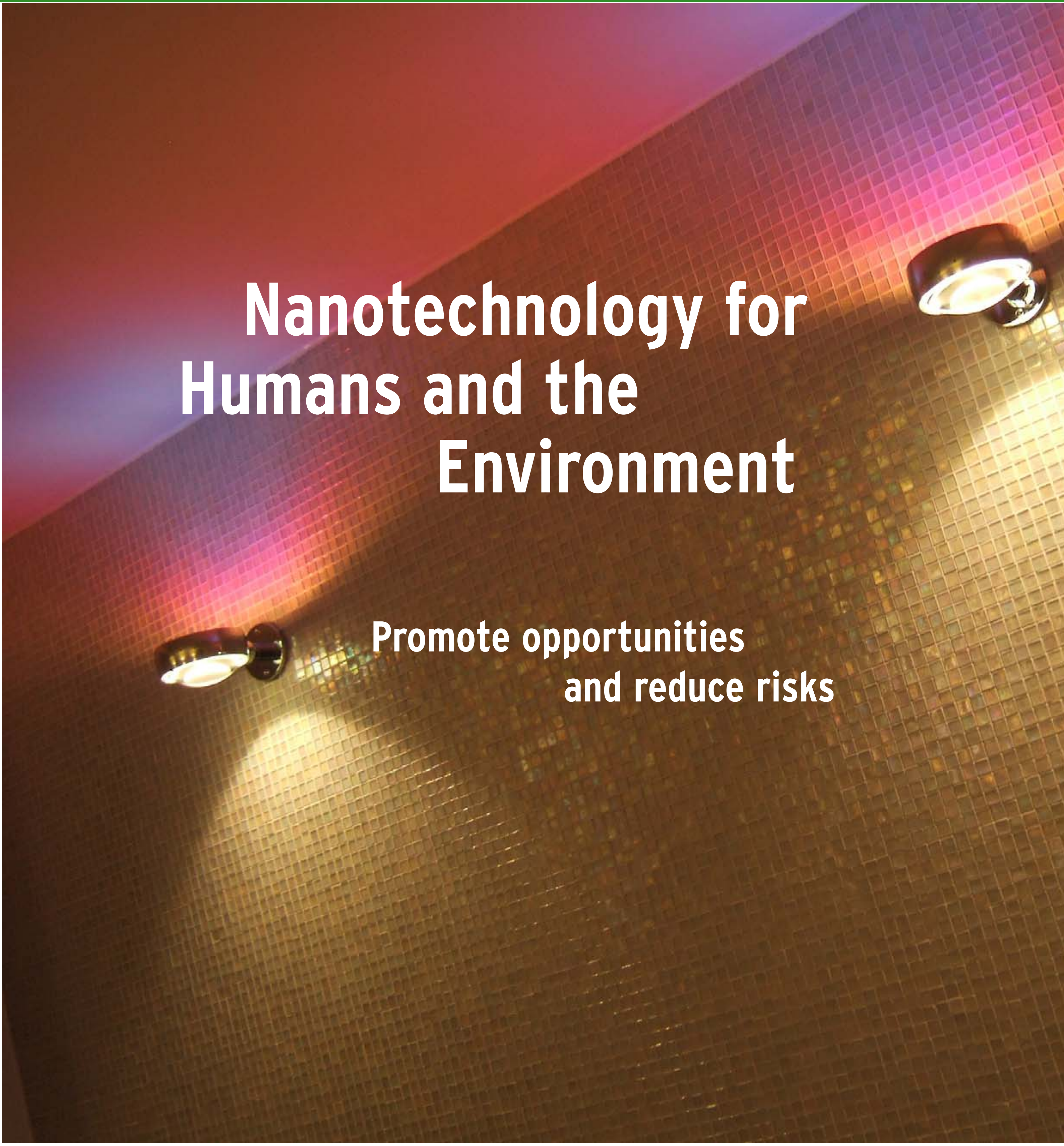

Nanotechnology for Humans and the Environment

Promote opportunities and reduce risks

Umwelt Bundes Amt

Für Mensch und Umwelt

Imprint

Publisher:	Umweltbundesamt Wörlitzer Platz 1 06844 Dessau-Roßlau
E-Mail:	pressestelle@uba.de
Internet:	www.umweltbundesamt.de
Authors:	Dr. Heidi Becker Dr. Wolfgang Dubbert Dr. Kathrin Schwirn Dr. Doris Völker
Editorial Deadline:	October 2009
Design:	UBA
Cover photo:	© Rainer Sturm / Pixelio.de

Contents:

1. Introduction

It is regarded as one of the key technologies of the future, and policy-makers, science and industry set great expectations in it: nanotechnology. The German Federal Environment Agency (Umweltbundesamt, UBA) understands nanotechnology to be systems for the investigation, specific creation and application of processes, and materials – termed "nanomaterials" in this policy paper – that are composed of definable structural elements in the order of 100 Nanometres* or less in at least one dimension. These nanomaterials comprise nanoobjects such as nanoparticles, nanofibres (rods and tubes) and nanoplates, which can be composed of different materials, as well as agglomerates, aggregates and other more complex structures derived from them. Synthetic nanomaterials possess novel properties that are important for the development of new products and applications. These new material and substance properties derive from specific surface and boundary layer properties, but also, in part, from the geometric form of the material.

The Federal Environment Agency assumes, on the basis of available technical literature** and the yearly increasing number of products, that nanotechnology will greatly influence industry and society in the coming decades, and that it has the potential to fundamentally change whole technological fields. Nanotechnology finds application in many widely-differing areas, such as the automotive industry, chemistry, pharmaceutics, medicine, bio- and environmental technology, communications technology and mechanical engineering as well as in the cosmetics and food industries. The number of companies engaged in the field of nanotechnology in Germany rose to more than 800 in 2008. Companies expect further positive developments. The industry foresees great market potential of up to one trillion US dollars worldwide in the year 2015 (estimate of the US National Science Foundation (NSF), 2000 and 2006).

In the opinion of many experts, nanotechnology has not only potential for economic development; improvements are also expected in environmental and health protection, such as an increase in resource efficiency and enhanced environmental protection.

However, despite rapid development in nanotechnology in recent years, and the growing number of products manufactured by means of nanotechnology, very little is known as yet about the exposure of humans and the environment to nanomaterials. Up to now, measuring techniques in the nanodimension have been very costly, and in outdoor areas insufficiently developed. The question as to the effect that synthetic nanomaterials have on humans and the environment has not yet been satisfactorily answered. On account of the new properties of synthetic nanomaterials, industrial development has to be accompanied by risk assessment, since potential damage and costs arising from the new technology have to be identified and then avoided, as is common with every new technology.

The German Federal Government and the European Commission reacted in recent years with a series of research projects, such as the project "Innovation and Technology Analysis of Nanotechnology" ("Innovations- und Technikanalyse zur Nanotechnologie") of the Federal Ministry of Education and Research (BMBF) (2002 to 2004), and projects initiated within the framework of "NanoCare" (2006 to 2009). With its Sixth and Seventh Research Framework Programmes, the European Union has been active in projects such as „NanoSafe 1“ (2003 to 2004) and "NanoSafe 2" (since 2005).

Previous research projects on the risk of nanomaterials, which cannot be dealt with extensively in this policy paper, provide an initial indication of possible toxic effects of nanomaterials and as well as grounds for further research. For comprehensive risk assessment there is at present a particular lack of long-term toxicological analyses. In many cases there is also a lack of data on ecotoxicological effects. The BMBF is therefore continuing its "NanoCare" project together with the "NanoNature" project for investigation of the possible threat to the environment. In order to be able to identify and define the need for research on the impact on humans and the environment, the Federal Environment Agency has drawn up a research strategy together with the Federal Institute for Occupational Safety and Health (BauA, general co-ordinator) and the Federal Institute for Risk Assessment (BfR). The Nano-Commission of the German Federal Government took up this strategy in its report (see Chapter 7 Further Reading).

