_nanoproduktregister_bf.pdf

Netherlands there is support for the introduction of a nanoproduct register and discussions are under way. In September 2010 the Belgian EU Council presidency also expressed support for a nanoproduct register. Advocates of a register emphasise that it would create transparency regarding nanomaterials on the market, enable public authorities to take action, if necessary, to recall products, and help consumers to make informed choices. On the industry side, meanwhile, the idea of introducing mandatory registration and a nanoproduct register is rejected on the grounds that it would entail considerable administrative effort and expense. This debate makes the study all the more topical.

1.4 Dialogue activities and public perception

As was described in the Report of the NanoKommission for 2008, the nano debate in Germany is distinguished from debates in neighbouring European countries particularly by the fact that dialogue was initiated early on. The diagram below illustrates the variety of activities for citizens or experts from various stakeholder groups organised by industry bodies, the scientific community, environmental and consumer organisations, or by federal or Länder governments. In Germany, nuanced stakeholder debate has become the established norm. The Eurobarometer survey report for 2010, moreover, shows that public knowledge has also increased. 64,7% of German citizens have heard of nanotechnologies (compared to an EU average of 46,3%). 46% think the benefits outweigh the risks, while 29% believe the risks are greater.[20]

In addition to setting up the NanoKommission, the Federal Government has also initiated various information and dialogue events in connection with nanotechnologies aimed particularly at German citizens. These include events such as the public dialogue held in summer 2010 as part of the Duisburg "Environment Market" (Duisburger Umweltmarkt), the NanoTruck roadshow,[21] brochures, focus groups and consumer conferences.

On the industry side, representatives of the German Chemical Industry Association (VCI), sub-sector associations and their member companies took part in various national and international dialogue initiatives. Specialist conferences were organised by the German Society for Chemical Engineering and Biotechnology, DECHEMA. Participants also included stakeholders from the scientific community, public authorities and NGOs. DECHEMA also ran a competition for schoolchildren[22] in which young people were asked to devise nanotechnology experiments. BASF's "Dialogueforum Nano", meanwhile, brought together environmental and consumer organisations, trade unions and churches with company representatives to develop recommendations on the issues of information and transparency throughout the product life cycle. The trade union IG BCE (Mining, Chemical and Energy Industrial Union) conducted an open workshop on prospects for nanotechnology innovations. In the Länder too, for example in Hesse, Baden-Württemberg, Saxony, Bavaria, Rhineland-Palatinate, Saarland and North Rhine-Westphalia, events of various types were organised concerning nanotechnologies. These ranged from information events for SMEs or the general public to consultative dialogue with experts within Länder government bodies.

Friends of the Earth Germany (BUND) continued to hold its annual series of events on nanotechnologies. These were run in conjunction with the Protestant Academy in Villigst. With titles such as "Nanotechnologies – Quo Vadis?" and "New Technologies and Sustainability – Green Nanotechnologies as a new model?", these events brought together experts and interested lay people to debate what would constitute a socially desirable future for nanotechnologies. In 2008 the Federation of German Consumer Organisations (VZVB) carried out a study entitled "Nanotechnologies: what consumers want to know" (Nanotechnologien: Was Verbraucher wissen wollen); it also published a position paper and conducted debates on the theme "A closer look at the miniature world of nanotechnologies" (Im Reich des Winzigen – Nanotechnologien unter der Lupe) with various stakeholders in Berlin.

20 Cf. European Commission 2010: Europeans and Biotechnology in 2010. Winds of change?, A report to the European Commission's Directorate-General for Research, available at: http://ec.europa.eu/public_opinion/archives/ebs/ebs_341_winds_en.pdf

21 For further information see: http://www.nanotruck.de/

22 For further information on the event Nano erleben – Abschlussveranstaltung des bundesweiten Wettbewerbs Nanotechnologie-Demonstrationsversuche (Experience nano – closing event in the nationwide competition on Nanotechnology demonstration experiments) see: http://events.dechema.de/NanoDemo.html

The NanoKommission, however, with its five Issue/Working Groups, a total of 28 dialogue sessions, a mid-term public presentation and a final conference in February 2011, remains a key instrument for dialogue in the exchange between science, politics and public authorities, industry and NGOs.

Without claiming to be exhaustive, the diagram on page 22/23 provides a snapshot of the varied activities in which the NanoKommission has engaged.

1.5 Economic impact

Systematically encouraging sustainable innovation is one of the keys to fostering economic growth and prosperity in the view of the German Federal Government, especially in difficult economic times. Activities relating to nanotechnologies are coordinated by the Federal Government's "Nano Initiative – Action Plan 2010", in place since 2006, and its High-Tech Strategies. As a driving force for innovation, nanotechnologies are also given pride of place as a key technology in the new "High-Tech Strategy 2020 for Germany".[23] In recent years research efforts and market applications for nanotechnologies in specific products and services have received a major impetus. Around 950 enterprises are currently engaged in the development, manufacture and distribution of nanotechnology-based products and processes in Germany. About 80% of these are SMEs.[24] This puts Germany at the head of the field in Europe. According to BMBF data more than 60 000 jobs in industry depend on the use of nanotechnologies and nanomaterials. Moreover, three of the world's five largest manufacturers of nanomaterials, BASF SE, Bayer Material Science AG and Evonik AG are headquartered in Germany. German industry therefore has a significant role to play in developing and establishing methods for the responsible use of nanomaterials throughout their life cycle.

Enterprises are supported by powerful industry federations. The German Chemical Industry Association (VCI), the Society for Chemical Engineering and Biotechnology (DECHEMA), the Association of German Engineers (VDI), the German Cosmetic, Toiletry, Perfumery and Detergent Industry Association (IKW), the Federation

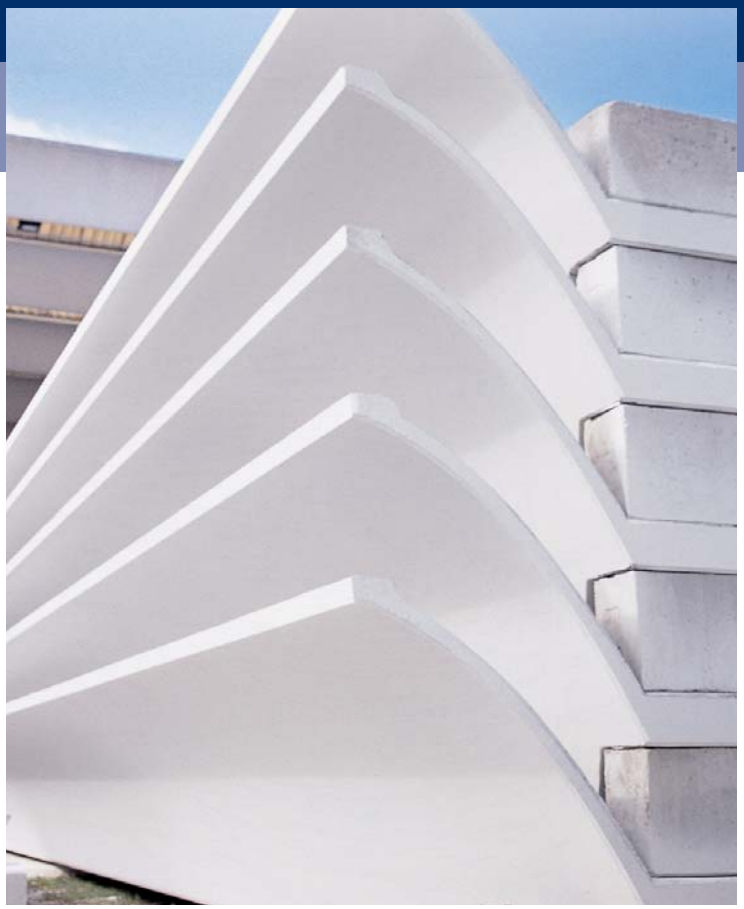


Figure 10: X-Seed precast concrete components

for Food Law and Food Science (BLL) and the German paint and printing ink industry association (VdL) have organised a large number of information and dialogue events on nanotechnologies in recent years, as well as exchange of knowledge with their member companies.

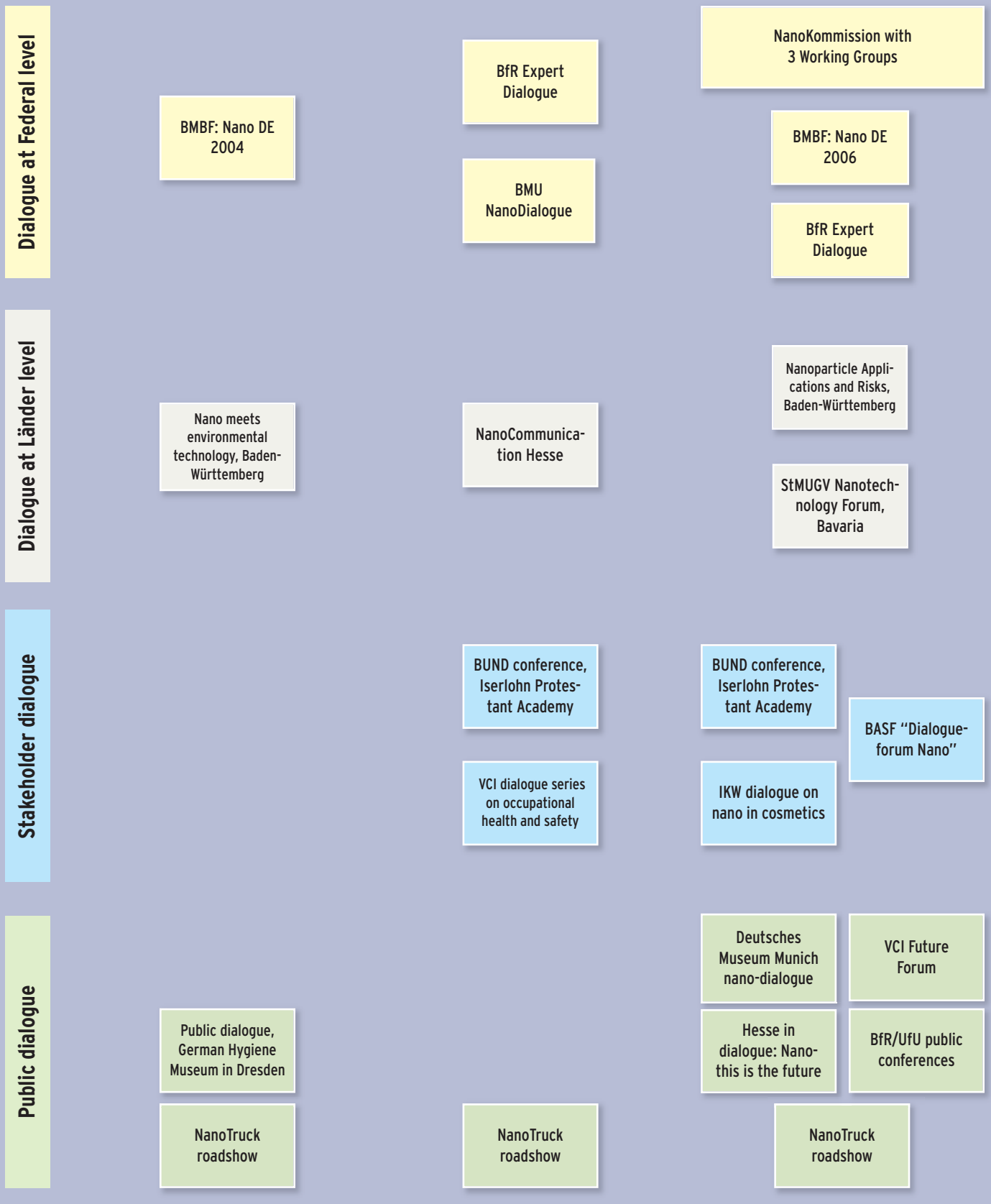
In connection with its High-Tech Strategy in particular, the Federal Government is banking on the potential of nanotechnologies to make a major technological contribution to resolving some of most pressing challenges facing society today, such as climate change, demographic change, mobility, civil security and communications. The German economy has also benefited from the huge investment in nanotechnology research and development.

Dialogue among stakeholders has also supported the process of awareness-raising and has identified important risk-related issues. The job of the NanoKommission is to drive this process forward along the path of responsible, sustainable development in dialogue with the different stakeholder groups, taking into account from the outset potential risks to the environment and to human health and addressing them adequately.

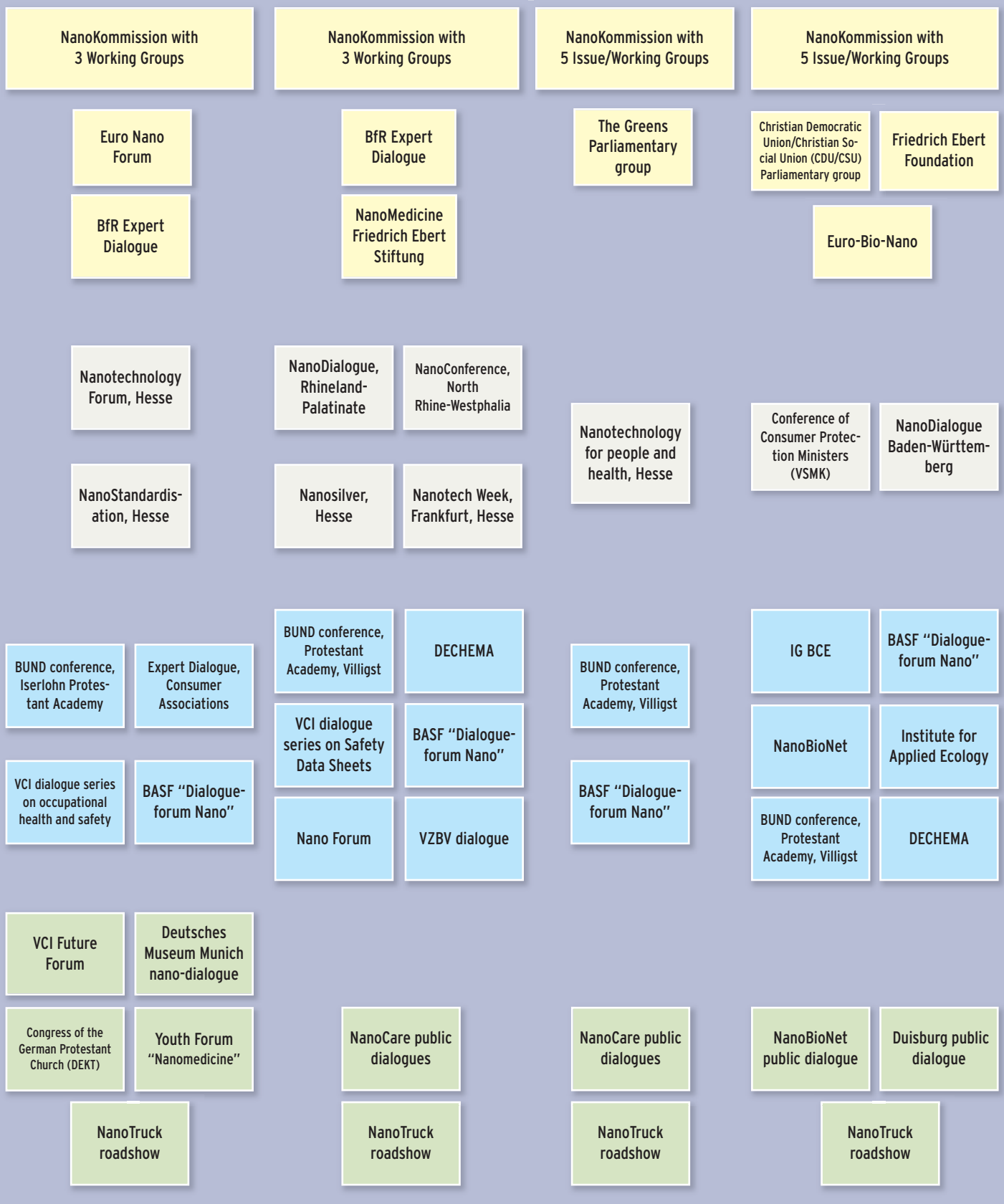
23 For further information on the German Federal Government's High-Tech Strategy see: http://www.hightech-strategie.de/

24 See Federal Ministry of Education and Research (BMBF) (2010): Minor interpellation by Bundestag members René Röspel, Iris Gleicke and others and the parliamentary group of the Social Democratic Party (SPD) on the "Current state and outlook for nanotechnologies", BT-Drs. 17/3557, 11 November 2010

Examples of the German Dialogue Landscape on Benefits



and Risks of Nanotechnologies



2 FINDINGS OF THE NANOKOMMISSION 2009-2011

2.1 Structure and objectives of the NanoKommission's second dialogue phase

Following its first dialogue phase from 2006-2008, the NanoKommission was reconvened for a second phase and the number of members increased to eighteen according to the mandated programme of work. The NanoKommission was intended to be a central, interdisciplinary and multi-stakeholder dialogue platform with the task of advising the Federal Government. A total of more than 100 experts were involved in five Issue/Working Groups and in the coordinating NanoKommission. Representatives of ministries at federal and Länder level and of higher federal authorities, from the scientific community, industry and NGOs (trade unions, environmental and consumer organisations, churches and a women's organisation) worked together on issues concerning the responsible use of nanomaterials.
At the beginning of the process, the following objectives were agreed for the work of the NanoKommission itself:

- To foster continuous exchange among interest groups and develop the communication structures established in the first dialogue phase
- To ensure that the whole work process continuously focuses on priority issues and cross-cutting issues
- To discuss, take decisions on and publish the findings of the NanoKommission's Issue/Working Groups
- To formulate recommendations to the Federal Government and, where relevant, to other stakeholders
- To comment on legislative processes (EU, national)
- To comment on the state of risk research and on any consequences arising out of this for the implementation of legislation.