An important part of the Federal Government's high-tech strategy is the "Nano-Initiative Aktionsplan 2010", which has been jointly developed by

* 1 nm = 10-9 m

** The main sources are compiled in Chapter 7 "Further Reading".

seven federal ministries. Within this framework, the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) set up the Nano Commission of the German Federal Government in the autumn of 2006 as a forum for discussion of the opportunities and risks of nanomaterials. In the so-called „Nano-Dialog 2006-2008“ stakeholders from government, industry, science, authorities and associations drew up consensual recommendations for the responsible handling of nanomaterials. Technical activities were divided among three working groups: Working Group 1: "Opportunities for the environment and health"; Working Group 2: "Risks and safety research"; Working Group 3: "„Guidelines for responsible handling of nanomaterials". The Federal Environment Agency participated in Working Groups 1 and 2 of the "NanoDialog 2006 to 2008". This stakeholder dialogue will be continued in a second round up to 2010. Furthermore, the Federal Environment Agency participates in discussions on the amendment of the REACH Regulation on the registration, evaluation, authorization and restriction of chemical substances to include nanomaterials (here, the general co-ordinator for Germany is the Federal Institute for Occupational Safety and Health (BAuA)), and in the OECD Working Party on Manufactured Nanomaterials (WPMN, see Sections 4.3 and 5).

As shown in an analysis carried out by the Federal Institute for Risk Assessment (BfR), discussion of nanotechnology in German media has given rise to little controversy. A further BfR study confirmed that nanotechnology enjoys a largely positive image among the general public. Consumers expect benefits, for instance, with detergents and varnishes, while scepticism prevails in the case of nanomaterials in food.

The Federal Environment Agency intends to support objective discussion of the opportunities and risks of nanotechnology. It also intends to make a contribution towards promotion of the opportunities of nanotechnology for environmental and health protection, as well as towards the assessment and avoidance of risks.

In this policy paper, different aspects of the opportunities and risks of nanotechnology are outlined. Not only are the environmental relief potentials of this innovative technology described – above all, in the areas of conservation of resources, energy efficiency and health protection – but also possible environmental and health risks as well as approaches towards their minimization.

2. Development and areas of application of nanotechnology products

The Federal Environment Agency expects numerous innovations with the aid of nanotechnology in varied technical areas, fields of application and industrial sectors. Though the development and market penetration of many nanotechnical processes and products are still in their infancy, a range of products is already on the market or awaiting market placement. A legal appraisal carried out on behalf of the Federal Environment Agency contains an initial survey of nanoproducts that are available on the German market or are in the process of development (as in 2007). A complete survey of such products is not available, since the registration and labelling regulations required for this purpose do not exist.

The following fields of application for nanotechnology can be identified exemplarily:

- Surface functionalization and finishing: for instance, thermal and chemical protective coatings, nanometre-thin coating of computer hard disks and biocidal protective coatings.
- Catalysis, chemistry and materials: for instance, catalytic nanomaterials, exhaust catalysts, nanoporous filters and nanoreactors.
- Energy conversion and use: for instance, dye-sensitized solar cells, fuel cells, high-performance batteries and light-emitting diodes.
- Construction: for instance, plastics with nanofillers, new metal compounds with modified mechanical and thermal properties as well as improvements in the properties of building materials through the use of concrete additives.
- Nanosensors: for instance, magnetic field sensors, optical sensors and biosensors (lab-on-a-chip systems*).
- Information processing and transmission: for instance, organic light-emitting diodes (OLED) and electronic components in nanodimensions.
- Life sciences: for instance, applications of nanobiotechnology in analytics and diagnostics, precisely-targeted drug delivery and biocompatible implants.

* A lab-on-a-chip system combines one or more chemical or biological laboratory reaction steps on a single chip.

The spectrum of nanoscale materials for use in production processes ranges from aggregates and powders of inorganic and organic nanomaterials that can be present in dispersed or emulsified form in a matrix, to nanocolloids, nanotubes and nanolayers as well as complex organic molecules. From the point of view of environmental and health protection it is decisive whether nanomaterials are firmly embedded in a matrix or are used in the form of free particles. As yet, little information is available on the release of originally firmly-embedded nanomaterials from products as a result of ageing or degrading processes (for example, in wastes). In the case of firmly embedded nanomaterials in coatings or dispersions, the Federal Environment Agency generally expects, on the basis of current knowledge, no large-scale release from these products.

Inorganic nanomaterials derived from metal oxides (in particular, silicium dioxide, cerium dioxide, titanium dioxide, aluminium oxide) are currently of great economic importance. Their main areas of application are in electronics, pharmaceutics, medicine, cosmetics as well as in chemistry and catalysis; for example

- titanium dioxide and zinc dioxide particles as UV absorber in sunscreens, and as additives in paints and photocatalysts,
- gold particles as markers in medicine, and for rapid biological tests,
- alumina particles as porous carriers for automotive catalytic converters, and
- cerium dioxide as fuel additive for optimization of combustion.

In the case of complex carbon molecules the following are presently of economic relevance: carbon black and technical soots, for example as fillings for rubber and pigments (toner). The industry anticipates considerable economic potential for carbon nanotubes (CNT) in the future, above all for application in sensorics and electronics (for example, flat TV screens and PC monitors, as well as for the curing of special materials).

Organic nanomaterials, such as polymer nanomaterials and nanotechnology-based active agents, can optimize the physiological efficacy of pharmaceuticals, active substances in cosmetics, plant protection agents and food components as well as technical properties (for example, in varnishes and printing inks). The industry anticipates an increase in product value, especially with binders for paints and varnishes, adhesive tapes and coating systems for textiles, timber and leather.

There is an abundance of different application possibilities for nanocoating systems with great market expectations:

- Hard layers (for scratch resistance).
- Tribological coatings (protection against wear),
- Antifogging coatings (for example, self-cleaning surfaces for glass or textiles).
- Anti-reflex coatings (for example, for increasing solar-cell efficiency).
- Corrosion protection coatings.

On account of possible effects of nanomaterials on human health and the environment (see Chapter 4), products and production processes have to be closely monitored that are particularly suspected of releasing nanomaterials. These include cosmetics, food, biocides, environmental remediation as well as the manufacture of nanomaterials itself.

Some authors assign nanotechnical products and

Table 1: The four generations of nanotechnical products and processes, according to O. Renn und M. Roco (2006).

First generation (presently topical)	Passive nanostructures; exemplary fields of application: coatings, nanoparticles, bulk goods (nanostructured metals, polymers and ceramics).
Second generation (initial applications from about 2005)	Active nanostructures; exemplary fields of application: transistors, amplifiers, adaptive structures etc.
Third generation (expected from about 2010)	3D nanosystems with heterogeneous nanocomponents and varied assembling techniques; exemplary fields of application: artificial organs and nanorobots.
Fourth generation (expected from about 2020)	Molecular nanosystems with heterogeneous molecules, on the basis of biomimetic processes and new design; exemplary fields of application: self-replicating nanostructured systems.

processes to four generations (see Table 1) that, in part, are already state-of-the-art, or whose realization experts expect by the year 2020. Previously-mentioned effects and application achievements are based almost exclusively on the first generation of nanotechnologies. On account of the expected medium-term emergence of applications of later generations, the Federal Environment Agency recommends that these be considered in future in the examination of risk and relief potentials of nanotechnologies, as well as in the development of models for the assessment of opportunities and risks.

3. Environmental relief potentials and potentials in health protection

Nanotechnology and nanotechnical products enable the more efficient use of raw materials and energy over the lifespan of a product, and as a result the reduction of pollutant emissions and energy consumption. The Nano-Commission of the German Federal Government lists in its report (see Chapter 7 Further Reading) a number of applications that are already commercially available.

The following examples highlight relief potentials for the environment and human health that arise in nanotechnical applications in terms of savings and improvements. It should be noted that the benefits for the environment and human health mentioned below are not the result of comprehensive assessment of relief potentials for the environment and human health. For that reason, further analyses and assessments (see Section 3.2) as well as consideration of possible risks would be required (see Section 4).

3.1. Examples of relief potentials for the environment and human health

Savings in raw materials through miniaturization

- The use of magnetic nanoparticles in adhesive bonding simplifies the reutilization of product components. The heating of particles by an alternating magnetic field can be used not only for the curing of thermally activatable polymer compounds, but also for the elimination of adhesive bonding.
- Through a reduction in coating thickness, raw materials can be saved with nanoscale coating and catalyst materials, materials optimized with nanoparticles in lightweight construction, low-wear and low-abrasion surfaces in mechanical engineering, and with highly-specified membranes in biotechnology.
- Due to their light weight, nanosensors can be operated highly efficiently. These sensors are primarily used in trace analysis and in the biomedical area. In vivo sensor systems for biomonitoring of vital bodily functions enable early detection of physiological disorders. Future opportunities lie also in environmental application for optimized and specific evidence of biological and chemical contamination (for example, lab-on-a-chip systems).

Energy savings through weight reduction or functional optimization

- Constructional elements for vehicles and aircraft made of nano-optimized plastics can cut fuel consumption through weight reduction. Admixtures of nanoparticles (2 to 5 per cent) can considerably improve the mechanical and thermal properties of plastics, with the result that these increasingly compete with metallic materials.
- While conventional light bulbs convert 5 per cent of electrical energy input into light, the conversion rate with energy-saving bulbs is 25 per cent, and with nano-based OLEDs (organic light-emitting diodes) up to 50 per cent. A report on OLEDs published by the US Department of Energy forecast an almost twofold increase in energy consumption efficiency compared to conventional luminescent materials with the same lifespan. Moreover, these lighting systems have a further advantage for recycling, since in contrast to fluorescent lamps they do not contain mercury.
- Nanotechnology finds application in the trend towards more efficient use of renewable energy, for instance with photovoltaics. Here, different nanomaterials are employed: nanocrystals can increase the otherwise relatively low efficiency of thin-layer solar cells, and silicon solar cells with nanoporous antireflection coatings increase the efficiency factor of sunlight. Dye-sensitized solar cells with nanocrystalline titania for efficient energy use are also on the market.
- Silica and nano-soot particles are already used to strengthen the rubber of modern car tyres. They give rise to lower rolling friction, thereby helping to save up ten per cent of fuel.

Improvement in the cleaning performance of filter systems

- Membrane processes are regarded as a technology with substantial market potential in the areas of wastewater treatment, potable-water treatment and water desalination. In wastewater treatment, „inverse nanotechnology“ (techniques for reduction of nanoparticles) is applied. Nanoporous membranes (nanofilters) can free pretreated wastewater of pathogenic agents (bacteria and viruses), and thus prevent the spread of pathogenic agents in the environment. Such a membrane filter process – co-developed, tested and promoted by the Federal Environment Agency – is to be found in operation in a number of municipal sewage treatment plants in Germany. Some manufacturers successfully market this process in foreign countries. Water desalination and the filtering of heavy metals and dioxins are also possible with the use of nanofilters. Here, precise separation and throughput can be more accurately controlled than in conventional processes.
- Nanotechnical products have up to now not played a major role in air pollution control. Nanocatalysts for the reduction of airborne pollutants and nanoporous membranes for their separation are occasionally used. Under the influence of light and water, nanocatalysts such as the photocatalyst titania can produce highly reactive hydroxyl radicals, which attack organic pollutants and microorganisms oxidatively. Research has shown that nanofilters can also be applied for the removal of pollutants and separation of by-products from gaseous media. Automotive exhaust-gas treatment can also be optimized with nanotechnology. The three-way catalyst contains catalytically-active precious metals (platinum, rhodium and palladium), whose particle size is in the nanoscale range. The smaller the dimensions of precious metal particles the greater their effect; the result is a reduction in the quantity of platinum group metals (PGMs) required. The development of nanoporous particulate filters for the withholding of nanoscale soot particles from exhaust gases is currently being carried out on behalf of the Federal Ministry of Economics (BMWi) within the scope of the joint "NanoKat" research project.

Applications in health protection

- The special properties of nanomaterials can be applied in health protection to increase permeability of the blood-brain barrier for therapeutic agents (for instance, for the medication of meningitis). Precisely-targeted therapy can minimize the use of drugs and reduce the overall impact on the body.
- Furthermore, the integration of nanomaterials with a permanent antimicrobial effect into surfaces – for example, nanoparticulate titanium dioxide or silver –offers the possibility of reducing germ-related health hazards in hospitals.
- There is already widespread use of nanoparticles of zinc dioxide and titanium dioxide in UV protection, which are applied in a suitable emulsion as a cream or spray. As a result, the use of harmful organic chemicals for sunscreening can be reduced.

Reduction in the use of hazardous substances, or their replacement

- The application of varied nanomaterials in the medical field – for instance, biocidal ultra-thin polymer coatings on long-term catheters – can also be advantageous.
- Nanoporous oxide layers (for example, silica) can be furnished with a biocidal substance, such as silver, which is emitted through nanopores in a controlled manner over a longish period of time. This can replace toxic organic biocides (for example, in timber preservatives and paints).
- Chrome Vl varnishes, which pose a potential risk to human health and the environment, can be dispensed with in corrosion protection for metals through the use of nano-based surfaces.
- Through specific reaction control with nanocatalysts the efficiency of chemical reactions can be increased and the output of environmentally harmful by-products thus reduced (catch phrase: resource efficiency).

Environmental protection through the use of nanoscale catalysts

- Systems with nanocatalysts are being developed in wastewater treatment. The use of highly reactive palladium catalysts on nanoscale magnetite particles can be an alternative to cost- and energy-intensive processes in the treatment of special industrial wastewater, such as wastewater polluted with halogenated hydrocarbons (HHC). This way, HHCs can be selectively converted into readily degradable, less-toxic compounds.
- Nanoparticles have been used for in situ groundwater remediation for many years. This can contribute to the elimination of organic or inorganic substances such as

heavy and semi-metals. Different materials – for example, nanoparticulate iron compounds such as nano zero-valent iron or carbo-iron – are already on the market. There are numerous research activities in this regard both in Germany and other countries.

3.2. Assessment of relief potentials for the environment and human health

Work on the environmental relief potential of nanotechnical products and processes has mainly registered such potential qualitatively. Precise data that substantiates the better environmental compatibility of nanotechnical applications becomes available only sporadically (for instance, Steinfeldt et al. (2004) and Oakdene Hollins (2007)). Two studies carried out on behalf of the Federal Environment Agency document further case studies, which show the efficiency potentials of nanotechnology-based applications following an ecobalance-like approach (see Section 5.1 "Research projects and expert reports on behalf of the Federal Environment Agency").

The results make clear that in the main high eco-efficiency potentials exist for the majority of the applications under investigation. Nanotechnical applications are not, however, associated per se with relief potentials, and they require case-by-case analysis. The Federal Ministry for the Environment, Nature Conservation and Nuclear Safety and the Federal Environment Agency have defined criteria for description of environmental relief (see Section 5.2) within the scope of the "NanoDialog". The contribution to climate protection, energy and resource savings, the substitution and reduction of environmentally hazardous substances as well as improvement in process-control security have accordingly to be determined within the framework of a life-cycle assessment (LCA). This way, the advantages and disadvantages of nanotechnical products and processes can be clarified in a comprehensible manner.