In February 2010 an interim review of the work of the NanoKommission's Issue/Working Groups was held in the form of a dialogue forum. The purpose of this event was to present preliminary findings and hold discussions with the interested public and experts.
The following sections of this report summarise the findings of the Issue/Working Groups at the end of their dialogue phase in autumn 2010 and present recommendations with regard to possible next steps. The detailed original documents on the work of the Issue/Working Groups are available to download from the website of the Federal Environment Ministry (BMU – www.bmu.de/nanokommission/). Also available are the Excel spreadsheets on preliminary benefit and risk assessment, with guidelines on proper application and additional explanations. At the end of the Report (Section 3), the NanoKommission draws its own conclusions and makes recommendations based on the findings of the Issue/Working Groups.

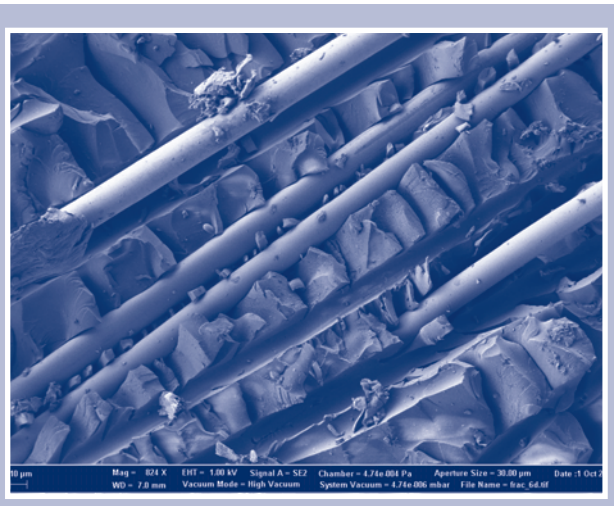


Figure 11: Fracture surface of a nano-modified glass fibre composite with CNT

During its second dialogue phase the NanoKommission had the support of an external coordination office, professional moderation and dialogue management and additional support for the preparation and coordination of its final report.

2.2 Monitoring implementation of the Five Principles of the NanoKommission

2.2.1 Remit of the Issue Group on implementation of the Five Principles

In the first Nano Dialogue phase, the former Working Group 3 produced a paper setting out Five Principles for the responsible use of nanomaterials.

These Five Principles are:

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

These principles were published in the Final Report of the NanoKommission for 2008.

In the Final Report on the first dialogue phase, the NanoKommission recommended that implementation of the principles should be monitored, names of companies/sectors which had committed to implementing the principles should be published, and that the principles should be reviewed after two years. They also recommended that the Principles Paper should be extended to apply to other sectors that use nanotechnologies or nanomaterials.

The NanoKommission's remit to the new Issue Group for the second dialogue phase was directly related to these recommendations:

- To monitor implementation of the principles for the responsible use of nanomaterials within the chemical industry (manufacturers of nanomaterials and of preparations which contain nanomaterials), to assess "principles" as an instrument and potential ways to optimise them.

- To expand the recommendations on practical guidelines for implementing the principles, especially to include issues relating to environmental and consumer protection.

To give concrete form to this basic mandate of the NanoKommission, the Issue Group divided its work into the following four "packages":

1. Review the use of guidelines to specify the principles
2. Assess approaches for monitoring implementation of the principles
3. Expand the recommendations in the areas of environmental and consumer protection
4. Discuss options for extending the scope of the principles to cover other sectors.

First of all the Issue Group sought to obtain an overview of awareness of the NanoKommission's Principles within the different sectors and of how widely they were being implemented. To do this it used information from a survey conducted by the VCI and analysed the guidelines produced by various sectors and companies which use nanomaterials. The results of this stock-taking exercise gave rise to intense debate and a produced a number of recommendations. The original Issue Group report on the course of the discussions and their outcome is available as a downloadable document (see above).

2.2.2 Findings of the Issue Group on implementation of the Five Principles

Awareness of the Five Principles

In winter 2009/2010 the German Chemical Industry Association (VCI) carried out a survey of its member organisations. Included in the questionnaire were a number of questions on implementation of the NanoKommission Principles. Out of 40 companies surveyed, 17 responded to the questions concerning the principles. Evaluation of the results by the VCI revealed that at the time of the survey none of the respondent companies made an explicit reference to the NanoKommission Principles.

Telephone interviews conducted by the Issue Group chairman with individual SMEs outside the chemical industry yielded a similar picture. Only a few of the respondents were aware that the Federal Government's NanoKommission even existed. None of the respondents in the SME sector were aware of the principles for the responsible use of nanomaterials.

Several possible reasons for this were put forward:

- Aside from holding an event to mark the publication of its final report, the NanoKommission did not actively communicate its work. The Report of the NanoKommission which contains the principles was not actively sent out to companies or sectoral bodies using nanomaterials.

- The principles were not published in a separate document. Instead, they were included in the NanoKommission's 70-page Report for 2008. This was perceived to be not very reader-friendly and hampered ease of access.

- The findings of the NanoKommission have so far only been published on the web pages of the Federal Environment Ministry (BMU).

- Other public bodies at federal and Länder level which provide information on nanotechnologies make no reference and provide no links to the principles.

- Industry bodies and large enterprises make no mention of the NanoKommission Principles in their web pages, or of any awareness-raising events related to them.

Beyond the controversially debated questions of the attribution of responsibility in this matter, the Issue Group makes the following recommendations:

- ➔ Partners in the NanoDialogue (public authorities, industry, trade associations, trade unions, churches and consumer organisations) should publicly express their commitment to the principles for the responsible use of nanomaterials, e.g. by including a specific declaration on their websites.

- ➔ Participants in the NanoDialogue should actively communicate the approach to other, non-participating companies, industry bodies and institutions.

- ➔ The Five Principles of the NanoKommission together with their accompanying explanations should be published in separate brochures. These brochures could be developed for example by the BMU and the industry associations and made easily accessible to interested parties, including via the internet.

- ➔ Public awareness-raising events on the responsible use of nanomaterials should be organised/attended to publicise and foster debate on the NanoKommission Principles. This applies especially to events run by the relevant ministries and industry associations. In this context it would be desirable to extend the scope of the principles to cover other sectors using nanomaterials as soon as possible.

- ➔ Efforts to include environmental and consumer protection aspects in recommendations for guidelines should be continued, taking into account the initial contributions from the discussions of the Issue Group.

Inclusion of the principles in sector guidelines and company codes of conduct

Alongside the results of the VCI survey, the additional interviews with individual SMEs and analysis of websites, the Group also carried out a review of sector guidelines and company codes of conduct to ascertain whether they made any direct reference to the principles, or whether the principles were being implemented in other ways. The Issue Group found that, eighteen months after the principles had been approved, not a single company or industry association specifically mentioned the principles in its literature although some had in fact been directly involved in developing them in the course of the last dialogue phase of the NanoKommission. Many companies and industry bodies, however, already apply other principles relating to the responsible use of nanomaterials, which cover similar areas. One such example is the Responsible Care® Charter of the chemical industry, or the various company codes of conduct reviewed by the Group (see detailed Report of the Issue Group).

Two of the companies participating in the dialogue (BASF SE and Bayer Material Science AG), and the VCI were examples where established management and communication practices were in place that covered the substance of the principles. In the case of sector guidelines, it should be noted that the guidelines examined by the Group had all been in place prior to the

publication of the NanoKommission Principles in 2008, with the exception of the German paint and printing ink industry association guidelines.

As regards implementation of the principles, the Issue Group therefore drew a distinction between:

1. "Explicit" commitment, where the company in question "publicly" declares its commitment to implementing the principles for the responsible use of nanomaterials; and

2. "Tacit" commitment, where the company declares that implementation of the relevant sections of the principles for the responsible use of nanomaterials is carried out within the company divisions concerned. However, the company makes no clear, outwardly evident connection between this practice and the NanoKommission Principles. Instead, it implements them "implicitly", e.g. as part of general company governance.

In the subsequent discussions it became clear that even where the content of an organisation's guidelines is similar, implicit implementation is neither visible nor verifiable from outside the company. Implicit implementation was considered to be just as appropriate as explicit implementation in terms of the level of protection provided – all of the dialogue partners agreed on this point – but it does not offer the possibility for external stakeholders to scrutinise processes and instruments and to request dialogue initiatives. This drawback was emphasised particularly by the NGOs and public authorities. As pointed out by the NGOs, it also runs counter to Principle 2 for the responsible use of nanomaterials, the transparency principle.

In the course of the Issue Group's dialogue, BASF SE introduced a specific reference to the NanoKommission Principles and provided a link to the original document.[25] German Statutory Accident Insurance (DGUV), another member of the Issue Group, produced a position paper making specific reference to the Five Principles.[26] The German paint and printing ink industry association (VdL) also included explicit mention of the NanoKommission Principles in its new sectoral code of conduct on the responsible use of nanomaterials in the workplace.[27]

Figure 12: Measuring nanoparticles with a scanning mobility particle sizer (SMPS)

Towards the end of the NanoKommission's second dialogue phase the Federal Institute for Occupational Safety and Health (BAuA) also published a declaration of explicit commitment to the principles for the responsible use of nanomaterials and outlined plans for their implementation.[28]

➔ In its Report, the Issue Group reiterates the recommendation from the NanoKommission's first dialogue phase calling for the provision of an internet platform publishing the names of companies, industry associations and institutions implementing the principles or taking them into account. It remains to be clarified whether these companies, industry associations and institutions would input this information themselves or whether a third party would be commissioned to undertake this task according to a set of criteria still to be established.

25 See: http://www.basf.com/group/corporate/de/sustainability/dialogue/in-dialogue-with-politics/nanotechnology/code-of-conduct

26 See: "Verantwortungsvoller Umgang mit Nanomaterialien – Position der gesetzlichen Unfallversicherungen" (Responsible use of nanomaterials – Position of the Statutory Insurers), available [in German] at: http://www.dguv.de/inhalt/praevention/themen_a_z/nano/Positionspapier_Nano.pdf

27 See: "VdL-Leitfaden für den Umgang mit Nanoobjekten am Arbeitsplatz" (VdL guidelines for the use of nano-objects in the workplace), available [in German] at: http://www.arbeitsinspektion.gv.at/NR/rdonlyres/DD4883A5-FDFE-481E-B852-D41721D4567A/0/Vdl_Nanoleitfaden_Lacke.pdf

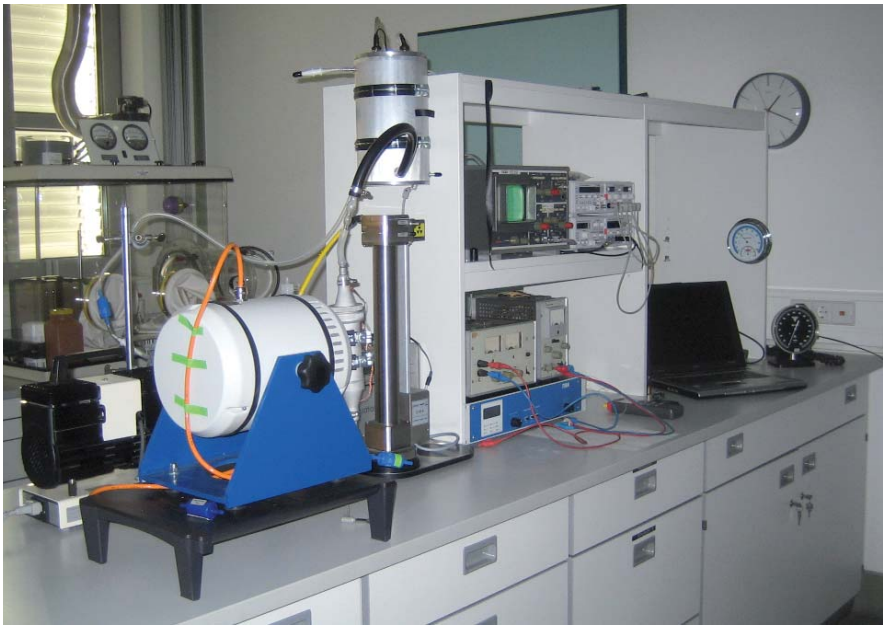


Figure 13: Using a shaker to test the release of nanomaterials under mechanical stress

The way of implementing the principles should be based on the specific conditions of each company, such as company size, position in the value chain, and the nature of a company's products. Implementation aids like guidelines must allow for diversity of this sort.

In addition, it might be appropriate for such guidelines implementing the principles into organisational routines to vary the depth and specificity of elaborating the principles according to the management and risk communication structures already in place. This is something that should also be considered when applying the assessment or testing matrices devised by the other Issue Groups.

Further development in the form of guidelines and other support for implementation

From the perspective of users of nanomaterials in industry, the NanoKommission Principles need to be given concrete form for implementation in practice, for example by means of sector-specific guidelines of the industry associations. During the second phase of the NanoDialogue, the VdL produced just such a set of guidelines for the German paint and printing ink industry. A joint code of conduct for occupational health and safety had already been put in place by the VCI and the BAuA before the Five Principles were developed in the NanoDialogue process. The VCI also had a number of guidelines on specific issues relating to the use of nanomaterials. These were used in developing the five NanoDialogue Principles. According to industry representatives, other sector-specific guidelines are currently being drawn up. Differences in focus and in depth of detail of these guidelines are due to differing requirements for the responsible use of nanomaterials in different industrial sectors of application. Industry representatives therefore do not consider it useful to establish a general format for guidelines with identical criteria for all sectors.

The Issue Group recommends that the NanoKommission should make the evaluation matrix (see below) available to authors of guidelines and codes of conduct to facilitate comparison and adjustment. The current version of the evaluation matrix produced by the Issue Group is a work in progress and requires further development if it is to be used widely to make definitive appraisals, should the need arise as a result of new guidelines being produced on the basis of the principles.

Criteria were evaluated qualitatively using a three-level scoring system: (-) = criterion has not been addressed; (o) = criterion has been partially/inadequately addressed; (+) = criterion has been addressed in full/extensively.

In order to provide interested stakeholders in industry with tools that are fit for purpose, the Issue Group believes it would be desirable to produce examples of implementation tools based on agreement between the partners in the NanoDialogue. This would entail especially

- Elaboration of a model set of guidelines for user industries, taking into account the predominance

28 See BAuA (2010): Umsetzung der Prinzipien zum verantwortungsvollen Umgang mit Nanomaterialien der NanoKommission der Bundesregierung (Implementing the principles for the responsible use of nanomaterials of the German Federal Government's NanoKommission), at: http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/Nanotechnologie/Nanomaterialien.html. On the Activities of the BAuA (2010), see: Forschung und Entwicklung zu Nanomaterialien am Arbeitsplatz (Research and development relating to nanomaterials in the workplace), available at: http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/Nanotechnologie/pdf/Forschung-Entwicklung.pdf?__blob=publicationFile

Table 1: Matrix for evaluation of guidelines			
	Criteria	Evaluation	
		Principles addressed (Qualitative assessment -, 0, +)	Principles given concrete form (Qualitative assessment -, 0, +)
	Equal consideration given to all protection targets (occupational health & safety / environment / consumers)		
1	**Definition and disclosure of responsibility and management (good governance)**		
	Definition of responsibility in the management context		
	Clarity of definition to outsiders		
	Regular or continuous reporting		
	Establishment of a clear and verifiable management system		
2	**Transparency regarding nanotechnology-related information, data and processes**		
	Information on use of nanomaterials and products derived from them		
	Information on relevant safety assessment issues		
	Information on measures applied and recommended for safe use		
	Information presented in appropriate way for target audience		
3	**Commitment to dialogue with stakeholders**		
	Conducting or fostering dialogue with interested stakeholders		
	Evaluation of dialogue activities		
4	**Establishment of risk management structures**		
	Appropriate application of the precautionary principle		
	Indications of possible substitution testing		
	Involvement of final consumers and partners in the supply chain		
	Documentation of knowledge gaps		
	Appropriate involvement in safety research		
5	**Responsibility within the value chain**		
	Availability of central basic data for toxicological and ecotoxicological assessment		
	Use of communication options		
	Policy transparency		

of medium-sized enterprises (with guidance for action, checklist-style layout, encompassing all areas of activity).

➔ Setting out examples of Good Practice, showing how larger enterprises in the sector have integrated the NanoKommission Principles into their existing structures.

Monitoring

As a possible instrument for monitoring implementation, the VCI suggested conducting a survey of its member companies. As described above, a first survey was carried out in 2009.

The other dialogue participants welcomed this voluntary initiative. At the same time, however, they perceived this first survey of the use of nanomaterials in industry as inadequate as it was limited to the relatively narrow circle of active VCI members. Some dialogue participants also pointed out that a survey does not equate to independent monitoring of implementation.

For the kind of monitoring that delivers scientifically sound results and is accepted as independent by third parties, there would have to be not only a statistically relevant population, but also above all transparent evaluation methods and independent verification. In addition, financial support would be needed from external donors. The Issue Group discussed how monitoring of this sort could be carried out as promptly and as economically as possible:

During the dialogue process, the VCI offered to include questions on the principles in its general Responsible Care survey in future with a view to achieving broader dissemination and generating stronger commitment to take part in the survey. This would also serve the purpose of spreading awareness of the principles and broaden the reach of the survey on the use of nanomaterials within the chemical industry. Moreover, the data could be checked by auditors, thus ensuring independent third-party verification.

Some participants also expressed the desire to be involved in the actual design of methods for transparent evaluation of the results. The VCI offered to involve the stakeholders in the survey design process.