There is a manifold need for information and research on environmental relief potentials:

- Clarification of questions concerning the potential sustainability of nanotechnical products and processes, the effects of nanotechnology on raw material and energy requirements as well as the assessment of possibly existing "ecological rucksacks". In the description of the environmental benefits of products in the course of their use, an analysis and assessment of the consumption of resources and energy for their manufacture is generally lacking. For proper assessment, preparation of an assessment model is expedient, and for this purpose the provision of sound data by the manufacturer is indispensable.
- Examination and assessment of both positive and negative effects of nanomaterials – directed towards the life-cycle of products – from the viewpoint of environmental and health protection as well as industrial safety.
- What effect does nanotechnology have on raw material and energy requirements? With this question, the increased employment of precious metals and rare elements in consumer products has also to be considered. For instance, nanosilver is commonly employed in the manufacture of textiles such as cleaning cloths, stockings and shirts. On account of the fact that these are disposable articles or products with a relatively short useful life, and that every time they are washed up to half of the content of silver particles is lost with wastewater, the Federal Environment Agency regards their use in such products as problematic. The statistical availability of silver – that is, the number of years in which silver will be available, excluding consideration of recycling – amounts to approximately 29 years. The Federal Environment Agency recommends, for the purpose of precautionary environmental protection, that the release of nanosilver into the environment be avoided, even if present consumption of silver in these applications is still low. The total quantity of silver used in Germany is estimated at 8 tonnes per year (2007), of which about 1.1 tonnes is used in the form of nanosilver (see also Section 4.2. "Ecotoxicological aspects").
- Which nanomaterials are appropriate for efficient treatment of contaminated groundwater and exhaust air, and how can these nanomaterials then be eliminated from the environment?
- What happens with these materials in the course of their "life" (production phase, use phase, waste phase) in the environment, and what effect do they have on the environment? With increasing use, the clarification of risks becomes all the more urgent.

4. Potential risks for humans and the environment – possible hazards, exposure and persistence

Through the increasing use of synthetic nanomaterials their increased release into the environmental compartments soil, water and air has also to be expected. Nanomaterials arise – similar to large airborne dust particles – not only through technical, but also through natural processes such as volcanic eruptions or forest fires. They also arise unintended in many technical processes, for example in grinding. These nanomaterials are highly varied in terms of form, composition and size, whereas synthetic nanomaterials are manufactured and designed on the basis of desired properties. Though investigations of naturally produced or combustion-related ultra-fine particles allow estimates of the behaviour and effect of synthetic nanomaterials in the environment, they do not suffice for reliable assessment of the risks of industrially produced nanomaterials. The wide-ranging application possibilities of nanomaterials require differentiated assessment of possible risks for human health and the environment.

Risks to human health and the environment are most likely with nanomaterials that are contained as free particles in products. A hazard is hardly to be expected so long as nanoparticles are firmly embedded in materials. But also in this case it has to be clarified whether, and in which form, nanomaterials can enter the environment during the manufacturing process or product use, through ageing and degradation or during disposal and recycling. Therefore the consideration of the entire life-cycle is the prerequisite for assessment of an environmental hazard, also in the case of nanomaterials.

Of decisive importance for estimation of the risk from nanomaterials is the form in which these come into contact with humans and the environment. There are other important questions, which have to be answered:

- How stable and persistent are these forms?
- Do they disaggregate or agglomerate?
- Do they dissolve in water?
- Do they interact with surfaces, other nanomaterials or chemicals?
- Are they degradable, and how do their properties change during this process?

The characterization of investigated materials with regard to size, form, dispersibility and surface quality is indispensable for determination of the toxicity of nanomaterials in biological systems. In biological systems, however, surface properties, in particular, can rapidly change, depending on the environment.

Due to their small size, nanoparticles can spread in the air across borders and also adhere to aerosols. Nanoparticles can penetrate living cells. They therefore have the potential to concentrate in organisms and to accumulate in the food chain.

As yet there are no findings concerning the degradation of organic nanomaterials in the environment. There are no indications that degradation of carbon nanomaterials (Fullerenes and nanotubes), which are already produced on a large scale, takes place in the environment.

The Federal Environment Agency takes the view that the labelling of products, to which nanomaterials have been added to improve performance characteristics, is only advisable within the scope of voluntary product labelling, such as the German Blauer Engel environment label, when an ecological and health-related assessment of nanomaterials is available. Only then could appropriate products be judged on the basis of existing substance evaluation, and requirements for product labelling with the Blauer Engel laid down. Up to now both the Federal Environment Agency and the environment label jury have spoken out against new proposals for labelling products containing nanomaterials with the Blauer Engel, referring to unresolved issues concerning the assessment of nanomaterials.

At the present time, labelling or registration of products with regard to their nanomaterial content is not regulated. Users of products cannot recognize whether or not they contain nanomaterials. Such information is, however, a prerequisite for the investigation and assessment of the origin and spread of particular nanomaterials in the environment. Within the framework of the amendment of the EU Cosmetics Directive and the Regulation on Novel Food, labelling is demanded for the first time. The new Cosmetic Regulation will come into force only in 2012, while the Regulation on Novel Food is in the process of revision.

4.1. Health aspects

Health risks that could arise from nanomaterials which are already on the market, have hardly been researched. Possible uptake of nanomaterials into the organism occurs by way of the respiratory tracts, the skin and the mouth, or through a combination of these paths.

The respiratory tracts are probably the most important uptake pathway. The number of research projects devoted to the effect of nanomaterials is still small; most scientific studies concern inhalational uptake through the respiratory tracts.

Nanoparticles penetrate into the alveolar region of the lung. Here, due to the small size of nanoparticles, the alveolar macrophages eliminate them to only an insufficient extent. The result can be inflammatory processes in the lung.

The transfer of particles from the alveoles into the lung epithelium and the interstitium, and from there to a modest extent into secondary organs, has been proven; from this, passage into the bloodstream can be inferred.

Non-toxic, bioconsistent nanomaterials can induce lung tumours in rodents by mechanisms similar to those of fine particles. These mechanisms include damage to deoxyribonucleic acid (DNA, genetic information) and enhanced cell proliferation, combined with persistent inflammatory reaction in the lung.

Evidence exists that certain carbon nanotubes, depending on their specific structure and length, cause acute pathogenic effects similar to those from asbestos fibre. These include decreased clearance by alveolar macrophages, pulmonary inflammation and fibrosis (abnormal formation of fibre-like scar tissue in the lung). When carbon nanotubes are injected into the abdomen of test animals, mesotheliomas (tumours in the skin covering the lung) develop that are typical for asbestos fibres.

It has been shown in animal experiments with rats that direct uptake is possible through the nose over the olfactory nerve to the brain, where nanoparticles accumulate in olfactory bulbs. Possible negative effects have, however, not yet been sufficiently researched.

Apart from intended uptake of nanomaterials through the mouth (for example, in drugs and medicines), unintended oral uptake has also to be considered (for example, in the form of food additives). Nanomaterials filtered out in the lung can also enter the gastrointestinal tract. Just a few studies have been concerned with the uptake and fate of nanomaterials in the gastrointestinal tract, and these studies generally appear to indicate very low gastrointestinal absorption.

In principle, two uptake pathways for nanomaterials are conceivable through the skin. They can penetrate the skin firstly through interspaces of the top layer of skin (stratum corneum) and secondly by way of hair roots. Intact, healthy skin apparently provides an effective barrier to titania nanoparticles. Particles have been detected between dead corneal cells as well as in hair follicles, however never in deeper skin layers or in contact with vital cells. Commercially available quantum dots (nanoscale structures, mostly of semiconductor materials) and Fullerenes easily penetrate the skin.

Quantitative data on the relative importance of isolated uptake paths is presently not available. It is clear, however, that particles that have entered the bloodstream can be transported into different organs (heart, liver, spleen, kidneys and bone marrow).

Investigations provide an indication that certain nanoparticles can penetrate biological barriers such as the blood-brain barrier. It has also to be assumed that the passage of nanoparticles over the placenta into the foetus is possible.

At the cellular level, barriers for larger molecules – such as the cell membrane – appear not to present an insurmountable obstacle for nanoparticles. Particles with a diameter of <40nm are apparently taken up into cells by an as yet unknown mechanism.

It has been observed with nerve cells that particles move along nerve fibres.

A multiplicity of interactions with cell components is possible with particles that penetrate into cells. It is conceivable that particles in the mitochondria interact with the respiratory chain and can thereby disturb energy production and lead to the production of reactive oxygen species (ROS). Nanoparticles with a diameter of <30nm can even penetrate the cell nucleus, whereby extremely small nanoparticles (<2nm) can assemble as clusters in the DNA double helix. The health effects of such possible interactions are still completely unknown.