Conclusions of the Issue Group

In this second dialogue phase the Issue Group addressed the issue of implementing the NanoKommission Principles. Representatives of the trade unions, environmental organisations and consumer associations stated that implementation by companies and industry associations had fallen short of their expectations. For a variety of reasons, implementation of the principles by companies tended to be implicit rather than explicit. Although implicit implementation might be just as good as explicit implementation in terms of the level of protection provided, it denies stakeholders the possibility of ensuring transparency and of scrutinising the processes and instruments used. One positive development, however, was the fact that during the course of the dialogue four companies and industry associations decided to lead the process by taking the initiative of developing guidelines.

Some members of the Issue Group proposed that the granting of public funding should be made conditional upon a binding commitment to apply the principles for the responsible use of nanomaterials that were developed in the NanoKommission' first dialogue phase and reinforced in the second phase. The Federal Institute for Occupational Safety and Health (BAuA) has already decided to go down this route. Other members, including representatives from the ministries, from other public bodies and from industry reject this idea, pointing out that EU research funding is granted on the basis of the "Code of Conduct for Responsible Nanosciences and Nanotechnologies Research".

Despite all the obstacles and hitherto unfulfilled expectations, the Group thinks it would be useful to continue to monitor the implementation of the principles and to define them in more detail. This will allow the potential of this approach to be developed and exploited.

In general terms, the content of the Five Principles of the NanoKommission for the responsible use of nanomaterials continues to have the full backing of all the dialogue partners.

2.3 Approaches for preliminary, integrated benefit-risk assessment of nanomaterials and nanoproducts

2.3.1 Setting and objectives

The mandate of the Federal Government's NanoKommission is to gather all the information available on benefits and risks of nanomaterials and nanoproducts in dialogue with different stakeholders, and thus foster the responsible use of nanomaterials. This is particularly important in the early stages of development of a technology like this due to the uncertainties surrounding it. In this context it makes sense to set out pragmatic approaches for orientation and assessment that take equal account of economic, environmental and social considerations before a product reaches the market-ready stage.

Between 2006 and 2008 the NanoKommission developed criteria for carrying out a preliminary risk assessment of nanomaterials in situations where a complete data base was not yet available. The idea behind this was to give companies a straightforward way of classifying their materials into categories ranging from "probably not hazardous" to "probably hazardous". This grading system can then be used as a basis for recommending appropriate measures. As a means of providing initial orientation, the preliminary risk assessment was welcomed by the stakeholders. At the same time it was emphasised that the criteria used for preliminary risk assessment needed to be refined and, in more general terms, that the framework for preliminary risk assessment needed to be expanded. The need for integrated consideration of potential benefits and risks was highlighted by the experience of Working Group 1 in the NanoKommission's first dialogue phase. The remit of this group was to identify potential benefits of nanotechnology for society. It became apparent that a methodological framework was needed in order to be able to make any sensible pronouncements regarding potential benefits, too. The methodological framework should include integrated consideration of potential benefits and risks from the outset, because it is only by weighing up these two aspects that any judgement can be made as to whether a particular nanotechnology application has potential benefits for society.

The NanoKommission therefore set up two Issue Groups to establish a basic framework for an integrated risk-benefit assessment and to continue developing the approaches devised during the previous dialogue phase. One of the Groups focused primarily on the potential benefits and risks of nanoproducts, while the other set out to establish categories for preliminary risk assessment of nanomaterials themselves.

2.3.2 Developing guidelines for collecting data and comparing benefit and risk aspects of nanoproducts

The first Issue Group, comprising around 20 stakeholders, put forward guidelines for gathering data and comparing the benefits and risks of nanoproducts throughout their life cycle. The Group's members developed a set of criteria for integrated benefit and risk assessment at the product development stage and summarised these in the form of preliminary guidelines. Key components include a product profile, a catalogue of benefit criteria and a set of risk criteria. In line with the groundwork on preliminary risk assessment carried out in the NanoKommission's previous dialogue phase, the group elaborated cross-sectoral evaluation criteria. These are divided into five categories: environment,

Figure 14: Folding arm awning with Swela Sunsilk Nano-Clean fabric

consumers, employees, society and company. The inclusion of social considerations here offsets the largely natural sciences-based focus of Issue Group 4. Using a checklist-style approach, the first step in the evaluation reveals any benefit and risk-related considerations that may arise at the different stages of a product's life cycle (manufacture, use, disposal) and how the product compares to a conventional reference product (not involving nanotechnology).

The objective of these efforts is to provide enterprises with a basis for making strategic decisions early on in the innovation process on the one hand, while also creating a systematic basis for dialogue between industry, consumer organisations and public authorities.

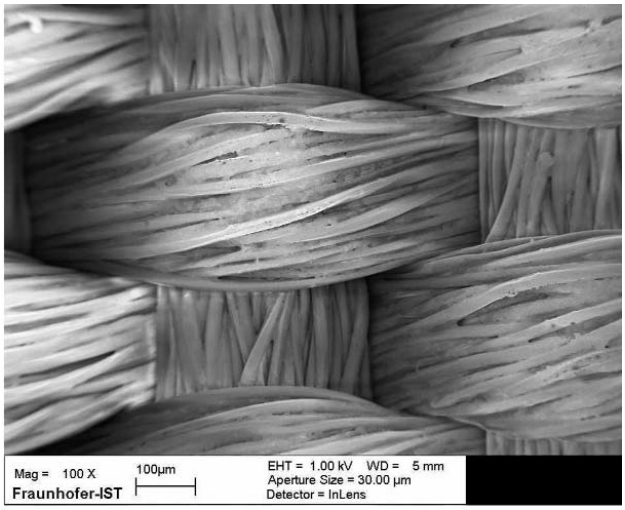


Figure 15: Scanning electron microscope image of the surface of a fabric treated with a nano-based material

Complementing these efforts, the Issue Group formulated directions for carrying out product evaluation and presenting the results. As mentioned above, the complete report of the Issue Group containing the draft guidelines, directions and an Excel spreadsheet with examples illustrating how they would be used in practice is available for download from the internet.

The applicability of the criteria on benefit/risk considerations was tested while the guidelines were being developed, using five case study examples. These included products already on the market (a glass cleaning product, PET bottles, awning fabric), products in development (a textile cleaning product) and materials at the very early stages of development (wind turbine rotor blades made from materials containing CNT). All of the case study examples provided useful insights as regards the applicability and limitations of the list of criteria. These were fed back into the subsequent stages of the Issue Group's work.

To illustrate what the results of a test might look like, two of the five case study examples (PET bottles and awning fabric) were worked up in full for publication based on the most recent version of the list of criteria.

Work on the other examples revealed that, in terms of enabling sound and comprehensive consideration of benefit- and risk-related factors, the list of criteria was of limited use in the case of products still in development, where an established supply chain down to the finished product does not yet exist (e.g. in the case of the wind turbine rotor blades made from materials containing CNT). The individual criteria still proved useful, however, for precautionary evaluation of products enabling a company to assess a product's state of development, drawing attention to potential risks and prompting further testing (e.g. in the case of the textile cleaning product).

It also became clear in this course of this work that the set of criteria was only applicable to a limited extent in the case of products for which a company had already obtained a scientific risk evaluation (e.g. in the case of the glass cleaning product). It was found that some of the criteria required a re-examination of data which the risk assessment had already provided. Potentially this could give rise to false interpretations. The companies concerned therefore decided against publication to prevent misinterpretation. The environmental and consumer associations were disappointed that the Report now contained only two sample cases. It would have been useful to have a larger number of sample cases to test the applicability of the list of criteria.

2.3.3 Criteria for preliminary, integrated benefit-risk assessment of nanoproducts

The starting point of the assessment criteria is to characterise the product by generating a product profile. Akin to the characterisation of substances in Safety Data Sheets, the user gathers together the available informa-

Figure 16: Testing for nanoclay migration from doped plastics

tion on the planned finished product, e.g. from the Safety Data Sheet or other product information sources (own information, information provided by suppliers). In addition, a reference product manufactured without the use of nanomaterials or nanotechnologies is used for comparison. The product profile asks for information on the following parameters:

Parameters concerning the nanoproduct:

- Designation of the product and technical functionality of the finished product
- Specification of the functional unit
- Function of the nanomaterial in the product
- Reference product and rationale for its selection

Parameters concerning the nanomaterial used

- Name of the nanomaterial and its manufacturer
- Information on the value chain
- Form factor, particle size and particle size distribution
- Surface functionalisation and coating
- Information from the safety data sheet and available scientific research studies (e.g. on toxicity and ecotoxicity)
- Other special features or characteristic properties

A multi-level Excel spreadsheet assists the user to describe the benefits of the product in sustainability terms and, where possible, to quantify this. The product is then also graded according to various risk criteria. Detailed sub-criteria were formulated for each of the two areas. In both areas, benefit and risk aspects are assessed throughout the entire product life cycle and compared to the reference product (without nanotechnologies). The key criteria for assessing benefit and risk aspects are presented in the simplified table below.

Companies could use guidelines like these as an early warning system in their product development process. At the same time, in keeping with the Five Principles of the NanoKommission, the guidelines also suggest ways of shaping communication and information on

Table 2: Comparison of potential benefit and risk aspects relating to nanoproducts

Potential benefit aspects	Potential risk aspects
Benefits for the environment • Reduced resource use: energy • Reduced resource use: water • Reduced resource use: raw materials • Prevention of greenhouse gas emissions • Reduced emissions of pollutants • Reduced waste volume and hazard	**Risks for the environment** • Volume used annually in the product • Probability of emissions • Measures to reduce emissions • Probability of exposure affecting environmental media: water, soil, air
Benefits for consumers • Products with improved functionality • Products with improved safety in use (including protection from disease) • Consumers benefit from improved cost-benefit ratio for products	**Risks for consumers** • Amount used in a product • Use by consumers • Probability of emissions • Measures to reduce emissions • Potential ways of exposure
Benefits for employees • Advantages resulting from simpler or safer handling • Health protection in the workplace (risk management)	**Risks for employees** • Amount used in the workplace • Probability of emissions • Measures to reduce emissions • Testing effectiveness of measures • Probability of exposure – presence of employees • Probability of exposure – measures to minimise exposure • Probability of exposure – effectiveness of measures
Benefits for society • Lower costs for protecting health and the environment • New skilled job opportunities, job security • Better product performance; improved export opportunities, improved market position and competitive edge	**Risks for society** • Potential external costs for society (health/welfare system and/or ecosystem) • Threat to peace within society • Incorrect use • Risks to the national economy • Social impact of the product
Benefits for the company • Building new markets, enhanced competitiveness • Improved product quality and performance • Reduced costs, e.g. by optimising production processes • Increased job and process safety	**Risks for the company** • Loss of image • Financial/economic losses • Uncertainty of long-term strategies; risks of investment

nanoproducts and show which information resources are already available for this purpose and which need to be generated. This could also help to improve stakeholder dialogue.

2.3.4 Conclusions of the Issue Groups on preliminary, integrated benefit-risk assessment

Some segments of the Issue Groups advocate continuing the work on preliminary, integrated benefit-risk assessment.

- It is recommended in particular that the criteria for social and company benefit and risk aspects should be further developed, as the Issue Group was not able to debate these conclusively. It would therefore be important to appoint a body or organisation as soon as possible to take charge of developing these areas further.

- The present Excel spreadsheet is regarded as a preliminary working document. Further development of these areas could provide, for example, a user-friendly, IT-based tool presenting benefit and risk factors and, where appropriate, a basic assessment of them. This could best be done in a project-based framework; scientific research institutions, for example, could develop the criteria further, while weighting of the criteria or setting the social context could be done in a stakeholder dialogue, if so desired.

Alongside more in-depth work on content, another decisive factor for the success of any future instrument for assessing benefit and risk aspects will be to ensure close coordination of communication with the outside world and with similar international projects, such as the Swiss Precautionary Matrix. The following measures are recommended to improve implementation:

- To familiarise government departments and sectoral authorities with the use of the guidelines, and to gather experience with their application; where appropriate, this should feed back into the continuing development process.

- Once it has been developed further, to publicise the instrument as a basic tool for assessing benefit and risk aspects associated with nanoproducts and to review measures and instruments that could be used to create incentives for industry to apply the guidelines. These could include: providing support for assessing information and using it to decide on options for action; providing opportunities for users of the guidelines to exchange information (workshop, interactive internet platform, etc.).

- To introduce the integrated guidelines into the international debate, for example discussions on the Swiss Precautionary Matrix, the deliberations on “Cooperation on Environmentally Sustainable Use of Manufactured Nanomaterials” led by Sub Group 9 (SG9) of the OECD Working Party on Manufactured Nanomaterials, or the nano dialogue at EU level.

As a prerequisite for continued development of the integrated guidelines for benefit and risk assessment, attention needs to be given to further refining their content. The Issue Group therefore suggests:

- Integrating into the guidelines the findings of the project “Sustainability check for nanoproducts”, currently being conducted by the Institute of Applied Ecology on behalf of the UBA.

The in-depth work on preliminary risk assessment carried out in a second Issue Group of the NanoKommission should also be integrated into the guidelines. The next section covers the findings of this second Issue Group.

2.3.5 Elaboration of criteria for preliminary assessment of the impact of nanomaterials on human health and the environment

The work of the second Issue Group builds on the matrix of criteria indicating “concern” and “no cause for concern” developed by the first NanoKommission. Based on this, a list of criteria was established in the current dialogue phase which includes guidance for preliminary assessment of nanomaterials in terms of their impact on people and on the environment. While the first Issue Group addressed products, the second

Issue Group focused on materials. The group has created an important basis for a preliminary assessment of nanomaterials. In cases where risk assessment is required by law or where comprehensive voluntary risk assessment is in place, these replace any preliminary assessment based on the present criteria. The list of criteria is aimed at the informed user (as opposed to lay people or scientists). The criteria are applicable to all engineered nanomaterials, in other words both to nanomaterials in research and development and to those already in use or available on the market. They can also be applied to free nanomaterials, including their aggregates and agglomerates,[29] and to products containing bound nanomaterials.[30]

Challenges for the Issue Group:

1. To describe scientifically accurate, and yet simple and practicable parameters for identifying the need for precautionary measures / criteria for concern and no cause for concern for uses of nanomaterials.

2. To elaborate simple assessment criteria that would also enable informed users to make an initial assessment.
   Due to the intended target group it seemed expedient to avoid developing criteria that could only be applied using complex measuring methods, going beyond the basic information generally required.

3. To take into account all the criteria established in the first dialogue phase.
   In the first dialogue phase, no emphasis was placed on developing a simple assessment tool. To avoid losing any of the criteria from the first dialogue phase, criteria that could not be met without specialist knowledge or considerable research effort were bundled together under the heading "scientific risk evaluation and research".

4. To establish benchmarks for assessment.
   When developing an assessment framework the Group did not favour weighting the criteria or placing them in hierarchical order; this was deemed neither necessary nor useful. Weighting of the criteria, in the Group's view, was in any case not possible at the abstract level, because the importance of particular criteria might increase or decrease depending on the application in question. On the other hand, however, simply grouping the criteria together would mean a loss of information and could result in errors.

Over the course of the four scheduled dialogue sessions and several additional consultations, the criteria were grouped into four blocks: probability of exposure, physico-chemical properties, behaviour in the environment, and toxicology and ecotoxicology.

Each of the criteria is formulated as a guiding question requiring a "yes" or "no" answer. Depending on the criterion in question, a "yes" or "no" response leads to one of the following categories: "No immediate need for precautionary measures / No cause for concern", or "Further consideration / Need for precautionary measures / Cause for concern". In the absence of information to answer the question, the response "data gap" can be given. It is envisaged that the user will check and respond to all of the criteria.

Each criterion is assigned a letter denoting the protection target(s) for which it is relevant (**U** = environment and people (Umwelt und Mensch), **A** = Employees (Arbeitnehmer), **V** = Consumers (Verbraucher)). This is useful for evaluating the results for each individual protection target. In some cases the criteria are accompanied by additional notes, e.g. relating to testing procedures. In the last column of the table the user is asked to state the basis for his/her decision (e.g. information source) to make this clear to third parties if needed.

The structure of the table is shown below based on the example of the criterion "Production volume" in the block "Probability of exposure".

The table for "Production volume" would then be followed by a list of all the other questions and explanations for each of the blocks of criteria: "Probability of exposure", "Physico-chemical proper-

29 This includes nanomaterials which may foreseeably occur during use, for example via special spray heads in aerosol sprays. Each term used is explained in the guidelines.

30 It is also recommended to assess nanomaterials which do not fall within the size range stipulated in the working definition, as this definition is a preliminary one and in other contexts other (e.g. larger) sizes may be relevant.

Table 3: Format of the list of criteria based on the example "Production volume"

Criterion	Protection target	Explanation	Further consideration / Need for precautionary measures / Cause for concern	No immediate need for precautionary measures / No cause for concern	Data gap	Documentation / basis for decision
Production volume	AVU	Is the volume of nanomaterial manufactured > 100 kg/year?				
		Yes	●			
		No		●		
		Cannot answer / do not know			●	

ties", "Behaviour in the environment", and "Toxicology and ecotoxicology".

The structure shown in the table above is identical for all of the blocks and focuses on the following key questions:

Probability of exposure

- Is the volume of nanomaterial manufactured > 100 kg/year?
- Is the material handled only in closed facilities?
- Is the material easily released? (dust, aerosol formation, waste water)
- Is the material used or intended for use in a consumer product?
- Is the material released intentionally into the environment? (e.g. groundwater remediation, agricultural applications)
- Is the nanomaterial easily released? (e.g. dust, aerosol formation, in water, by abrasion)
- Is the nanomaterial easily released during product disposal/recycling? (e.g. dust, aerosol formation, water, matrix destruction)

Physico-chemical properties

- Does the nanomaterial have a fibre, tube or rod-like morphology?
- Is its surface > 6/100 nm^{-1}
- Is the nanomaterial known to be chemically, catalytically or biologically reactive or is the mate-

rial manufactured specifically to produce reactive properties?