The distribution of nanomaterials in the body appears to depend on size, form and substance properties. Biodegradable nanomaterials – for example, dextran particles or liposomes – are metabolized and excreted. As yet little is known about the behaviour of non-degradable nanomaterials. Initial studies show that accumulation occurs particularly in detoxication organs (that is, in the liver and kidneys). Whether a health risk occurs through this accumulation of materials in the body is not yet sufficiently researched.

4.2. Ecotoxicological aspects

Since, due to their small size, new functualities of nanomaterials can be determined compared to their macroscopic form, in the case of environmental exposure there is also the risk of changed behaviour and an undesirable impact on different ecosystems. Here, a potential hazard is most likely in the case of deliberate introduction of nanoscale products. Nanomaterials from products embedded in a matrix could, however, also enter into the environment through abrasion or washout. Evidence of this is provided by Swiss investigations, which show that titania particles in façade paints, which produce self-cleaning surfaces, are washed out of house façades and leached into soil or water. Particles contained in consumer products can also impact the environment. Studies from the USA and Sweden have established that nanosilver particles, which are employed in the manufacture of socks and sports clothing on account of their bactericidal effect, are detached from textiles during washing and discharged into wastewater. In connection with the growing number of products that contain nanosilver particles, an increase in the silver content of sewage sludge is to be expected. It needs to be investigated whether this can disrupt the bacterial community in sewage treatment plants. The effect of nanosilver on organisms in surface waters, sediments and soils is also not being sufficiently investigated. The Federal Environment Agency recommends, for the purpose of precautionary environmental protection, that the release of nanosilver into the environment be avoided.

The number of scientific investigations into the effects of nanomaterials on the environment has greatly increased in recent years. Most of the studies have been concerned with ecotoxicological effects on organisms in aquatic ecosystems, and in particular on microorganisms, aquatic invertebrates and different fish species. It has been shown that even relatively low concentrations of C60 molecules ("Buckminster-Fullerenes") and nanoscale titanium dioxide in water, depending on the type of application, can have a lethal effect on water fleas. Another study shows that contamination with nanoscale silver leads to a higher mortality rate with water fleas than contamination with silver in microscale form in the same concentration.

The uptake of many nanomaterials through the gills and other epithelia of aquatic organisms is well-known. A study on the Japanese medaka shows that fluorescent nanomaterials accumulate in different organs and can also overcome the blood-brain barrier in these organisms. During the embryonic development of the zebrafish even low concentrations of nanosilver particles increased the incidence of malformation. With high concentrations the mortality rate among embryos also increased. Carbon nanotubes delayed the hatching of zebrafish.

Studies on the ecotoxicology of nanomaterials in soil ecosystems are still very rare. In the case of mammals, the results of laboratory analyses for the modelling of the effect on human health can also be applied to a limited extent to animals in the wild. There is a particular need for research into the effects of nanomaterials on other vertebrates, invertebrates and plants. The few existing studies show inter alia reduced enzyme activities, such as those of the antioxidant enzyme catalase and the detoxifying enzyme glutathione S-transferase (GST) in wood lice after uptake of titania nanoparticles, as well as reduced reproduction rates among earthworms following exposure to carbon nanotubes. Only a few studies have been concerned up to now with the toxic effect on primary producers. Tests with alumina nanoparticles showed reduced root growth in different agricultural crops (for example, corn, cucumbers, soy and carrots). This effect did not occur with larger alumina particles. A further example is a publication on copper nanoparticles that accumulate in the cells of plant seedlings of mung beans and wheat and lead to reduced root growth.

Little is yet known about the accumulation of nanomaterials in organisms, or their accumulation via the food chain. Interaction of nanomaterials with other environmental chemicals has also hardly been investigated. Certain nanomaterials are suspected of acting as vectors for the transport of toxic chemicals. An investigation on algae revealed that the toxicity of the polycyclic hydrocarbon phenanthene increased after sorption of aggregated C60 molecules /"Buckminster-

Fullerenes"). This was attributed to enhanced bioavailability of phenanthrene following transport to the cell membranes of algae.

4.3. Further development of statutory regulations

There are as yet no regulations in Germany that are specifically related to nanotechnology and its application. Initial regulations with specific rules on the authorization, safety testing and labelling of nanomaterials in consumer products have meanwhile been passed by the European Parliament. It is intended to regulate the application of nanomaterials in cosmetic and food products in a new cosmetics regulation and a new regulation on novel food.

Definitions of nanomaterials provide the basis for regulations. These have to be further developed, and should also take nanomaterials such as agglomerates and aggregates into consideration. For besides the size of nanomaterials, their specific surface and boundary layer properties are important for the risk assessment of materials.

Initiatives for the adaptation of the REACH Regulation and the Biocidal Product Directive are described below.

Nanomaterials and REACH

The REACH Regulation (Regulation (EC) No. 1907/2006 on the registration, evaluation, authorization and restriction of chemical substances) is fundamentally appropriate, as the key European chemicals regulation, for the registration and control of the risks of nanomaterials for human health and the environment.

There is, however, no specific reference to nanomaterials in the REACH regulation. What is lacking are clear specifications and implementation guidelines, which guarantee that nanomaterials are easily recognized and reliably assessed, and that appropriate risk management measures are developed.

An EU working group (REACH and CLP Competent Authorities' subgroup on nanomaterials – "CASG Nano") is elaborating proposals on the regulation of nanomaterials in accordance with REACH.

An adapted, specific evaluation strategy is required for nanomaterials. Valid and appropriate tests with nanomaterials have to be ensured. Existing testing and evaluation procedures as laid down in REACH cannot be applied to nanomaterials without modification and enhancement.

Conditions have to be created by the European Commission to ensure that manufacturers and importers conduct their own risk assessment of nanomaterials independent of bulk material (chemicals that are manufactured in large quantities). The REACH Regulation should therefore oblige manufacturers and importers of nanomaterials to submit their own dossiers or sub-dossiers with data on all necessary endpoints (results of toxicological, ecotoxicological or physiochemical tests) as well as specific information on exposure and risk management measures. Besides the development of key points for guidelines on these nano-specific aspects, the "CASG Nano" working group is also deliberating on whether amendment of the REACH Regulation and its Annexes is necessary.

The Federal Environment Agency works closely on implementation of REACH and its adaptation to nanomaterials with the Federal Environment Ministry (BMU), other authorities concerned with risk assessment (Federal Institute for Occupational Safety and Health (BAuA) and Federal Institute for Risk Assessment (BfR)), the Federal Office for Chemicals and the European Chemicals Agency ECHA), with a view to creating the conditions required for the testing, evaluation and management of nanomaterials in accordance with the REACH Regulation.

Nanomaterials within the framework of the Biocidal Products Directive

The Biocidal Products Directive 98/8/EC defines biocidal products as active substances and preparations, which are intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means. In Germany, around 20,000 biocidal products are on the market, which – a joint evaluation of active substances having taken place in the EU – are successively issued with authorization. There are already a number of products that contain nanomaterials with a biocidal effect.

In the present version of the Biocidal Products Directive nanomaterials are not explicitly considered. As with the REACH Regulation, clear legal specifications are lacking, which guarantee that nanomaterials are easily recognized and reliably assessed, and that appropriate risk management measures are developed. There is also a lack of procedures for monitoring exposure potential.

As in the case of REACH, the European Commission has therefore to adopt requirements in the Biocidal Products Directive obliging manufacturers and importers to carry out their own risk assessment of biocidal nanomaterials. In testing active substances for inclusion in Annex I of the Biocidal Products Directive it is therefore necessary, in the case of active substances in the nano form, to consider all specific, required endpoints in the dossier or sub-dossier. Appropriate test strategies and methods have to be developed and made binding.

The Biocidal Products Directive is presently being amended. The Federal Environment Agency is participating in discussions on the amendment, and advocates that due to their particular properties biocidal active substances composed of nanomaterials be treated as independent active substances with their own identity. The necessary data requirements, which cover the special risks of nanomaterials, have to be adapted or developed by the European Commission.

Demands on evaluation are comparable to those under REACH. Standardized evaluation of nanomaterials in chemicals law should therefore be aspired.

4.4. Assessement of risks – the need for information and research

As yet there is insufficient information for reliable and comprehensive analysis of the risks of nanomaterials.

Information is urgently required from manufacturers on nanomaterials used by them and placed on the market. Appropriate information systems and corresponding requirements for the submission of information covering the production and use of different nanomaterials are of high, short-term priority. Data on the characterization and functionality of employed nanomaterials should flow into such information systems. This could be realized within the framework of a registration provision. Information on the behaviour of nanomaterials on exposure and their fate in the environment, as well as on their toxic and ecotoxic effects, should be submitted by manufacturers in documentation concerning registration and authorization within the framework of chemicals law. There are huge gaps in knowledge on nanomaterial exposure and effect. One focal point of research should therefore be the need for the assessment and regulation of risks. Since all authorities concerned with risk assessment are faced with the same problem, the Federal Institute for Occupational Safety and Health (BAuA, as general co-ordinator), the Federal Institute for Risk Assessment (BfR) and the Federal Environment Agency (UBA) have drawn up a joint research strategy entitled "Nanotechnology: Health and Environmental Risks of Nanomaterials". This strategy identifies prioritized research topics concerning risk assessment for the protection of human health and the environment.

Since, on account of the large number of variedly modified nanomaterials, it will not be possible to test all variants, parameters have to be established for the characterization of nanomaterials that have a particular influence on health and environmental risks. The objective should be to create categories of nanomaterials with similar effects. Appropriate reference values (for example, mass, particle size and surface) should be established, so that evaluation and interpretation of the results of investigations are as comparable as possible.

A prioritized demand for research and information is particularly apparent in the following areas:

- Use and application of nanomaterials
  Exemplary assessment of products, which are already or will shortly be placed on the market (such as cosmetics, household products and biocidal products), and which can or could enter the environment in relevant quantities. These also include coatings of textiles and other materials – for example, food packaging – that often enter the environment as waste.
- Release of nanomaterials
  Exposure scenarios throughout the entire lifecycle of nanomaterials.
- Behaviour and fate of nanomaterials in the environment
  Investigations into the behaviour of nanomaterials in the environment (persistence, bioaccumulation, interaction with nutrients and chemicals, also as a function of their size, charge, coating and / or surface structure).
- Measuring procedures
  Development and optimization of appropriate measuring procedures for determination of human and environmental exposure.
- Effect assessment
  Validation and – where applicable – further

development or optimization of test procedures for ascertainment of effects on humans and the environment. Investigation of relevant toxicological and ecotoxicological endpoints of nanomaterials as well as of interaction between nanoparticles.
Verification of the appropriateness of in vitro assays (experiments carried out in a controlled, artificial environment outside living organisms) through in vivo assays (experiments carried out in living organisms).

- Characterization and categorization as well as assessment of the effect of nanomaterials
Identification of relevant parameters for characterization of the properties of nanomaterials.
Establishment of parameters that allow categorization of nanomaterials with regard to their effect and behaviour.
- Test strategies
Development of appropriate, intelligent test and assessment strategies for the ascertainment of health-related and ecotoxicological effects.
Ascertainment of dose-effect characterization for different uptake paths.

An extensive description and explanation of research requirements are to be found in the joint research strategy of the above-mentioned federal superior authorities.

5. Activities of the Federal Environment Agency

The Federal Environment Agency wants to provide information on environmentally relevant aspects of nanotechnology, fill gaps in knowledge and identify further need for action. It wants to support and further develop the positive effects of nanotechnology, determine environmental relief potentials, identify risks for the environment and human health and take precaution measures for their reduction.

5.1. Research projects and expert reports commissioned by the Federal Environment Agency

The date stated in the headings of individual projects is the year of publication.

Legal Appraisal of Nanotechnologies – Rechtsgutachten Nanotechnologien (2007)

In existing environmental legislation there are, as already mentioned, no specific provisions on nanomaterials. Existing regulations are inadequate to deal with the particular risks emanating from nanomaterials. Chemicals law does not distinguish, for instance, between the nano form and the macro form of a substance. Furthermore, the quantitative thresholds laid down in chemicals law are inappropriate for nanotechnology. In their Legal Appraisal of Nanotechnologies, Ökoinstitut – Institute for Applied Ecology – and sofia – Society for Institutional Analysis – addressed the need and possibilities for regulation of nanotechnology within the existing statutory framework at a national and EU level. The appraisal identifies regulatory gaps in existing national and EU environmental legislation with regard to nanotechnologies, indicates possibilities for the adoption of nano-specific and nano-appropriate provisions in environmental legislation, and provides recommendations for further regulatory action. The appraisal proposes a multi-step regulatory concept, according to which, in an initial step, the problem of information should be tackled. The information on risk thus gained should then be evaluated and systematized with respect to the possible resulting need for regulation.

http://www.umweltdaten.de/publikationen/fpdf-l/3198.pdf

Technical procedure for the testing of nanoparticles – Technisches Vorgehen bei der Testung von Nanopartikeln (2007)

Standardized tests for the determination of environmental effects were developed for "classic chemicals" and can only be applied to a limited extent to the testing of nanoparticles. Since special methods for nanoparticles do not exist, the analysis of nanomaterials presents a particular challenge. The exchange of information between experts with regard to their experiences as well as basic developments and a comparison of research results is very important. Only this way can results be substantiated and new insights gained. The basis for this is the documentation and publication of all relevant information on individual studies. The objective of the study carried out by the Fraunhofer Institute for Molecular Biology and Applied Ecology (IME) was therefore to provide recommendations, based on the evaluation of relevant literature on the environmental behaviour and ecotoxicology of nanomaterials, concerning the technical procedure to be followed in the testing of nanomaterials, as well as on the information that should be covered by the documentation requirement. This study covers inter alia topics such as the preparation of nanoparticle suspensions, the characterization of nanomaterial and suspensions in water, the choice of test organisms and endpoints as well as the question of a reference material.

http://www.umweltdaten.de/publikationen/fpdf-l/3484.pdf

Sustainable water management and nanotechnology – market of the future – Zukunftsmarkt Nachhaltige Wasserwirtschaft und Nanotechnologie (2007)

Nanotechnologies can contribute towards the preclusion or elimination of water contamination as well as the control of water quality. The world market for water supply will probably grow strongly. Experts forecast its value at over 400 billion US dollars in the year 2010, with membrane technologies playing a key role.

The high dynamics of nanotechnology development is reflected in the steadily growing number of patents and publications. Novel filtration membranes and nanomaterials for catalytic, adsorptive or magneto-separation treatment of wastewater represent an important segment, where marketable products already exist. In the long term, the convergence of electronics, biotechnology, nanotechnology and microsystems technology offers new perspectives and applications, also for water supply.

On account of its solid basic research, Germany has great competence in membrane and nanofiltration technology, which can serve as a sound basis for the exploitation of foreign markets. Departure points for policy measures are the initiation and implementation of measures to accompany innovation for further development of these technologies as well as for the exploitation of international markets. Support for manufacturers in the development of serial applications and processes can be provided by way of the environmental innovation programme of the Federal Environment Ministry (BMU)*, so that innovative approaches derived from research lead rapidly to products that can be marketed internationally. High environmental standards in Germany and the EU – that other countries might then adopt – improve export opportunities.

http://www.umweltdaten.de/publikationen/fpdf-l/3455.pdf

Assessment of total environmental exposure to silver ions from biocidal products – Beurteilung der Gesamtumweltexposition von Silberionen aus Biozid-Produkten (2008)

On account of its bactericidal properties silver is already employed in numerous everyday products as well as in medicine, and is gaining increasingly in importance. It is found in biocides – for example in dissolved and colloidal form – as free or embedded nanoparticles. As a result of the great interest in the use of silver, its potential release into the environment is important. The report prepared by the Fraunhofer Institute for Molecular Biology and Applied Ecology (IME) and the Fraunhofer Institute for Systems and Innovation Research (ISI) therefore concerned estimation of the risk of release of silver into the environment. In addition, information was gathered on products containing silver and the quantities of silver employed, the fate and behaviour of silver in the environment as well as ecotoxicological data on silver compounds and silver nanoparticles. On the basis of this data the experts carried out risk estimation and highlighted gaps in information concerning, for example, the input quantity of silver in dissolved, colloidal and nanoparticulate form in products, as well as the level of its release from products into the environment. There is little knowledge of the concentration of silver ions in the environment, which is decisive for the toxic effect. The specific lack of knowledge about silver nanoparticles concerns their ecotoxicity compared to that of non-nanoscale silver compounds. Little is also known about the influence of changed environmental conditions on the fate and effect of silver nanoparticles (for example, on degradation of organic substances in the soil).