- Is the material readily soluble in water, resulting in loss of its nanostructure?

- According to the parameters for dust formation, can the material's propensity to generate dust be classified as "minimal"?

Behaviour in the environment

- Is the nanomaterial completely degradable?

- Is the nanomaterial permanently embedded in a stable matrix and hence cannot be released or moved into the environment?

Toxicology / ecotoxicology

At the present time there are no clearly accepted criteria indicating no cause for concern in toxicological and ecotoxicological terms. It is therefore not currently possible to make a preliminary assessment in this regard. Full scientific risk evaluation is required. According to some of the Issue Group representatives this clearly limits the applicability of the preliminary assessment tool in general. For the purposes of assessment, however, all available information such as information from public databases and suppliers should be taken into account as far as possible.

- Are there any indications of toxic effects that are relevant for humans?

- Are there any indications of ecotoxic effects that are relevant for the environment?

If the answer is yes to either or both of these questions, then human and/or environmental exposure should be investigated more closely. This should take place within the framework of a scientific risk evaluation.

Full details of the criteria and explanations of the information required in the responses are available as a downloadable file on the internet. The list of criteria can also be downloaded as an Excel spreadsheet.

2.3.6 Evaluation of the criteria table

The criteria table is aimed at raising users' awareness of potential causes for concern and factors giving no cause for concern, as well as highlighting gaps in the users' information. If there are data gaps for many criteria in the table, this is indicative of a significant lack of knowledge with regard to the nanomaterial in question and its uses. More detailed examination of the relevant criteria is therefore needed before any steps can be taken to place the material on the market, for example. The fewer the data gaps identified and hence the greater the number of criteria to which a response is given, the more comprehensive and meaningful the assessment. The data are not aggregated and no quantitative indicators (e.g. risk index, etc.) are defined, as this would result in a loss of information. At the end of the assessment process, emphasis is given instead to interpreting the significance of each answer, and this can be done either through in-house discussions or in dialogue with experts, other users or stakeholders.

Evaluation takes the form of a table in which the number of similar answers for each "block" of criteria is given and differentiated according to protected resources. These combined responses are then calculated as a ratio of the total number of responses. Initial interpreting aids include:

- The proportion of responses in the data gap field within each block gives an indication of the extent to which the user of the criteria lacks knowledge concerning the relevant use of the nanomaterial / nanoproduct. It can therefore be used as an indicator of uncertainty in the assessment.

- The share of responses in the field "Further consideration / Need for precautionary measures / Cause for concern" within a given block indicates that additional or more detailed information needs to be generated in order to examine the criteria in question in a more differentiated manner.

- The share of responses in the "No immediate need for precautionary measures / No cause for concern" field within a given block provides an indication of whether and to what extent suspicions regarding potential impacts arising from the use of the nanomaterial in question can be allayed.

Here too, however, detailed consideration of the specific use is indispensible in order to take account of prevailing differences in the weighting of criteria.

- A large share of responses in the “No immediate need for precautionary measures / No cause for concern” field in the "Probability of exposure" block (minimal probability of exposure) can be considered to indicate (increased) likelihood that there is no cause for concern, since lack of exposure means that no effects are to be expected. This trend should likewise be interpreted with caution, taking into account the different weightings given to criteria.

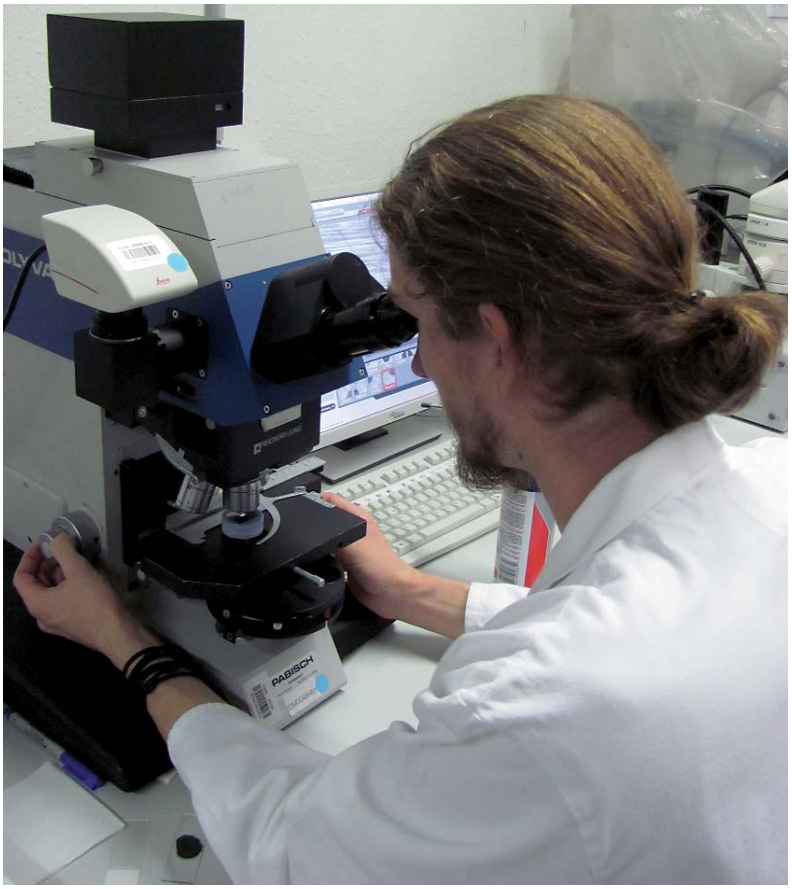


Figure 17: Light microscopy examination of a fibre composite component

If the user of the criteria identifies potential grounds for concern regarding the use of a nanomaterial, s/he could consider first of all discussing and verifying the result of his/her assessment with expert help. If the assessment indicates “Further consideration / Need for precautionary measures / Cause for concern”, options for conducting scientific risk evaluation of (this use of) the nanomaterial should be explored. In the event of a concern arising with regard to the environment, but no grounds for concern are identified relating to employees and consumers for the use in question of the nanomaterials, the scientific risk evaluation can include a “targeted risk assessment” focusing on the specific protection target.

2.3.7 Conclusions of the Issue Group on elaboration of criteria for preliminary assessment of nanomaterials

The criteria developed by the Issue Group reflect the debate conducted by the group within a narrow timeframe. To ensure that this set of criteria can be successfully established as a simple tool for initial assessment of the potential impact of nanomaterials, it may be helpful to consider the following:

- Experience relating to application of the criteria in practice should be gathered and taken into account when developing criteria further.
- The work carried out on the list of criteria should, if possible, be continued in cooperation with those working on the Swiss Precautionary Matrix and in relation to the issues outlined above.
- The criteria should also be incorporated into related international dialogue processes or projects and studies aimed at developing instruments for assessing nanomaterials.
- Users of the criteria should be able to draw on experts to help with interpreting the results and, where relevant, identifying information or appropriate risk management measures.
- Exchange of experience among users of the criteria would be useful.
- Subject to successful practical testing, the criteria could be incorporated into a broader context. For

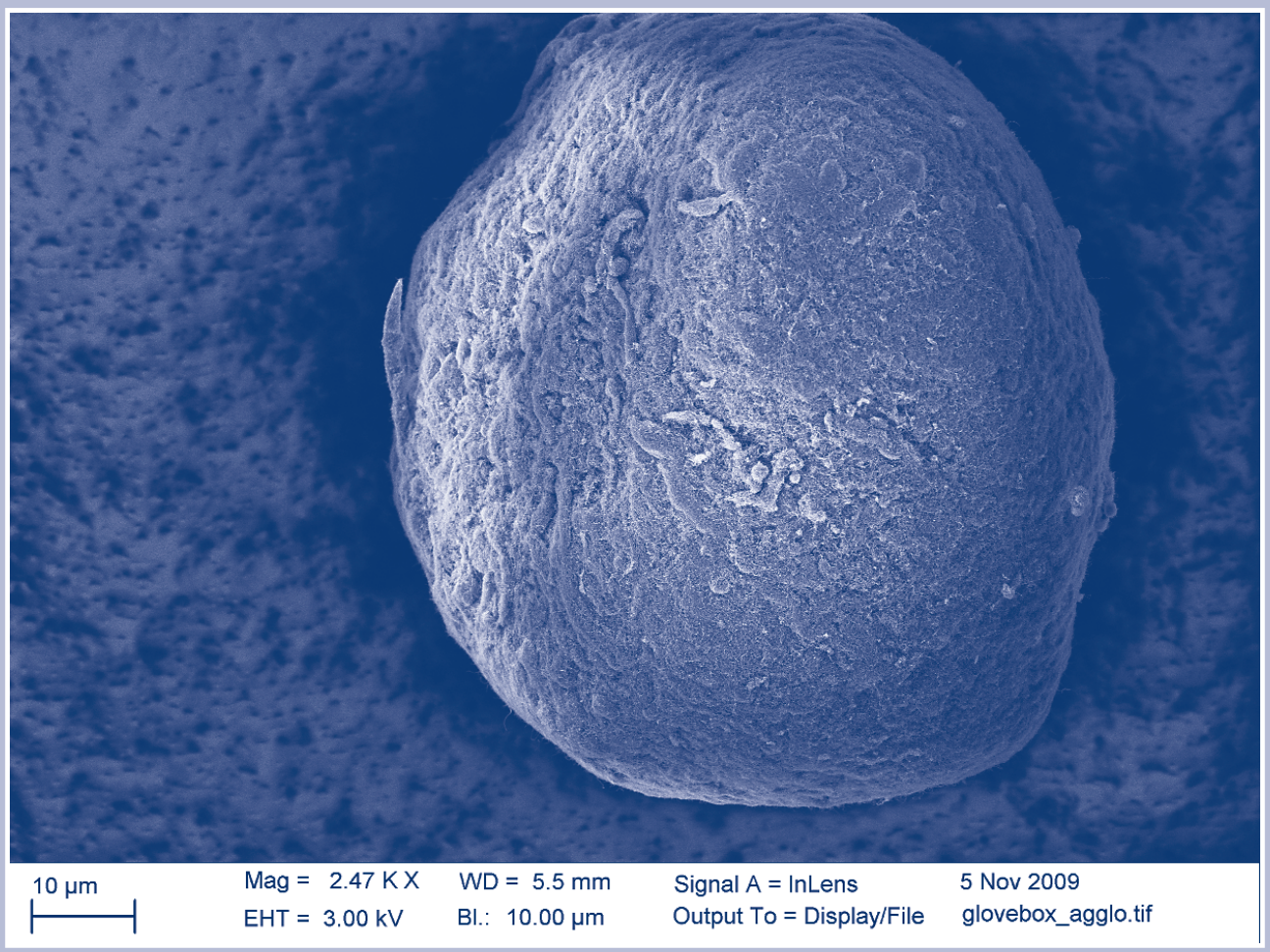


Figure 18: Highly entangled aggregation of manufactured carbon nanotubes

example, this tool could be applied to the context of implementing the principles for the responsible use of nanomaterials,[31] where it could be used particularly to improve risk management and ensure transparency in communication.

The Issue Group recommends:

➔ Establishing an advisory service at the level of a federal agency. An advisory service could gather experiences of using the criteria and harness these to develop the criteria further. In addition, it could assist users of the criteria to interpret the results and, where necessary, to identify relevant information and develop appropriate risk management measures. Another component of the advisory service's remit could be to organise an exchange of experience among criteria users.

31 See Report of the NanoKommission for the first dialogue phase and the report by Issue Group 1 in the present report in section 2.3.4

2.4 Regulation of nanomaterials

2.4.1 Remit of the Issue Group on regulation

Early in its second dialogue phase the NanoKommission assigned this Issue Group the task of analysing the basic issues and options for regulation based on the precautionary principle and, where possible, to make recommendations to the Federal Government on regulation of nanomaterials. The Group's report covers the international debate on a definition, presents explanations of the precautionary principle, compiles and comments on the existing provisions and discusses a variety of different regulatory instruments. Its recommendations were aimed at the Federal Government not only as the national regulatory authority, but also as a stakeholder in the context of EU regulatory activities. The 70-page report is available on the website of the BMU (www.bmu.de/nanokommission/). Stakeholders from the scientific community, various federal ministries and higher federal authorities, from industry and NGOs used their four sessions and subsequent written commentaries to generate a continuous and constructive dialogue and exchange of information and opinion. The following section presents the key findings and recommendations of the Group.

2.4.2 Foundations of the debate on regulation

The regulation group addressed the following main issues:

- As regards the issues of a definition, a nanoproduct register and labelling, no consensus was reached within the Group to enable common recommendations to be made. As the state of debate nevertheless needed to be presented to the Federal Government, tables were produced showing Group members' opinions on these issues.

- The precautionary principle, as a general principle of law, was elucidated according to the decision-making body concerned, with distinctions being drawn between legislation, administration and jurisdiction. The precautionary principle lays down a duty of protection (hazard control / risk prevention) of human health and life and the environment and thereby also creates a framework for dealing with gaps in knowledge (see next section).

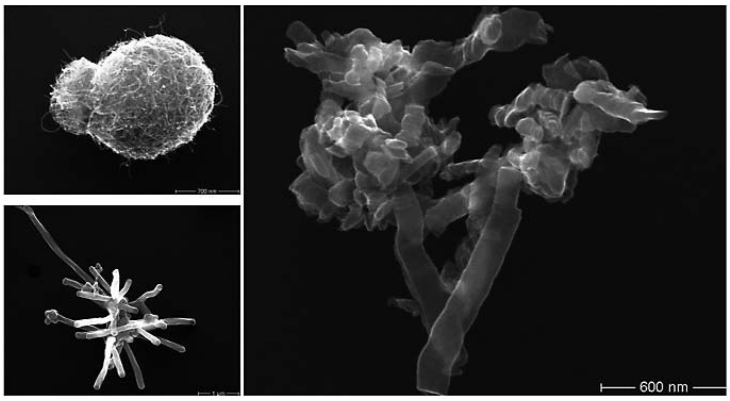


Figure 19: Carbon nanofibres – test samples under the scanning electron microscope

- Concerning a number of regulatory provisions, such as REACH, and in areas such as occupational health and safety, food law, cosmetics, biocidal products and plant protection products, the Group was able to arrive at a common interpretation of what is required, and to formulate specific recommendations, which are presented below.

- As regards existing provisions, the report sets out both positive aspects and shortcomings identified on a consensual basis by the Group.

- In addition, positions and demands of stakeholders that went beyond the consensus position within the Issue Group are presented transparently.

- Debate within the Group was heated on matters relating to a general authorisation procedure (with the aid of positive lists), individual authorisation procedures, labelling, and the issue of a product register. As the focus of debate in this Group was on assessing the regulatory provisions themselves, it was not possible to deal with downstream regulatory instruments in sufficient depth.

The precautionary principle as a guiding concept

In situations where there is uncertainty and/or a lack of knowledge regarding the consequences of new tech-

nologies, substances, products or production processes, the question arises as to whether the state can legitimately intervene to protect the environment and human health. The precautionary principle, given concrete form in relation to the environment by the European Commission in 2000 (COM (2000) 1 final), provides guidance here that is also relevant in legal terms. The precautionary principle is firmly established today as a general principle of law as a component of the constitutional goal of environmental protection set out in the Basic Law for the Federal Republic of Germany,[32] of the corresponding aims of the European Union[33] and as a component of the principle of sustainable development in international law (c.f. Principle 15 of the Rio Declaration on Environment and Development).

In situations where – as is often the case with innovations – there is a lack of reliable scientific evidence establishing a connection (causality) between a technology, substance, product or production process and an adverse effect, it is not possible to assume that there is sufficient probability of an adverse effect occurring. Sufficient probability in this context refers to the sort required (in the legal sense) for conventional hazard control. Against this background, the precautionary principle may be applied particularly in cases where there is a need for action because of a potential hazard to human health or to the environment, but insufficient scientific information is available to show sufficient probability of an actual hazard.

This means that for the purposes of risk prevention it is legitimate for the state to take action in the form of precautionary measures if there is merely an abstract possibility of harm occurring to people or to the environment. As a result, the point at which intervention becomes permissible is brought forward, enabling the government to take action before the hazard threshold is reached.

In order to avoid unwarranted – and legally questionable – application of the precautionary principle, the grounds for invoking the precautionary principle must be established. To do this, a distinction needs to be drawn between two consecutive steps: risk identification (also referred to as risk estimation or scientific risk assessment) and normative risk assessment. Where it is not possible to identify clearly the grounds for recourse to the precautionary principle, the burden of proof is reversed, enabling the legislator to make provisions on the basis of the precautionary principle. Responsibility for rebutting the presumption of hazardousness made by the legislator then falls to the originator of the risk.

If action is deemed appropriate, a wide range of options is available. While upholding the principle of economic freedom that ensures opportunities for innovation, the choice of action must be guided by the abstract level of concern, which in turn needs to take into account the potential extent of any adverse effects. In this regard it can be helpful to work with formulae along the lines of “the more/less... the better/worse”, based on the criteria indicating concern or no cause for concern developed by the NanoKommission in its first dialogue phase. Legally binding measures that might come into consideration range from rules concerning provision of information, reporting obligations, and labelling requirements, to rules relating to liability (including liability regardless of fault) and mandatory prior authorisation requirements (prohibition of activities unless authorised), which may also be based on a rebuttable presumption of hazardousness with the burden of proof resting on the risk originator. Other measures that might be considered include research funding, public information campaigns on the potential negative consequences of a product or process, or making recommendations.[34]

The precautionary principle therefore plays an important role in the introduction and use of nanotechnologies, especially if knowledge is largely lacking with regard to any hazards they may pose. The precautionary principle allows the opportunities and risks posed by technologies to be systematically identified and assessed. Decisions concerning regulation can thus be prepared in such a way as to ensure that the development of these technologies is supported while limiting potential risks.

32 Article 20a of the Basic Law for the Federal Republic of Germany
33 Cf. aim of the European Union set out in Article 191 (2), 2nd sentence of the Treaty on the Functioning of the European Union (TFEU)
34 Cf. COM (2000) 1 final, especially p. 4

2.4.3 Recommendations on regulation

This section summarises the recommendations of the Issue Group to the Federal Government alongside the comments of the NanoKommission.

REACH

In the opinion of the Issue Group, when the REACH Regulation concerning the registration, evaluation, authorisation and restriction of chemicals comes up for revision in 2012, some of its provisions should be amended to include the specific requirements of nanomaterials. In addition, the REACH Annexes and the ECHA Guidance documents (guidelines for implementation) also need to be brought up to date and amended in a timely manner in the light of new research findings concerning nanomaterials.

The Issue Group views the following as priorities:

- Introduction of a definition enabling clear identification of nanomaterials and clarification of the definition of "substance" in the REACH Regulation
- Adjustment of requirements for provision of information on nanoscale substances
- Further review and, where appropriate, adjustment of testing methods and strategies, e.g. in the OECD context
- Provisions to incorporate nano-specific information into Safety Data Sheets
- Adjustment of transitional deadlines for the registration of nanoscale substances
- If necessary, lowering of the tonnage thresholds for a nano-specific assessment programme and chemical safety reports based on it.

No consensus was reached on:

- Treating nanomaterials as new substances (non-phase-in substances) as a matter of principle
- Lowering the 0.1% threshold in the provisions on nanomaterials in articles
- Establishing criteria that enable differentiation of nanomaterials which have the same chemical composition but different properties and may need to be registered as separate substances
- The possibility of excluding the nanoforms of substances listed in Annex IV and V from the provisions on exemptions
- Considering the downstream user who produces a nanosubstance from the bulk form of a material to be the manufacturer within the meaning of REACH, where appropriate.

Figure 20: Measuring out fine dusts and nanoparticles in a glove box

Please refer to the report of the Issue Group for more detailed information on specific opinions.

Occupational health and safety

The German Hazardous Substances Ordinance (Gefahrstoffverordnung) and the Technical Rules for Hazardous Substances governing its implementation in practice (Technische Regeln für Gefahrstoffe – TRGS) form the bedrock of national regulation of nanomaterials in relation to occupational health and safety. Complementing these are guidance documents produced by the Federal Institute for Occupational Safety and Health (BAuA) and the German Chemical Industry Association (VCI). Minimisation of exposure is a fundamental

requirement in all of these instruments. Another requirement, however, is that sufficient information must be available on the properties of a substance to enable a hazard assessment to be carried out and to provide the basis for planning appropriate protective measures. The Issue Group was unable to reach a consensus on whether additional provisions need to be introduced in Germany at the level of an Ordinance.

As regards a general limit for biopersistent nanoparticulate dusts, the group agreed unanimously that the available scientific data should be reviewed with a view to establishing whether setting such a limit is feasible or advisable. As a specific step, the Group suggests that the preliminary work done by the Federal Institute for Occupational Safety and Health (BAuA) should be made available to Sub-Committee III of the German Government's Committee on Hazardous Substances (Ausschuss für Gefahrstoffe – AGS). On precautionary grounds, the Group also recommends putting in place transitional provisions until sufficient data are available. The Group continues to support efforts to review the introduction of limits for nanodusts and establish what those limits should be.

➔ The Group perceives a need for action to develop procedures for testing nanomaterials and establish specific exposure data.

The Cosmetics Regulation

The new EU Regulation (EC) No 1223/2009 on cosmetic products first of all stipulates that only safe products may be placed on the market. Prior to being placed on the market every cosmetic product must therefore undergo a qualified safety assessment. The provisions of the new Regulation also apply to cosmetics containing nanoparticulate ingredients, and are set to come into force for the most part in 2013. The European Commission must be notified in future regarding the use of certain nanomaterials in cosmetics. Where there is any doubt as to safety, the Commission can require safety data to be submitted. Substances intended for use as preservatives, colourants or UV filters must undergo separate authorisation for inclusion in the relevant positive list of permitted substances. The Cosmetics Regulation also introduces the requirement to append the word "(nano)" to the substance name on the product ingredients list. Specific requirements for nanomaterials are based on the definition of nanomaterials established by the EU's Scientific Committee on Consumer Products (SCCP). It is also noted that this definition should be adapted as and when a new definition is agreed at international level.

All in all, the Issue Group thought that the new Cosmetics Regulation provides a good basis for regulating nanomaterials. Some Group members, however, were critical of:

➔ the relatively narrow definition of nanomaterials, which excludes soluble nanomaterials and materials with size-dependent properties which are larger than 100 nm

➔ the fact that nanomaterials are not subject to an authorisation requirement unless they are intended for use in products for which a positive list of permitted substances exists (UV-filters, colourants and preservatives)

➔ the fact that the Regulation does not come into effect until 2013, whereas a multitude of products are already on the market.

Food Law

Three regulatory areas relating to food law were discussed in the Issue Group: novel food, additives, and food contact materials.

As regards the consultations on the revision of the Novel Food Regulation (Regulation (EC) No 258/97 was undergoing revision in Brussels in December 2010) the Group basically welcomed increasing the specificity of the existing provisions with regard to the use of nanomaterials in food. However, no agreement was reached on the required scope of the relevant provisions. It was also noted that there is a lack of clarity as regards areas in which nanomaterials are already being used in foods. Unsurprisingly, discussions on these issues were intense, reflecting the fact that this area has a direct bearing on consumers and is therefore politically highly sensitive. (See also the full report of the Group for tables showing the stakeholder positions.)

Figure 21: Plastic with nanoclay gas barrier

Applications of nanoscale ingredients for technological purposes such as preservatives, flow aids or colourings fall within the scope of Regulation (EC) No 1333/2008 on food additives. The 2008 Regulation makes provision for re-evaluation of safety and, where appropriate, re-authorisation of food additives if they are used in a form that differs from the form previously used and assessed by the relevant authority. In principle the Regulation contains no provisions concerning specific testing procedures for nanomaterials – or for food additives not used in nanoparticulate form. Provision for specific labelling of nanoscale ingredients is also absent. Specific testing methods are stipulated in the course of the case-by-case authorisation procedure, along with conditions for use and labelling requirements.

Discussions on the Regulation on food contact materials ((EC) No 1935/2004) focused on packaging that acts as a barrier, or has coatings to block out liquids, gases or UV light, packaging materials with built-in antibacterial properties or packaging materials with an indicator function that can sense and signal if a food is spoiled. The discussions also covered nanomaterials used to modify the function of surfaces in food manufacture (e.g. on conveyer belts, transport containers, or mixers) to achieve a variety of effects, such as dirt-repellency ("lotus effect") or antibacterial surfaces, energy efficiency, or improved adhesion properties. Regulation (EC) No 1935/2004 regulates the safe and appropriate use of food contact materials.

The Issue Group considers the current Regulations on novel foods, food additives and food contact materials, which were the focus of its discussions, to be basically adequate.

Some of the Group's members considered the envisaged authorisation procedures and safety assessments to be adequate. Case-by-case authorisation, they felt, provided sufficient scope for authorities to stipulate specific testing requirements where necessary, impose restrictions on the use of a substance, or lay down labelling requirements if there were reasonable grounds for doing so. Other Group members, meanwhile, felt that fundamental requirements were not met by the existing legislation, such as inclusion of a definition of nanomaterials or nano-specific testing requirements for official authorisation procedures or for appropriate safety assessment by manufacturers. They also recommend introducing a general labelling requirement instead of labelling on a case-by-case basis only.

During the reporting period of the NanoKommission and its Issue Groups, Guidelines on the assessment of nanoscale substances by the European Food Safety Agency (EFSA) were being drafted for all three regulatory areas. The positions set out here on regulation relate to the state of debate as of August 2010.

Biocidal and plant protection products

In summer 2011 a new European Regulation on the placing on the market of plant protection products ((EC) No 1107/2009 – Plant Protection Regulation) will replace the current Plant Protection Directive. The existing Biocidal Products Directive is currently being recast as a Regulation. Applications of nanomaterials in these areas range from materials such as nanosilver, which has biocidal properties, to plant protection products encased in nanomaterials to enable dosed release.

Current European law[35] contains no separate provisions concerning biocidal products and plant protection products which contain substances at the nanoscale.

➔ For the new Regulation on plant protection products, too, in the interests of ensuring harmonisation of the different provisions the Group recommends establishing a uniform definition of nanomaterials and supporting efforts to this end. To promote harmonisation, the properties of substances should be identified in the manner prescribed under REACH.

➔ The Group recommends carrying out a review to ascertain whether current guidelines on testing adequately take into account the specific properties of nanomaterials, or whether they need to be adapted. Established procedures for testing formulations and modifications to formulations should also be reviewed. Important preliminary work in this area
is currently under way in the OECD.

➔ It is recommended that due attention be paid to the specific uses of plant protection products and biocidal products to take into account any risks specifically associated with the use or application of nanosubstances over and above the general substance assessment.

Recommendations on product registers

Product registers can serve a wide range of different purposes, and may therefore vary widely in many regards, such as responsibility for collecting and processing information, access for different parties, nature of information contained in them and the purpose for which they are intended. Accordingly, various types of product register were discussed. Possible objectives that could be served by a nanoproduct register include:

- to create transparency with regard to which products contain what kind of nanomaterials;
- to enable traceability of nanomaterials with a view to assisting authorities, manufacturers and distributors of nanoproducts to take appropriate risk management measures (e.g. product recall)
- to guarantee freedom of choice for consumers, in other words to give them the option of buying products with or without nanomaterials.

Therefore, different levels of disclosing information could be considered for different types of register. Bearing in mind the need to protect the intellectual property of manufacturers or distributors, the Group discussed several options, including: a register in which all the information provided is publicly accessible; a register in which only certain information is publicly accessible; or alternatively, which produces a publicly accessible annual report with information on the register's content. No common position was arrived at within the Group on this issue.

The information contained in a product register depends on the purpose of the register and its accessibility (whether it is a public database). Some stakeholders advocated including the following information:

- Product name and trade name
- Manufacturer / distributor
- Nanomaterials used in the product (substance identity)
- Uses
- Guidelines on safe use / risks of the product (for occupational health and safety, analogous to Safety Data Sheet)
- Link to the corresponding substance in the REACH database.

In the course of the discussions it was pointed out that REACH, the Novel Food Regulation, the Cosmetics Regulation and the Regulations on biocidal and plant protection products all require registration, especially for authorisation of substances and articles. Industry representatives consider these provisions, and the infor-

35 The Group considered the EU Biocidal Products Directive, the new Regulation on biocidal products currently in preparation, and the EU Regulation on Plant Protection Products

mation they provide to the authorities, to be adequate and reject the idea of introducing a general nanoproduct register. The environmental and consumer organisations emphasised that existing provisions do not adequately meet the interests of consumers as regards information on nanoproducts. Moreover, they pointed out, current registration procedures (with the exception of notification under the provisions of the Regulations on Biocidal Products and on Cosmetics) make no distinction between materials in the nanoform and those in larger form. As a result, public bodies have no information as to whether registered substances are used in the nanoform.

➔ All stakeholders consider it essential that public bodies (monitoring bodies, poisons information centres, emergency centres, etc.) should have access to the information contained in product registers. If safety-related information cannot be made available to the public in a specific case, reasons for this must be given.

Labelling of consumer products

Discussions on product labelling focused exclusively on labelling of consumer products[36] in which nanomaterials are **not** bound within a stable matrix.

At present, only the Cosmetics Regulation makes explicit provision for labelling of nanomaterials in products. According to the position of the Council on the first reading of the draft proposal for a revised Novel Food Regulation of March 2010, specific labelling obligations may be stipulated in the authorisation of a novel food. The European Parliament, meanwhile, advocates a general labelling requirement for the use of nanomaterials in foods and has reaffirmed its position on this matter in the second reading. Consultations have not yet been concluded (as of this writing in December 2010). The conciliation procedure is due to begin in the near future. At the first reading of the proposal for a Regulation on the provision of food information to consumers, the European Parliament voted in favour of introducing a general labelling requirement for nanomaterials in foods. The Commission has responded positively in principle to the amendment proposed by Parliament in this regard.

The proposal was also taken up by the Belgian presidency of the Council in the Council debate on the proposal for a Regulation. According to this proposal, the suffix "(nano)" should be appended to ingredient listings for any food ingredient present in the form of a manufactured nanomaterial. Consultations on this matter have yet to be concluded.

Introduction of nano-specific labelling is also under discussion for the new legislation on biocidal products:

➔ Opinions varied widely within the Group as regards cases where a labelling obligation for nanomaterials might be expedient. Positions concerning which products should be subject to labelling ranged from "all consumer products and applications in the open environment" to "cases where potential grounds for concern cannot be ruled out", "products that have hazardous properties", and "voluntary labelling only".

In the interests of ensuring freedom of choice, some stakeholders favoured binding provisions as they questioned the effectiveness of voluntary labelling. Others are of the opinion that product safety is guaranteed by the German Equipment and Product Safety Act (Geräte- und Produktsicherheitsgesetz) and by authorisation procedures. Therefore they stated that compulsory labelling of products which have no hazardous properties is superfluous.

Advocates of binding provisions want these to apply to authorised products too, not as a warning but as information for consumers. Opponents of compulsory product labelling point to existing labelling requirements for products with hazardous properties (e.g. CLP Regulation).

36 This refers mainly to products that are used frequently and which come into especially close contact with the human body, or which are used in the open environment. Hence, for example, the discussion does not cover computer components or individual vehicle parts containing nanomaterials.

Figure 22: OLEDS

2.5 "Sustainable Nanotechnologies – Green Nano": A shared paradigm

2.5.1 Remit of the Working Group on developing a shared paradigm

One of the primary issues of the NanoKommission is the question: what opportunities are there in our society for developing a culture of innovation that upholds the principle of sustainability and the precautionary principle in an area of technology such as nanotechnology? In an innovation process, a shared paradigm *(Leitbild)* can provide useful guidance, reduce complexity and provide structures. It describes the socially desirable aspects of a technology and links this with what is feasible in practice. Establishing a shared paradigm for nanotechnologies can help to bridge uncertainties regarding potential benefits and risks and the potential success or failure of innovations – uncertainties that represent some of the most fundamental obstacles to innovation.

The task of developing a shared paradigm that enjoys broad social acceptance can only be carried out by means of dialogue. The NanoKommission therefore set up a Working Group in 2009 to address issues concerning a shared paradigm for sustainability in the field of nanotechnologies and to specify requirements and criteria that need to be taken into account when designing these technologies. The Working Group on "Sustainable Nanotechnologies – Green Nano" held two sessions to debate the question of what such a paradigm would mean in concrete terms and what "design principles" would be needed to implement technology and product design based on it.

In the context of the dialogue forum held as an interim review of the NanoKommission's work (Zwischenbilanz der NanoKommission) in early 2010, a shared paradigm for technology development and conceptions for broad social debate about this paradigm were presented. In addition, members of the Working Group took part in a conference on "Green Technologies" organised by the Protestant Academy in Schwerte, holding discussions with experts and lay people.[37] Drawing on previous experience with developing technology-related templates, notably "Nachhaltige Chemie" (Green Chemistry), adopted in Germany as a result of concerted efforts by the Federal Environment Agency, the German Chemical Society (GdCH) and enterprises in the chemical industry, the Working Group produced a discussion paper on a shared paradigm for sustainable nanotechnologies entitled "Considerations for sustainable design of nanotechnologies" (Aspekte einer nachhaltigen Gestaltung von Nanotechnologien).

2.5.2 Key discussion points for developing a shared paradigm

Today "sustainability" is widely considered to be the key principle for ensuring a viable future for society. Nanotechnologies open up interesting opportunities for more sustainable economic development, even though many developments are still in their infancy and hence the direction in which these technologies will actually evolve often

Figure 23: "Waterplay", fibres made from cellulose acetate and silicon dioxide, Philipps University Marburg, Department of Chemistry

37 For more information [in German] see: http://www.kircheundgesellschaft.de/akademie/dokumentation.htm

remains unclear. With an eye to sustainability objectives, developing a shared paradigm could prove useful by way of a "technology push", in other words targeting support to particular applications and giving priority to the pursuit of innovations in fields that society considers desirable. The aim of exerting influence in this way is twofold: to steer the development of nanotechnologies in the direction of sustainable applications (e.g. reducing pressures on the environment and protecting resources), but also to foster sustainability in the design of the technologies themselves (Green Nano).

The primary target audience for feedback processes on the design of sustainable nanotechnology development comprises those engaged in basic research, in research promotion and funding programmes (e.g. the Federal Government's High-Tech Strategy), in strategic corporate development, in company research and development departments, and in stakeholder organisations, especially those concerned with environmental and consumer protection, trade unions and churches/academies (multipliers). The groups also need to be involved in an ongoing feedback process concerning the design principles suggested here. In terms of economic players, the focus is primarily on companies engaged in research, technology developers and manufacturing enterprises. Downstream user industries, too, exert considerable influence on upstream developments.