http://www.umweltdaten.de/publikationen/fpdf-l/3673.pdf

Environmental relief effects through nanotechnical processes and products – Entlastungseffekte für die Umwelt durch nanotechnische Verfahren und Produkte (2009)

In this study, the authors from Bremen University identify positive effects on the environment

* BMU programme for the support of innovations for the reduction of environmental pollution that have a demonstrative character.

from the application of nanotechnology, compared to conventional product solutions. For example, the addition of finely distributed organic nanoparticles to a plastic (polybutylene terephthalate, PBT) can significantly improve its flow characteristic. That has advantages for injection moulding and leads to energy savings of up to 20 per cent through lower injection pressures and lower processing temperature. The electrical, automotive and household goods industries use this plastic for a huge number of applications.

Exceptional environmental relief potential arises through a new process for the manufacture of solderable surface finishes for printed circuit boards. The new organic surface finish is composed of a complex of nanoscale "organic metals" (polyaniline) and silver, is just 55 nm thick, and offers better protection against oxidation than conventional layers that are 6 to 100 times thicker. The manufacturers claim efficiency gains in material use of several hundred per cent. Energy consumption and CO_2 emissions decrease by around 10 per cent. The application of carbon nanotubes for antistatic foil – as used by the semi-conductor industry for the packaging of electronic components – can reduce greenhouse warming potential and acidification potential by more than 10 per cent compared to conventional conductive foils based on polycarbonates with the additive carbon black. The project has been concluded. The final report will be available in the course of 2009.

Investigations into the application of nanomaterials in environmental protection – Untersuchungen des Einsatzes von Nanomaterialien im Umweltschutz (2009)

Golder Associates GmbH has carried out two case studies. In one, an eco-balancing evaluation was carried out of two approaches to UV irradiation of water contaminated with tetrachlorethene (perchlorethene PCE). The object of the investigation was the employment of a combination of nanoscale titanium dioxide and oxygen in comparison to the application of iron(ll) compounds with hydrogen peroxide (photo-Fenton process). The case study showed that with long-term photocatalytic use of nanoscale titanium dioxide a much greater environmental impact is to be expected than with conventional processes. This is attributable, in particular, to greater consumption of resources in the mining and transportation of titanium dioxide in the upstream chain.

In the second case study, an investigation was carried out into improvement in air quality in vehicle interiors with the aid of cabin air filters. Nowadays, over 90 per cent of new vehicles are equipped with such air filters, which not only withhold dust and particles such as pollen, diesel soot and tyre abrasion particles, but can also eliminate odorous substances and gases. The case study compares a conventional car combination-filter based on polypropylene fibres and active carbons with combination filters that are additionally coated with nanofibres composed of polymer (for example, polyamide). The nanofibre coating leads to lower filter air-flow resistance with unchanged particle filtration efficiency. As a consequence, less energy is required to press the polluted air through the filter. Estimations of potential fuel savings and possible CO2 reduction produced only very modest advantages for nanofibre-coated filters. Environmental relief would only be noticeable with the use of a large number of filter elements. Efficiency gains in material use were not considered.

The project has been concluded. The final report will be available in the course of 2009.

Specific identification of synthetic nanoparticles in the air – Spezifische Identifizierung künstlicher Nanopartikel in der Luft (2010)

The study had the objective of describing the technical possibilities for identification of synthetic particles in air samples. Limit values for the control of air quality primarily serve the protection of human health and ecosystems against harmful effects, whereby standardized measuring processes are an indispensable requirement. The Fraunhofer Institute for Wood Research (WKI) – Department for Materials Analysis and Indoor Chemistry – provides in a summarized report the sources of nanoparticles of relevance to the air, their physiochemical properties and release paths in connection with the use of nanoscale products as well as their literature references. The report is supplemented with a survey of currently available analytical methods for the characterization of airborne nanoparticles and the technical possibilities for specific identification of synthetic nanoparticles. The report concludes with a summarized assessment of research needs, bearing in mind the necessity of both qualitative and quantitative documentation of synthetic nanoparticles in the future.

The following results should be particularly emphasized:

- An analytical measuring technology for the specific identification of synthetic nanoparticles in air samples, suitable for use in measuring networks, is not available. Analyses of individual particles with high-resolution microscopic and spectroscopic processes are available, but they require a lot of time and are costly, and their use is still restricted to the research area.
- There is a need for research and development in many areas of nanoparticle measuring technology. This ranges from the provision of a traceable standard for particle number concentration to the definition of methods for determining parameters that can be applied for the characterization of size, form and structure.
- With this report, a comprehensive review of literature is available on the current status of measuring technology with regard to the characterization of nanoparticles. Life-cycle analyses, which describe all processes from the manufacture of a product to its use and ultimate disposal, are appropriate for determining the potential release of synthetic nanoparticles into the air.

The project has been concluded. The research report will be available in the course of 2010.

Analysis of the toxicokinetics of nanoparticles in vivo – Untersuchung zur Toxikokinetik von Nanopartikeln in vivo (2009)

Current studies point to an increased potential hazard for human health from exposure to manufactured nanoparticles. Nanoparticles can enter the organism through different paths, but in particular through inhalation or oral absorption. Few studies exist as yet that describe the uptake of nanoparticles and their distribution in the body and target organs, and thus the systemic availability and actual concentration of particles in the organism. Initial evidence indicates transfer of inhaled nanoparticles over the lung epithelium into the system circulation. Within the scope of the research project, experts from the Helmholtz Zentrum München (German Research Centre for Environmental Health) studied the distribution of radioactively marked titania nanoparticles in rats one hour, 24 hours, one week and one month after one-off exposure, by means of quantitative biokinetic analyses.

The project is presently in progress and will be concluded in 2009.

Study on the emission of nanoparticles during the life-cycle of selected products – Studie zur Emission von Nanopartikeln aus Produkten in ihrem Lebenszyklus (2010)

The aim of this project, which is being conducted by the Institute of Energy and Environmental Technology (IUTA), is estimation of the extent to which the environment and humans are exposed to synthetic nanomaterials. The experts should describe exposure paths with relevant releases into different environmental media and, where available, to substantiate these with specific data. In so doing, data should be examined on nanoparticle release during production by way of discharged air, wastewater and in the form of waste, in the course of transport and during further processing into a final product. Investigations should also be undertaken into exposure during the use of finished products containing nanomaterials (for example, from abrasion, wear or washing), as well as into the behaviour of nanomaterials after use during disposal, dumping, incineration or recycling. As far as possible, relevant influencing variables should be taken into account, which lead to nanomaterial exposure during their entire life-cycle. On the basis of acquired information, the experts should identify nanomaterials that should be urgently investigated with regard to environmental exposure, and specify the main exposure paths in the life-cycle of products composed of or containing nanomaterials. This way, reduction possibilities can be identified in production processes. The results should contribute towards recognition of nanomaterial exposure paths, and as a consequence to the investigation of nanomaterial fate and behaviour in the environment and, where appropriate, the evolvement of risk reduction measures.

The project is presently in progress and will be concluded in 2010.

Measurement of abrasion particles from textiles

As a result of contact with the Hohenstein Textile Testing Institute, the Federal Environment Agency received five textile samples that contained varied concentrations of titania nanoparticles. The Agency carried out pilot tests on abrasion behaviour using the samples. These showed that particles with a diameter of less than 350 nm – that is, also "classic" nanoparticles with a diameter of up to around 100 nm – did not detach, while larger particles of 350 nm to 2 μm (micrometres) did detach. These preliminary results will have to be substantiated in further trials. The Federal Environment Agency intends, by means of specific abrasion tests, to examine the influence of textiles of varied used and wear on the release of nanoparticles. For this purpose, the Hohenstein Institute provided further textile samples, which were coated with varied concentrations of nanosilver particles. For testing purposes the Federal Environment Agency made use of two commonly-used devices for the creation of abrasion under controlled conditions in a test chamber. Initial tests began in the spring of 2009.