The design of nano-based processes, products and nanomaterials on the basis of the shared paradigm of "Green Nano" – as a responsible, voluntary approach to sustainable technology development (as opposed to a regulatory approach) – should gain more attention than in the past. Lest there be any misunderstanding: principles of design are not an alternative to the necessary regulatory risk management measures. They should be seen instead as one element in a broader effort to harness all available means to foster sustainable technology development and risk management based on the precautionary principle.

Dialogue on shared paradigms is launched in a very early stage of the innovation process, similar to a process of preliminary risk assessment with the aid of criteria for concern and no cause for concern. As the dialogue focuses both on minimising risks and on exploiting potential benefits, it brings together the, often separate, debates on risks and benefits at the very early stages of innovation.

Figure 24: Water drops on a lotus leaf

Which paradigm? What do "sustainable" and "green" actually mean?

The design principles presented below relate to the goal of developing "sustainable nanotechnologies" (or "green nano" in international parlance), by which we mean explicitly taking into account environmental, health and safety considerations.

The paradigm of "sustainable nanotechnologies" encompasses a rather broad spectrum of options, ranging from emissions reduction and environmental remediation measures at one end of the scale to biomimetics at the other. The goal is not only to minimise and pre-

Figure 25: Nano cubes for hydrogen storage

vent adverse effects ("design for safety"), but also to bring about positive benefits for human health and the environment ("benign by design"[38]).

The design principles of the "Green Nano" paradigm outlined below are subdivided into four main areas (see Figure 26): Biomimetics, Minimum Risk, Resource Efficiency, and Energy and Environmental Technologies, with the innovation steps depicted in the Figure below being generally expected to widen incrementally from bottom left to upper right. Explanations and examples relating to the Figure are given in the report of the Working Group, available as a downloadable document on the BMU website (www.bmu.de/nanokommission/). The design principles should not, of course be (mis)understood as rules. They are goals, or guides for reflection. Tensions are bound to arise between the requirements of different design principles; there may even be contradictions. Using the design principles to implement the overall aims is therefore part of a broad and complex optimisation process.

Limits of sustainable design

At present, most innovations in the nanotechnology field remain technology-driven. Innovation processes are largely determined by new technological possibilities. Moreover, many innovation processes are still at an embryonic stage of development. This of course limits their scope just as much as the fact that very little is known at present about the potential benefits and risks of a given innovation.

Ultimately, however, it is not the technology alone that will determine the potential benefits and risks of nanotechnology-based innovations. The applications, operating conditions and contexts in which they are used are at least as important in this regard. The more the effects of materials, processes and products are determined by the purpose and context in which they are used, the greater the need to draw on additional design principles relating specifically to those purposes and contexts. The need for dialogue is thus likely to increase rather than decrease.

38 Cf. Anastas, Paul T. (1994): Benign by Design Chemistry, ACS Symposium Series, Vol. 577

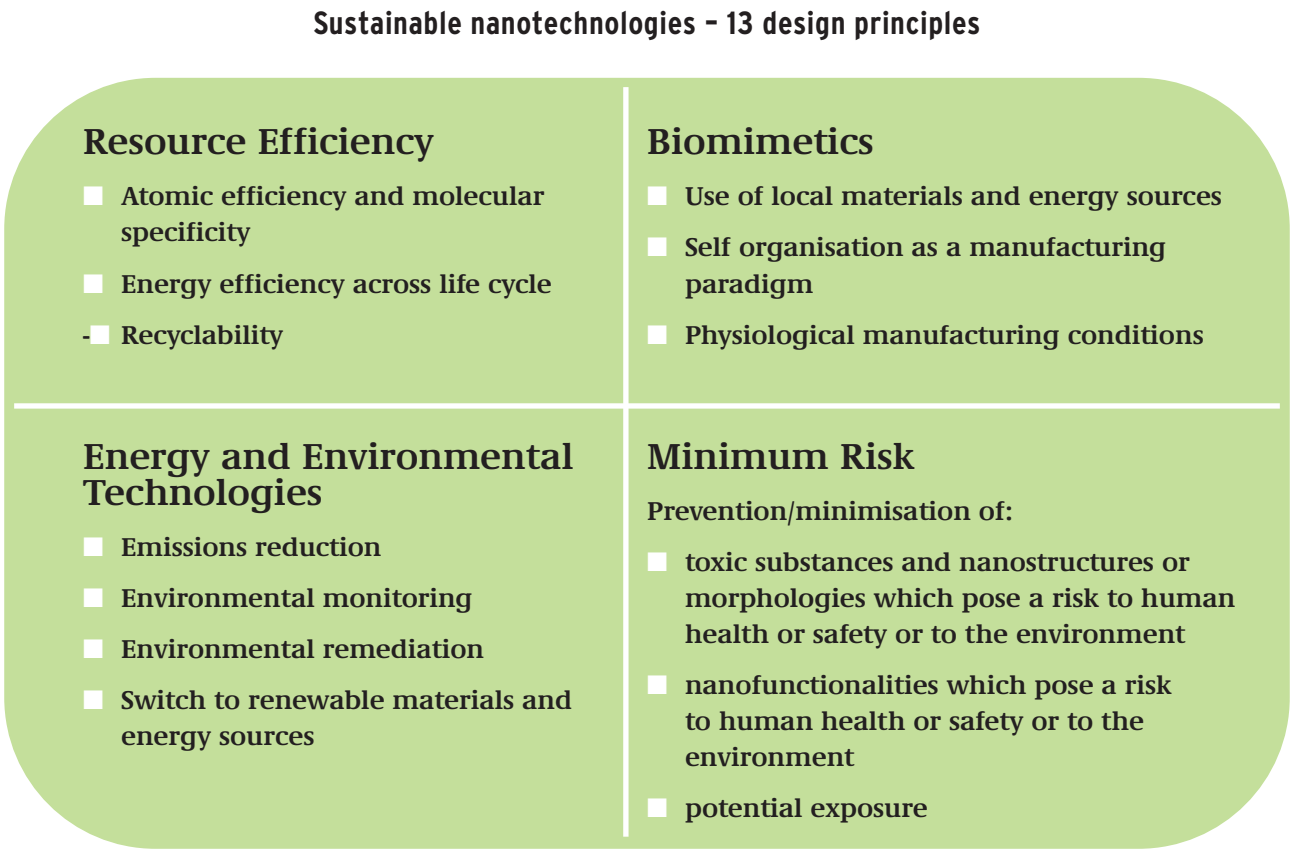


Figure 26: How the design principles are organised

2.5.3 Recommendations of the Working Group on developing a shared paradigm for "Sustainable Nanotechnologies – Green Nano"

With many technological developments, the question of what is scientifically and technically feasible and economically desirable usually precedes any question of potential risks or social acceptability. Approaches involving technology development based on a shared paradigm take a different path. Questions are first of all asked regarding visions of the future that are supported by society, and the technologies are then driven forward in accordance with the desired goals of society.

Die Arbeitsgruppe empfiehlt:

➔ Formulating a concept for further work on a shared paradigm for "Sustainable Nanotechnologies – Green Nano" and coordinating this with the responsible government bodies. When doing this, consideration should be given to the Federal Government's High-Tech Strategy and Action Plan, and to the coordinated research strategy of the higher federal authorities. A review should be carried out as to whether further research on the paradigm and its design principles is needed.

➔ Examining whether multi-stakeholder dialogue on paradigms and principles could continue but with a shifting of focus to specific sectors. Dialogue events could help to focus attention specifically on promoting innovation processes in accordance with the "Green Nano" paradigm and provide a forum for discussion on which innovations are desirable and which are not, involving participants from manufacturers, user industries, small and medium-sized enterprises, and representatives of the scientific community, politics and public administration, as well as NGOs.

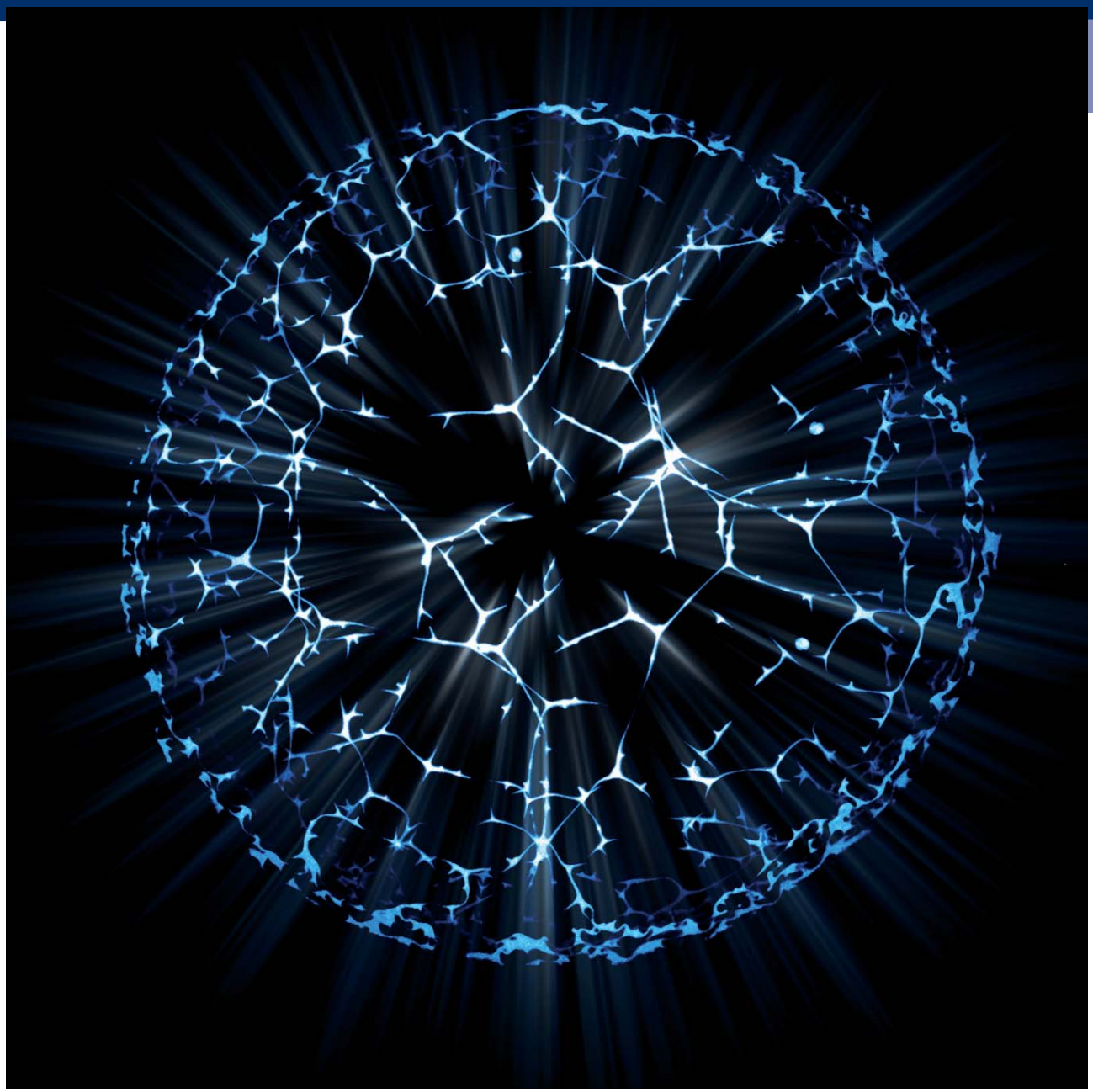


Figure 27: Labelled 6 nm DNA strands on a silanised SiO2 surface

3 FINAL RECOMMENDATIONS OF THE NANOKOMMISSION

In the opinion of the NanoKommission, we must work towards a culture of innovation in which investigation and assessment of potential risks, responsible and safe manufacture and use of nanomaterials and regulation based on the principles of precaution and sustainability are integrated into the innovation process at an early stage. An innovation culture of this sort encompasses several areas of activity:

- Harnessing the innovative potential of nanotechnologies specifically to resolve important problems and tackle future challenges, especially those relating to reducing pressure on the environment and fostering advances in medicine and sustainable use of our limited natural resources.

- Speeding up efforts to close current gaps in knowledge regarding the potential impacts on human

health and on the environment of nanomaterials and products manufactured using nanomaterials.

- Exploring new methods of risk prevention by agreeing on assessment procedures to enable prompt preliminary assessment of nanomaterials according to their potential risks and benefits, prior to or complementing statutory regulation.

- Responsible practice on the part of industry and society regarding the development and placing on the market of nanomaterials and nanoproducts.

- Improving market transparency for consumers regarding nanoproducts.

- Early integration of sustainability objectives into public research promotion and funding priorities and corporate product development strategies.

The deliberations of the various NanoKommission Issue/Working Groups revealed that while there was certainly agreement on a range of general fundamental issues, opinions differed widely on the need for societal/political activities, especially concerning issues relating to regulation. This is also reflected in the final recommendations of the NanoKommission.

3.1 NanoKommission recommendations on accompanying social and risk-related research

The NanoKommission reiterates its recommendation to the Federal Government from its first dialogue phase, namely to develop a cross-departmental strategy for research relating to safety and risk issues and to increase funding significantly for research in these areas. Efforts should focus on

- ➔ closing the research gaps relating to risks in the field of life-cycle management and prioritising research on risks relating to consumer applications and environmental impacts of nanomaterials. Development of a cross-departmental strategy for research should build on an evaluation of previous research funding and set priorities in line with activities in the international context, including the 8th Framework Programme for Research of the EU.

Research strategy development should be open to suggestions from stakeholders in society. The NanoKommission agrees that responsibility in this regard should be shared between ministries, their executive authorities and industry. The NanoKommission advocates making a list of current and completed research projects available to the public on the internet and keeping it regularly updated. At the time of writing, DECHEMA and VCI are in also in the process of preparing a publication on safety research in the chemical industry.

- ➔ The NanoKommission recommends setting up a central website under the auspices of a federal authority to gather together the datasets from risk-related and accompanying social research conducted in Germany. This would allow SMEs in particular to obtain a rapid overview of safety research already undertaken. From an international perspective it would also be important to make the publications available in English, and to integrate the content into the OECD database.[39]

3.2 NanoKommission recommendations on the regulation of nanomaterials and nanoproducts

In general, the NanoKommission acknowledges and agrees with the findings of the Issue Group on regulation of nanomaterials. Many of the considerations addressed by the Group are likely to be taken up again in the near future in the context of the revision of European regulations, and indeed in some cases this has already happened.

The NanoKommission believes that efforts currently under way and actively supported by Germany to adopt a uniform, standard definition of nanomaterials are particularly important for progress in the debate on regulation.

39 Cf. OECD Database, available at: http://webnet.oecd.org/NanoMaterials/Pagelet/Front/Default.aspx?

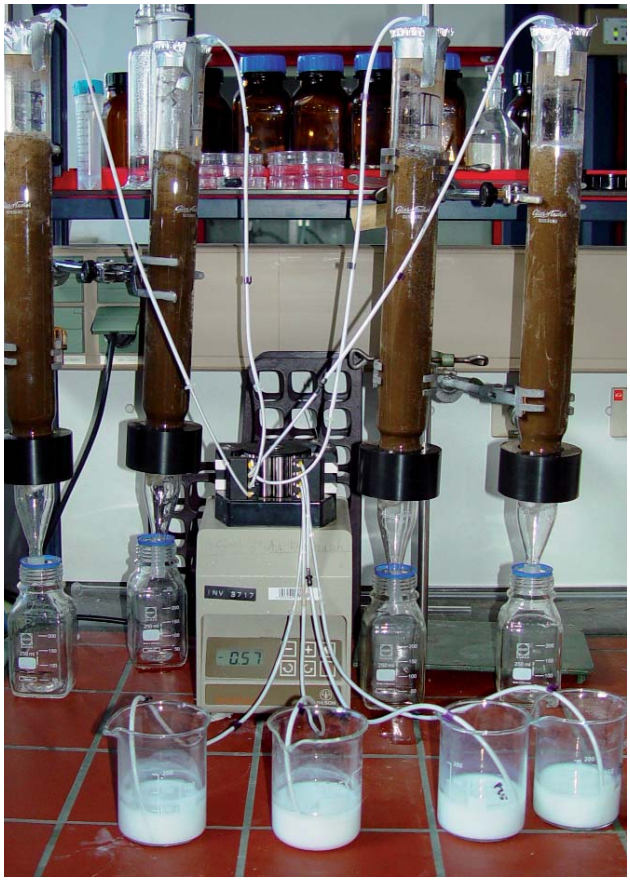


Figure 28: Setting up laboratory experiment to test leaching in soil (in accordance with OECD Guideline 312)

3.2.1 EU Regulations and Directives

The members of the NanoKommission consider the REACH Regulation basically adequate for the purpose of regulating substances at the nanoscale. When REACH comes up for revision in 2012, however, some of its provisions should be amended to include the specific requirements of nanomaterials. In addition, the REACH Annexes and the ECHA Guidance documents also need to be brought up to date and amended in a timely manner in the light of new research findings concerning nanomaterials.

Priorities in this regard are:

- Introduction of a definition of nanomaterials
- Adjustment of requirements for provision of information on nanoscale substances
- Further review and, where appropriate, adjustment of OECD testing methods and strategies
- Provisions to incorporate nano-specific information into Safety Data Sheets
- Adjustment of transitional deadlines for the registration of nanoscale substances
- Reviewing the tonnage thresholds for a nano-specific assessment programme and chemical safety reports based on it.

Some members of the NanoKommission and its Issue Group felt there was a need to amend the provisions of REACH in other respects too (see Section on this group).

The NanoKommission agrees that the EU Regulations and Directives currently in force or in development in the regulatory areas of “novel foods”, “food additives” and “food contact materials” provide an adequate basis for regulation of nanomaterials . Within the NanoKommission, however, there are considerable differences of opinion concerning the definition of nanomaterials, labelling and laying down nano-specific testing procedures as a prerequisite for registration, notification as well as on authorisation of substances and products.

The NanoKommission basically considers the EU Regulation on cosmetic products as a sound basis for the regulation of nanoproducts. Some members, however, are critical of

- the relatively narrow definition of nanomaterials in the Regulation
- the fact that nanomaterials are not subject to an authorisation requirement unless they are intended for use in products for which a positive list of permitted substances exists (UV-filters, colourants and preservatives)
- the fact that the Regulation does not come into effect until 2013.

The NanoKommission members recommend reviewing current European legislation on biocidal products and plant protection products to establish whether current guidelines on testing adequately take into account the specific properties of nanomaterials, or whether they need to be amended. In doing so due attention should be paid to the specific uses of plant protection products and biocidal products.

3.2.2 Occupational health and safety

The NanoKommission underscores the recommendations for further work to establish general limits for occupational health and safety and welcomes the proposed cooperation between the Federal Institute for Occupational Safety and Health (BAuA) and the German Government's Committee on Hazardous Substances (AGS). It also suggests that this work be presented rapidly in the international arena.

3.2.3 Product register

It was not possible to reach a common position on a conception for a legally binding product register, its function or its potential purpose. Industry representatives consider the existing product lists and registers based on REACH and EU legislation relating to cosmetics, the food sector and plant protection products to be sufficient. They expressed concerns that an additional product register could potentially result in duplication of current requirements regarding provision of information. If introduced at all, a product register should only include products with hazardous properties – and nanoproducts and nanomaterials do not in themselves possess hazardous properties. Other NanoKommission members, meanwhile, stated a need for a legally binding nanoproduct register to create transparency for all market participants (downstream users, distributors and consumers) as well as for the public administration and the legislator. Consumers should be able to choose for themselves whether to buy particular products with particular ingredients. A product register could also assist authorities to take appropriate risk management measures (e.g. product recall) by ensuring traceability of nanomaterials.

3.2.4 Labelling

There are distinct differences of opinion within the NanoKommission on the issue of voluntary or mandatory labelling, and on the potential scope of labelling schemes. Some NanoKommission members, especially representatives of consumer and environmental protection organisations, favour compulsory labelling of all nanomaterials intended for consumer use and applications that are open to the environment. Others, notably industry representatives, hold the view that labelling should only be required in certain cases.

3.3 NanoKommission recommendations on implementation of the Principles for responsible use of nanomaterials

During the past two years, the recommendations of the previous NanoKommission for implementing the principles it developed on responsible use of nanomaterials have not yet been acted upon. One reason for this is undoubtedly lack of awareness of the principles. Some companies have begun to apply the basic ideas implicitly, but without making specific reference to the NanoKommission's Principles Paper. This, however, makes it difficult to achieve the common goal of transparent implementation of the Principles Paper throughout the industry. With the exception of the German paint and printing ink industry association, which has produced corresponding guidelines, there has scarcely been any success in communicating the basic objectives of the Principles Paper to user industries at large.

The NanoKommission is aware that issues relating to regulation are likely to take priority over ideas based on voluntary measures within industry. Given that consensus still prevails regarding the principles, however, the NanoKommission expects much clearer steps to be taken to implement the principles in a transparent manner within industry. Civil society representatives in particular in the NanoKommission consider this to be vital in terms of public confidence in the responsible development of nanotechnologies. Success in this regard will require better information on the Principles Paper being made available by the sectoral bodies involved in the NanoDialogue, and active support for the process on the part of the Federal Government.

The NanoKommission recommends:

➔ That action should be taken by both public administration and industry to improve dissemination of the principles in line with the proposals of the Issue Group (see Section 2.2).

- The NanoKommission reaffirms its recommendation from 2008 that the guidelines should be expanded to include environmental and consumer protection, as the first phase of the NanoDialogue only addressed occupational health and safety.

- Developing a plan for monitoring implementation: in future prompt and continuous monitoring should be carried out to ascertain whether measures put in place to promote dissemination and awareness of the principles actually improve implementation.

The NanoKommission would like to draw attention particularly to the German Statutory Accident Insurance (DGUV), BASF SE, the German paint and printing ink industry association and the Federal Institute for Occupational Safety and Health (BAuA), all of which have now expressed their explicit commitment to the NanoKommission Principles. These pioneering activities are seen as the first signs of success from the dialogue process despite the fact that the overall findings of the Issue Group were rather negative.

Another success of the dialogue process in the eyes of the NanoKommission is the VCI's initiative to raise awareness of the principles by conducting a survey and promote monitoring of their implementation jointly with the stakeholders.

3.4 Recommendations for further work on criteria for preliminary benefit-risk assessment

Given the complexity of the issues relating to nanomaterials and nanoproducts, only initial steps have been taken towards developing practicable criteria for preliminary benefit-risk assessment. Work on developing a comprehensive matrix integrating benefit and risk aspects has not yet been completed. Both of the Issue Groups produced valuable contributions, notably regarding continuous sustainability assessment of nanoproducts throughout the product life cycle including consideration of social aspects. Criteria for preliminary risk assessment of nanomaterials were also formulated. The guidelines and list of criteria will help companies to identify potential risks associated with particular development trajectories early on and steer development towards safer alternatives. The work of the Groups in this area should be continued in an appropriate form. This requires further in-depth scientific study of both benefit and risk criteria for which potential measuring procedures need to be applied, and proposals regarding appropriate interpretation of the results. The purpose of this should be to establish how to evaluate benefit and risk factors at an early stage, what key information is already available or needs to be generated, and where necessary what measures to take as a consequence.

- The NanoKommission recommends to the Federal Government that the valuable work begun by the two Issue Groups should be pursued, combining it in a research and consultancy project. Where appropriate, the advances in knowledge resulting from the NanoDialogue should be consolidated with a broad group of stakeholders.

- The NanoKommission recommends carrying out more practical testing in this area involving future users in industry, including SMEs.

- In this context it would be expedient to enhance cooperation with the developers of the Swiss Precautionary Matrix, as they have already gained experience of using preliminary risk assessment tools and, where applicable, measures that need to be taken as a result. The aim of this could ultimately be to coordinate efforts and present them jointly in the international arena.

3.5 Recommendations for developing and applying a shared paradigm (Leitbild) for "Sustainable Nanotechnologies – Green Nano"

In the effort to foster a new culture of innovation in Germany based on commitment to the principle of sustainability and the precautionary principle, the search for a socially acceptable, shared paradigm can provide valuable support. The Working Group on "Sustainable Nanotechnologies – Green Nano" came into being as a result of additional interest in this area on the part of

NanoKommission members from the scientific community, environmental organisations, industry and the public administration. The resulting design principles are seen as a useful basis, and it would be desirable to develop them further. They could help to consider societal concerns and needs early on in the process of product development, and embed innovation strategies in the social context. Innovations that are guided by shared paradigms win society's trust, without which success in the market is not possible. If these paradigms and their design principles are developed in an open manner involving a variety of stakeholders, public confidence in the players will probably increase.

The NanoKommission therefore recommends to the Federal Government:

➔ To promote research and development into a shared paradigm (Leitbild) for sustainable development of nanotechnologies and nanotechnology design principles and to disseminate these to a broad range of players in basic research, academies, scientific organisations and trade associations, in research promotion and funding bodies, in corporate research and development and corporate strategic development. This process should also be opened up into a multi-stakeholder process.

3.6 Outlook for the German NanoDialogue

The members of the NanoKommission assume that debate in German society concerning the potential benefits and risks of nanotechnologies will continue. The number of nanoproducts on the market or soon to be placed on the market will continue to rise. Over the next two years, key issues concerning regulation will be addressed and decided, especially at EU level, but also in Germany.

The NanoKommission therefore recommends to the Federal Government:

➔ To continue the dialogue on nanotechnology in an appropriate manner, ensuring continued involvement of the current NanoDialogue partners. Topics that should be covered in dialogue events include:

- The state of regulatory processes relating to nanotechnology in the EU
- Current activities in the OECD on the issue of nanotechnology
- Current national activities on nanotechnologies such as regulatory processes, implementation of the Federal Government's Action Plan, cross-departmental strategy on research, particularly research on safety and risk issues concerning nanotechnologies, and on issues concerning information for consumers and consumer protection.

In addition, the NanoKommission recommends:

➔ Holding an annual central dialogue event to foster cooperation among stakeholders, to facilitate exchange and expansion of knowledge by means of face-to-face encounter, and to debate the use of nanotechnologies in different sectors.

➔ The NanoKommission reiterates its suggestion that the Federal Government should establish a national, cross-departmental internet platform providing information on developments and activities in the field of nanotechnologies.

4 ANNEX

List of abbreviations

A:	Arbeitnehmer/Arbeiter (employees)
AGS:	Ausschuss für Gefahrstoffe bei der Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BauA – http://www.baua.de/prax/ags) – BAuA Committee on Hazardous Substances
BAM:	Bundesanstalt für Materialforschung und -prüfung – Federal Institute for Materials Research and Testing
BAuA:	Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (www.baua.de) – German Federal Institute for Occupational Safety and Health
BfR:	Bundesinstitut für Risikobewertung – Federal Institute for Risk Assessment
BGBl:	Bundesgesetzblatt – Federal Law Gazette
BIAC:	Business and Industry Advisory Committee
BLAC:	Bund/Länderausschuss für Chemikaliensicherheit (www.blac.de) – Federal/Länder Working Committee on Chemical Safety
BLL:	Bund für Lebensmittelrecht und Lebensmittelkunde e.V. (www.bll.de) – German Federation for Food Law and Food Science
BMAS:	Bundesministerium für Arbeit und Soziales – Federal Ministry of Labour and Social Affairs
BMBF:	Bundesministerium für Bildung und Forschung – Federal Ministry of Education and Research
BMELV:	Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz – Federal Ministry of Food, Agriculture and Consumer Protection
BMG:	Bundesministerium für Gesundheit (www.bmg.bund.de) – Federal Ministry of Health
BMU:	Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit – Federal Ministry for the Environment, Nature Conservation and Nuclear Safety
BMVg:	Bundesministerium für Verteidigung – Federal Ministry of Defence
BMVBS:	Bundesministerium für Verkehr, Bau und Stadtentwicklung – Federal Ministry of Transport, Building and Urban Development
BMWi:	Bundesministerium für Wirtschaft und Technologie – Federal Ministry of Economics and Technology
BSU:	Behörde für Stadtentwicklung und Umwelt, Hamburg (www.hamburg.de/bsu/) – Office for urban development and environment, Hamburg
BUND:	Bund für Umwelt und Naturschutz Deutschland (www.bund.net) – Friends of the Earth Germany
BVL:	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (http://www.bvl.bund.de) – Federal Office of Consumer Protection and Food Safety
BW:	Baden-Württemberg
CLP:	Classification, Labelling and Packaging – Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
CNT:	carbon nanotube
COM:	Communication from the European Commission to the European Parliament and the Council
DaNa:	BMBF research project: DaNa - acquisition, evaluation and public-oriented presentation of society-relevant data and findings relating to nanomaterials (www.nanopartikel.info/cms)

DECHEMA:	Gesellschaft für Chemische Technik und Biotechnologie e.V. – Society for Chemical Engineering and Biotechnology
DFG:	Deutsche Forschungsgemeinschaft (www.dfg.de) – German Research Foundation
DGB:	Deutscher Gewerkschaftsbund (www.dgb.de) – Confederation of German Trade Unions
DGUV:	Deutsche Gesetzliche Unfallversicherung (www.dguv.de) – German Statutory Accident Insurance
DHMD:	Deutsches Hygiene-Museum Dresden (www.dhmd.de) – German foundation and museum of health education and health care, Dresden
DIN:	Deutsches Institut für Normung (www.din.de) – German Institute for Standardisation
DMM:	Deutsches Museum München – German Museum Munich
DNA:	Deoxyribonucleid acid
DNEL:	Derived no-effect level
EC:	European Community
ECHA:	European Chemicals Agency (http://echa.europa.eu)
EFSA:	European Food Safety Authority
EN:	European Standard
EU:	European Union
FhG:	Fraunhofer-Gesellschaft (www.fraunhofer.de) – a German applied research organisation
FTIR:	Fourier transform infrared spectroscopy. Spectroscopic method permitting qualitative and quantitative determination of diverse components even when detection limits are low and measurement ranges wide.
GdCH:	Gesellschaft Deutscher Chemiker – German Chemical Society
HGF:	Helmholtz-Gemeinschaft Deutscher Forschungszentren (www.helmholtz.de) – Helmholtz Association of German Research Centres
HLPUG:	Hessisches Landesprüfungs- und Untersuchungsamt im Gesundheitswesen – Land of Hesse bureau for testing and research in public health care
IFA:	Institut für Arbeitsschutz der DGUV – Institute for Occupational Safety and Health of the DGUV
IG BCE:	Industriegewerkschaft Bergbau – Chemie – Energie – German Union of mining, chemical and energy industry workers
IME:	Fraunhofer-Institut für Molekularbiologie und Angewandte Ökologie (www.ime.fraunhofer.de) – Fraunhofer Institute for Molecular Biology and Applied Ecology
InnoZent OWL:	InnovationsZentrum für Internettechnologie und Multimediakompetenz der Region Ostwestfalen-Lippe – Innovation Centre for Internet Technology and Multimedia Competence in the Ostwestfalen-Lippe Region
INOS:	Forschungsprojekt des BMBF: Identifizierung und Bewertung von Gesundheits- und Umweltauswirkungen von technischen nanoskaligen Partikeln – Research project of the Federal Ministry of Education and Research on identification and assessment of the impacts on health and on the environment of engineered nanoscale particles
IKW:	Industrieverband Körperpflege und Waschmittel – German Cosmetic, Toiletry, Perfumery and Detergent Industry Association
ISO:	International Organization for Standardization (www.iso.org)
IUCLID:	International Uniform Chemical Information Database
IUPAC:	International Union of Pure and Applied Chemistry

IUTA:	Institut für Energie- und Umwelttechnik e.V. (www.iuta.de) – Institute of Energy and Environmental Technology
JRC:	Joint Research Centre
LAUG:	Länderarbeitsgruppe Umweltbezogener Gesundheitsschutz – Working Group of the German Länder on environmental health
LFGB:	Lebensmittel- und Futtermittelgesetzbuch – German Food and Feed Code
LUBW:	Landesanstalt für Umwelt, Messungen und Naturschutz Baden-Württemberg – Institute for the Environment, Measurements and Nature Conservation of the Land of Baden-Württemberg
MAK-Kommission:	Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe (http://www.dfg.de/dfg_profil/gremien/senat/gesundheitsschaedliche_arbeitsstoffe/index.html) – German Research Foundation's Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area
MPG:	Max-Planck-Gesellschaft (www.mpg.de) – Max Planck Society
NGO:	Non-governmental organisation
NM:	Nanomaterial
nm:	Nanometre
NP:	Nanoparticle
OECD:	Organisation for Economic Cooperation and Development (www.oecd.org)
OLED:	Organic light-emitting diode
PBT:	Persistent, bioaccumulative and toxic
PET:	Polyethylene terephthlatate
PNEC:	Predicted no effect concentration
PPP:	Plant protection product
REACH:	Regulation (EC) No 1907/2006 concerning the registration, evaluation, authorisation and restriction of chemicals
RoHS:	Restriction of Hazardous Substances
SCCP:	Scientific Committee on Consumer Products
SCENHIR:	Scientific Committee on Emerging and Newly Identified Health Risks
SE:	Societas Europaea – European Company (public company under European law)
SiO_2:	Silicon dioxide
SME:	small and medium-sized enterprises
SRU:	Sachverständigenrat für Umweltfragen – German Advisory Council on the Environment
StMUGV:	Land Ministry for the Environment, Health and Consumer Protection, Bavaria
TEGEWA:	Verband der Textilhilfsmittel-, Lederhilfsmittel-, Gerbstoff- und Waschrohstoff-Industrie e.V., Frankfurt (www.tegewa.de) – Frankfurt-based trade association of the German chemical industry serving manufacturers of processing aids for the textile, leather and tanning industries and of detergent bases
TFEU:	Treaty on the Functioning of the European Union
TÜV:	Technischer Überwachungs-Verein – German Technical Inspection Association
TUHH:	Technische Universität Hamburg-Harburg – Hamburg University of Technology
TRGS:	Technische Regeln für Gefahrstoffe – German technical regulations on hazardous substances

TWG:	Technical working group
U:	Umwelt – Environment
UBA:	Umweltbundesamt (www.umweltbundesamt.de) – German Federal Environment Agency
UFT:	(Zentrum für) Umweltforschung und nachhaltige Technologien, Universität Bremen (www.uft.uni-bremen.de) – (Centre for) Environmental Research and Sustainable Technology, University of Bremen
UfU:	Unabhängiges Institut für Umweltfragen e.V. (www.ufu.de) – Independent Institute for Environmental Concerns
UMK:	Umweltministerkonferenz (der deutschen Bundesländer) – Conference of Environment Ministers (of the German Länder)
UV:	Ultraviolet
V:	Verbraucher – consumers
VCI:	Verband der chemischen Industrie e.V. (www.vci.de) – German Chemical Industry Association
VDI:	Verein Deutscher Ingenieure e.V., Düsseldorf (www.vdi.de) – Association of German Engineers
VdL:	Verband der Lack- und Druckfarbenindustrie – German paint and printing ink industry association
VSMK:	Verbraucherschutzministerkonferenz (der Länder und des Bundes – www.verbraucherschutzministerkonferenz.de) – Conference of Consumer Protection Ministers (of the German Federal Republic and Länder)
VZBV:	Verbraucherzentrale Bundesverband e.V. (www.vzbv.de) – Federation of German Consumer Organisations
WECE:	Women in Electrical and Computer Engineering (www.wece.ece.ufl.edu/)
WG:	Working group
WGL:	Wissenschaftsgemeinschaft Gottfried Wilhelm Leibniz e.V., Bonn (www.leibniz-gemeinschaft.de) – Gottfried Wilhelm Leibniz Scientific Community, known as the Leibniz Association, Bonn
WoE:	Weight of Evidence
WPMN:	Working Party on Manufactured Nanomaterials
ZGV:	Zentrum Gesellschaftliche Verantwortung der Evangelischen Kirche in Hessen und Nassau (www.zgv.info/) – Centre for Social Responsibility of the Protestant Church in Hesse and Nassau

Links for further information

Links to guidelines addressed by the Issue Group on principles

Federal/Länder authorities

Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA – Federal Institute for Occupational Safety and Health) / Verband der Chemischen Industrie e.V. (VCI – German Chemical Industry Association):
Leitfaden für Tätigkeiten mit Nanomaterialien am Arbeitsplatz (Guidelines for activities involving nanomaterials in the workplace)
www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/Nanotechnologie/pdf/Leitfaden-Nanomaterialien.pdf

DGUV: Positionspapier der Deutschen Gesetzlichen Unfallversicherung zum verantwortungsvollen Umgang mit Nanomaterialien (German Statutory Accident Insurance position paper on the responsible use of nanomaterials)
www.dguv.de/inhalt/praevention/themen_a_z/nano/index.jsp

Hessen-Nanotech: Informationsplattform Nano-Sicherheit (Information platform nano-safety)
www.nano-sicherheit.de

Hessen-Nanotech: Supplement "Innovationsfördernde Good-Practice-Ansätze zum verantwortlichen Umgang mit Nanomaterialien" (Supplement on “Fostering innovation through good-practice approaches to responsible use of nanomaterials”)
www.hessen-nanotech.de/mm/Suppl-NanoKomm_final_Web.pdf

Hessen-Nanotech: Sichere Verwendung von Nanomaterialien in der Lack- und Farbenbranche – Ein Betriebsleitfaden (Safe use of nanomaterials in the paint and printing ink industry – Company guidelines)
www.hessen-nanotech.de/mm/Betriebsleitfaden_NanoFarbeLacke_Vorab.pdf

IFA – Institute for Occupational Safety and Health of the German Statutory Accident Insurance:
Schutzmaßnahmen bei ultrafeinen Aerosolen und Nanopartikeln am Arbeitsplatz (Protective measures relating to ultrafine aerosols and nanoparticles in the workplace) www.dguv.de/bgia/de/fac/nanopartikel/schutzmassnahmen/index.jsp

LUBW Landesanstalt für Umwelt, Messungen und Naturschutz Baden-Württemberg (Institute for the Environment, Measurements and Nature Conservation of the Land of Baden-Württemberg):
Nanomaterialien – Arbeitsschutzaspekte (Nanomaterials – Occupational health and safety issues)
www.lubw.baden-wuerttemberg.de/servlet/is/6644/?shop=true

Industry bodies

Verband der Chemischen Industrie e.V. (VCI – German Chemical Industry Association): Responsible Production and Use of Nanomaterials www.vci.de/default~cmd~shd~docnr~122306~lastDokNr~-1.htm

Industrieverband Körperpflege- und Waschmittel e.V. (IKW – German Cosmetic, Toiletry, Perfumery and Detergent Industry Association): Sicherheitsbeurteilung für Pflege- und Reinigungsmittel, die Nanomaterialien enthalten und/oder Nanoschichten erzeugen (Safety assessment of body care and cleaning products which contain nanomaterials or form nano-layers) www.ikw.org/pdf/broschueren/Nano_d.pdf

Industrieverband Körperpflege- und Waschmittel e.V. (IKW – German Cosmetic, Toiletry, Perfumery and Detergent Industry Association): Nanopartikel in kosmetischen Mitteln (Nanoparticles in cosmetic products)
www.ikw.org/pdf/broschueren/Nano_IKW231107.pdf

Verband der deutschen Lack- und Druckfarbenindustrie e.V.(VdL – German paint and printing ink industry association): Standpunkt zum Verantwortlichen Umgang mit Nanomaterialien in der Lackindustrie (Position on responsible use of nanomaterials in the paint industry)
www.lackindustrie.de/default2.asp?cmd=shd&docnr=125998&rub=651&tma=1&nd=

Verband der deutschen Lack- und Druckfarbenindustrie e.V. (VdL – German paint and printing ink industry association): VdL-Leitfaden für den Umgang mit Nanoobjekten am Arbeitsplatz (VdL guidelines for the use of nano-objects in the workplace) www.lackindustrie.de/default2.asp?rub=676&tma=728&cmd=shd&docnr=127627&nd=&ond=tv

Companies

BASF SE: Guide to safe manufacture and for activities involving nanoparticles at workplaces in BASF AG
www.basf.com/group/corporate/de/content/sustainability/dialogue/in-dialogue-with-politics/nanotechnology/employees

BASF AG: Code of Conduct Nanotechnology
www.basf.com/group/corporate/de/sustainability/dialogue/in-dialogue-with-politics/nanotechnology/code-of-conduct

Evonik Degussa GmbH: Nanotechnologie – Sichere Produktion (Nanotechnology – safe production)
www.degussa-nano.com/nano/de/nachhaltigkeit/sicherheit/

Bayer MaterialScience: Nanomaterial Product Stewardship (registration required for access)
http://baycareonline.com/nano_stewardship.asp

Bayer Code of Good Practice for safe handling of nanomaterials in production and on-site use
http://baycareonline.com/nano_stewardship.asp

4.5 Lists of participants

NanoKommission of the German Federal Government

Name	Institution
Chairman St a.D. Wolf-Michael Catenhusen	Chairman of the NanoKommission
Prof. Dr. Christian Calliess	Freie Universität Berlin, School of Law
Patricia Cameron	Friends of the Earth Germany – BUND
Dr. Rainer Jansen	Federal Ministry of Education and Research – BMBF
Michael Jung	Nanogate AG
Dr. Martin Kayser	BASF AG
Dr. Holger Krawinkel	Federation of German Consumer Organisations – vzbv
Dr. Peter Markus	Evangelische Akademie Villigst (Protestant Academy, Villigst)
Dr. Thomas Müller-Kirschbaum	Henkel AG & Co. KGaA
Dr. Hanns Pauli	Confederation of German Trade Unions – DGB
Dr. Gerd Romanowski	German Chemical Industry Association – VCI
Dr. Peter Rudolph (from 31.3.2010)	Ministry for the Environment, Health and Consumer Protection of the Land of Brandenburg (MUGV)
MinDirig. Hubert Steinkemper	Federal Ministry for the Environment, Nature Conservation and Nuclear Safety – BMU
MinDirig. Dr. Walter Töpner	Federal Ministry of Food, Agriculture and Consumer Protection -BMELV
Prof. Dr. Arnim von Gleich	University of Bremen
Dr. Hans-Jürgen Wiegand	EVONIK Degussa GmbH
Dr. Peter Wolfgardt (until 3.3.2010)	Bavarian Land Ministry of Labour and Social Order, Family and Women – StMAS
Expert support – BMU	
Dr. Anke Jesse	Federal Ministry for the Environment, Nature Conservation and Nuclear Safety – BMU
Cornelia Leuschner	Federal Ministry for the Environment, Nature Conservation and Nuclear Safety – BMU
Organisational support	
Dirk Jepsen	Ökopol GmbH
Antonia Reihlen	Ökopol GmbH
Silke Detlefs	Ökopol GmbH
Final report	
St a.D. Wolf-Michael Catenhusen	Chairman of the NanoKommission
Dr. Antje Grobe	Stiftung Risiko-Dialog (Risk Dialogue Foundation)

Issue Group on implementation of the Five Principles

Name	Institution
Spokesperson of the Issue Group:	
Dr. Torsten Wolf*	Federal Institute for Occupational Safety and Health – BAuA
Dr. Heidi Becker*	Federal Environment Agency – UBA
Dr. Markus Berges	IFA – Institute for Occupational Safety and Health, DGUV
PD Dr. Gaby-Fleur Böl / Dr. Astrid Epp*	Federal Institute for Risk Assessment – BfR
Dr. Dietmar Eichstädt	German paint and printing ink industry association – VdL
Dr. Gabriela Fleischer	Consumer Council, German Institute for Standardisation – DIN
Cornelia Leuschner*	Federal Environment Ministry (BMU), Division IG II 6
Dr. Carolin Kranz	BASF SE
Prof. Dr.-Ing. Wilfried Kühling	Friends of the Earth Germany – BUND
Dr. Jürgen Milde	German Statutory Accident Insurance – DGUV
Dr. Ralf Nehring*	LAUG, Ministry of the Environment, Forestry and Consumer Protection
Dr. Jacques Ragot	Bayer Material Science AG
Dr. Martin Reuter	German Chemical Industry Association – VCI
Dr. Sieglinde Stähle	German Federation for Food Law and Food Science – BLL
Dr. Frank Vogelsang	Rhineland Protestant Academy
Henning Wriedt	Beratungs- und Informationsstelle Arbeit & Gesundheit (Occupational Health Advice and Information Centre)
Silke Detlefs	Ökopol GmbH

* As the Federal Government is the recipient of the NanoKommission's recommendations, representatives of the various government bodies have a different role to that of the stakeholders in the Issue Group. Participants from the federal ministries and institutions within the ministries' remits were mandated to provide expertise and advice to support the work of the Issue Group. Expert input provided by these individuals does not necessarily represent the official position of the ministry concerned.

Issue Group on guidelines for collecting data and comparing benefit and risk aspects of nanoproducts

Name	Institution
Spokesperson of the Issue Group: Michael Jung	Nanogate AG
Ralf Bosse	Schmitz-Werke GmbH & Co. KG
Alexandra Caterbow / Sonja Haider / Doris Möller	Women in Europe for a Common Future – WECF
Dr. Sabine Dippner*	Federal/Länder Working Committee on Chemical Safety / Office for urban development and environment, Hamburg – BLAC /BSU
Dr. Wolfgang Dubbert*	Federal Environment Agency – UBA
Dr. Alex Föller	TEGEWA
Dr. Roland Franz	Fraunhofer Institute for Process Engineering and Packaging
Dr. Peter German	Expert in environmental medicine
Dr. Ralf Greiner*	Max Rubner Institute
Dr. Ilka Grötzinger*	Federal Ministry of Health – BMG
Dr. Georg Hofmeister	Hofgeismar Protestant Academy
Prof. Dr. Rüdiger Iden	BASF SE
Dr. Anke Jesse*	Federal Ministry for the Environment, Nature Conservation and Nuclear Safety – BMU
Andreas Keil	InnoZent OWL
Dr. Peter Krüger	Bayer MaterialScience AG
Cornelia Leuschner*	Federal Ministry for the Environment, Nature Conservation and Nuclear Safety – BMU
Dr. Wolfgang Luther	Association of German Engineers – VDI, Technologiezentrum GmbH
Christina Meßner	Gesamtverband Textil und Mode – Textile and Fashion Confederation
Dr. Asmus Meyer-Plath*	Federal Institute for Materials Research and Testing – BAM
Dr. Karin Michel	Henkel AG & Co. KG aA
Martin Möller	Öko-Institut e.V. (Institute of Applied Ecology)
Isabelle Mühleisen	Federation of German Consumer Organisations, North-Rhine Westphalia
Stefan Ruholl	Schmitz – Werke GmbH & Co. KG
Rüdiger Stegemann	Friends of the Earth Germany – BUND
Elke Walz*	Max Rubner Institute
Dr. Heinz Zeininger	Siemens AG
Silke Detlefs	Ökopol GmbH
Antonia Reihlen	Ökopol GmbH, Moderator

Issue Group on criteria for preliminary assessment of nanomaterials with regard to their impact on human health and the environment

Name	Institution
Spokesperson of the Issue Group: Dr. Kerstin Hund-Rinke	Fraunhofer Institute for Molecular Biology and Applied Ecology
Dr. Rolf Buschmann	Federation of German Consumer Organisations, North-Rhine Westphalia
Prof. Dr. Thomas Gebel*	Federal Institute for Occupational Safety and Health – BAuA
Dr. Mario Götz*	Federal Institute for Risk Assessment – BfR
Stefan Grötschel*	Federal Institute for Occupational Safety and Health – BAuA
Stephan Hackmann	Centre for Environmental Research and Sustainable Technology (UFT), University of Bremen, (Confederation of German Trade Unions – DGB)
Dr. Anke Jesse*	Federal Ministry for the Environment, Nature Conservation and Nuclear Safety – BMU
Oliver Kalusch	BBU (Federal Association of Environmental Action Groups)
Dr. Harry Keidel*	Ministry of the Environment, Forestry and Consumer Protection, Rhineland-Palatinate
Dr. Nils Krüger	Evonik Degussa GmbH
Dr. Thomas Kuhlbusch	Institute of Energy and Environmental Technology – IUTA
Cornelia Leuschner*	Federal Ministry for the Environment, Nature Conservation and Nuclear Safety – BMU
Dr. Hubert Meisinger	Protestant Church of Hesse and Nassau / Centre for Social Responsibility – ZGV
Dr. Karin Michel	Henkel & Co. KGaA
Prof. Dr. Hartwig Muhle	Friends of the Earth Germany – BUND
Dr. Barbara-Christine Richter	Bayer Material Science AG
Jan Henrik Schlattjan*	Land of Hesse Bureau for testing and research in the public health sector – HLPUG
Katja Stephan	Forschungszentrum Jülich GmbH
Dr. Doris Völker*	Federal Environment Agency – UBA
Dr. Karin Wiench	BASF SE
Dr. Petra Wolff*	Federal Ministry of Education and Research – BMBF
Dr. Sibylle Zielke*	LAUG, Ministry of Social Affairs, Women, Family and Health, Lower Saxony
Silke Detlefs	Ökopol GmbH
Antonia Reihlen	Ökopol GmbH, Moderator

Issue Group on reviewing regulation of nanomaterials and nanoproducts

Name	Institution
Spokesperson of the Issue Group: Prof. Dr. Christian Calliess	Freie Universität Berlin, School of Law
Katharina Adler**	Federal Ministry of Food, Agriculture and Consumer Protection – BMELV**
Inga Beer*	Federal Environment Agency – UBA
Elmar Böhlen*	Federal Institute for Occupational Safety and Health – BAuA
Monika Büning	Federation of German Consumer Organisations – vzbv
Dagmar Friese*	Federal Ministry of Health – BMG
Prof. Dr. Martin Führ	Darmstadt University of Applied Sciences
Dr. Ilka Grötzinger*	Federal Ministry of Health – BMG
Andreas Hermann	Öko-Institut e.V. (Institute of Applied Ecology)
Dr. Rolf Hertel*	Federal Institute for Risk Assessment – BfR
Liane Horst*	Federal Ministry of Education and Research – BMBF
Dr. Anke Jesse*	Federal Ministry for the Environment, Nature Conservation and Nuclear Safety – BMU
Dr. Helmut Klein*	Federal Ministry of Labour and Social Affairs – BMAS
Dr. Hans-Jürgen Klockner	German Chemical Industry Association – VCI
Dr. Nils Krüger	Evonik Degussa GmbH
Martina Kohlhuber*	LAUG, Bavarian Land Office for Health and Food Safety – Environmental Health
Dr. Dietmar Kopp*	Federal Ministry of Economics and Technology – BMWi
Cornelia Leuschner*	Federal Ministry for the Environment, Nature Conservation and Nuclear Safety – BMU
Dr. Hanns Pauli	Confederation of German Trade Unions – DGB
Walther Quasigroch**	Federal Ministry of Food, Agriculture and Consumer Protection – BMELV**
Dr. Marcus Schaper	Loccum Protestant Academy
Dr. Jutta Schaub*	Federal Ministry of Food, Agriculture and Consumer Protection – BMELV
Prof. Dr. Arno Scherzberg	University of Erfurt
Dr. Frauke Schröder*	Federal Institute for Occupational Safety and Health – BAuA
Dr. Agnes Schulte*	Federal Institute for Risk Assessment – BfR
Dr. Sieglinde Stähle	German Federation for Food Law and Food Science – BLL
Jurek Vengels	Friends of the Earth Germany – BUND
Dr. Heiner Wahl*	Federal Ministry of Labour and Social Affairs – BMAS
Dr. rer. nat. Rudolf Weinand	Evonik Degussa GmbH
Dr. Karin Wiench	BASF SE
Silke Detlefs	Ökopol GmbH
Antonia Reihlen	Ökopol GmbH, Moderator

** Ms Adler and Mr Quasigroch provided support in written form but did not attend the Issue Group sessions

Working Group on developing a shared paradigm for "Sustainable Nanotechnologies – Green Nano"

Name	Institution
Spokesperson of the Working Group: Prof. Dr. Arnim von Gleich	University of Bremen
Patricia Cameron	Friends of the Earth Germany – BUND
St a.D. Wolf-Michael Catenhusen	Chairman of the NanoKommission
Dr. Antje Grobe	Stiftung Risiko-Dialog (Risk Dialogue Foundation)
Cornelia Leuschner*	Federal Ministry for the Environment, Nature Conservation and Nuclear Safety – BMU
Dr. Gerd Romanowski	German Chemical Industry Association – VCI
Dr. Klaus Günther Steinhäuser*	Federal Environment Agency – UBA
Antonia Reihlen	Ökopol GmbH, Moderator

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