Further measurements of the release of nanoparticles from varnishes and paints as well as from DIY (do-it-yourself) activities are planned for 2010.

Support of environmental associations

Within the scope of its support of the environmental projects of environmental protection and nature conservation associations as well as of civil action groups and organizations, the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety presently finances the following projects concerned with nanotechnology: Bund für Umwelt und Naturschutz Deutschland (BUND) (Friends of the earth – Germany) promotes public debate with the project "Nanotechnology and Environmental Protection: Exploit Opportunities, Minimize Risks". While Öko-Institut – Institute for Applied Ecology is conducting the project „Analysis and strategic management of the sustainability potentials of nanoproducts“.

5.2. Participation in and co-operation with national and international bodies

Research strategy of German federal superior authorities

As already mentioned in Section 4.3, the authorities concerned with risk assessment have been faced with the problem of filling knowledge gaps concerning the assessment of the risks of nanotechnology as quickly and effectively as possible. Research projects in large research associations that have been initiated by the European Union and the German Federal Ministry of Education and Research are frequently orientated towards the possibilities and objectives of the participating institutes (for example, studies on cell cultures). They are therefore generally not able to meet the specific demands of the authorities concerned with risk assessment. The Federal Institute for Occupational Safety and Health (BAuA) (general co-ordinator), the Federal Institute for Risk Assessment (BfR) and the Federal Environment Agency have therefore drawn up a joint research strategy entitled "Nanotechnology: Health and Environmental Risks of Nanomaterials" in order to specifically identify the need for research on the regulative assessment of risk.

The federal superior authorities presented their draft research strategy at a conference jointly organized by the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU), the Federal Ministry of Labour and Social Affairs (BMAS), the Federal Ministry of Food, Agriculture and Consumer Protection (BMELV) and the Federal Ministry for Education and Research (BMBF) on 30 November 2006. The recommendations of the 120 participants from science, industry, associations and NGOs, together with the comments of national and international experts, are reflected in the final version of the strategy.

The Federal Environment Agency brought the research strategy before the OECD Working Party on Manufactured Nanomaterials and into Working Party 2 of the "Nanodialog" (see Section "NanoDialog"). Proper funding for more than mere isolated implementation of the strategy has not yet been settled.

http://www.umweltbundesamt.de/technik-verfahren-sicherheit/dokumente/forschungsstrategie.pdf

"NanoDialog"

The Federal Ministry for the Environment, Nature Conservation and Nuclear Safety set up the Nano-Commission of the German Federal Government in the autumn of 2006 to promote discussion on the opportunities and risks of nanomaterials in a stakeholder dialogue with participants from government, environmental protection and nature conservation, and the drawing up of consensual recommendations for the responsible handling of nanomaterials. The technical groundwork was carried out by three working groups: WG 1 "Opportunities for the environment and human health", WG 2 "Risks and safety research" and WG 3 "Guidelines for responsible treatment of nanomaterials". The

Federal Environment Agency participates in WG 1 and 2, as well as in continuation of the "Nano-Dialog" ("NanoDialog" 2009-2010).

OECD Sponsorship Programme

The Federal Environment Agency participates internationally, together with the Federal Institute for Occupational Safety and Health (BauA) and the Federal Institute for Risk Assessment (BfR), under the general co-ordination of the Federal Environment Ministry (BMU), in the Working Party on Manufactured Nanomaterials (WPMN) of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology of the Organization for International Co-operation and Development (OECD). At the WPMN members discuss, inter alia, the possible hazards of nanomaterials. In this connection, the OECD launched a programme of tests, with Member States agreeing on a priority list of 14 representative nanomaterials from which human and environmental exposure are to be assumed, and a list of more than 50 endpoints for which they should be tested ("OECD Sponsorship Programme"). By the end of the year 2010, substance dossiers will be produced, which besides a precise description of the respective nanomaterial will also contain information on physiochemical properties, environmental behaviour and toxicological and ecotoxicological risks. German participation in this programme of tests is co-ordinated by the Federal Environment Agency. At the same time, Germany bears the main responsibility for the testing of titania nanomaterials, has partial responsibility for nanoparticles composed of silver, and also participates in the testing of four further types of nanoparticles (carbon black, zinc oxide, cerium dioxide and carbon nanotubes). The Federal Environment Agency participates further in the drawing up of guidelines on sample preparation and measuring technology (dosimetry), in the identification of the main focal points of international research on nanorisks, in the setting up of an international database, as well as, in future, in working groups on the ascertainment and reduction of environmental exposure and the benefits of nanomaterials for human health and the environment.

Scientific Knowledge for Environmental Protection (SPEK)

The European network SKEP (Scientific Knowledge for Environmental Protection) promotes cross-border research on the opportunities and risks of so-called converging technologies, which include nanotechnology and its combination with bio- and information technology. The Federal Environment Agency is a member of this network, and provided money for the joint European invitation to tender for a research project entitled "Impacts of Emerging Technologies for Environmental Regulation". Besides Germany, ten other EU Member States participated in the invitation to tender. Within the network, a "Technical Working Group" is responsible for development of specific objectives and research issues. The invitation to tender focuses on the challenges and possibilities of regulation of such technical developments.

DECHEMA/VCI Working Group

In Germany, the Federal Environment Agency participates in the working group "Responsible Production and Use of Nanomaterials" that was set up by DECHEMA / VCI (Society for Chemical Engineering and Biotechnology / German Chemical Industry Association). This working group intends to identify the opportunities and risks of nanotechnology. It plans to support industry in the economically and technically successful application of nanotechnology, taking account of ethical, ecological, societal and economic aspects. The Federal Environment Agency thus has access to information on new process developments at first hand.

National and international standardization

Within the framework of the International Standardization Organization (ISO) and the German Institute for Standardization (Deutsches Institut für Normung – DIN), the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety and the Federal Environment Agency are involved in several standardization activities related to nanotechnology. The ISO has set up a technical commission (TC 229) on "Nanotechnologies" with four working groups: "Terminology and Nomenclature", "Measurement and Characterization", "Health, Safety and Environment" and "Material Specifications". At the German level, DIN has set up a working committee on "Nanotechnologies" (NA 062-08-17 AA).

6. Summary and recommendations for action

Unambiguous definition of nanomaterials is of fundamental importance for intended regulations on nanomaterials, since not only the legal obligations have to be clear, but also just what is subject to them. For this purpose it is necessary, among other things, to enhance such definitions. Nanomaterials such as agglomerates and aggregates should also be defined, since besides the size of nanomaterials their specific surface and boundary layer properties are also important for risk assessment.

The Federal Environment Agency expects numerous innovative developments from nanotechnology in different technical areas, application fields and industrial sectors. Nanotechnology and nanotechnical products enable in many cases more efficient use of raw materials and energy over the entire life of a product as well as a reduction in pollutant emissions and energy consumption.

Apart from economic benefits, a wide range of nanotechnology applications offer environmental relief potentials. With realization of these potentials, through specific promotion of such applications, a reduction in demands on the environment can be achieved and, in some cases, harmful effects on human health diminished.

The Federal Environment Agency supports the promotion of nanotechnology in applications that relieve the environment. The prerequisite is, however, that its possible risks first be identified and minimized. In order to be successful in this, further information is required:

1. Substantiation of the positive potential requires assessment of nanotechnical processes and products in terms of their benefits for the environment compared to conventional alternatives. For this purpose, an assessment procedure has to be developed, under the decisive participation of the Federal Environment Agency, that is recognized by industry on the one hand and competent authorities on the other. It is vital for proper assessment that manufactures provide sound data. This way, consumer trust in such products can be promoted.
2. Besides the opportunities of this technology, its risks also deserve attention. In view of highly dynamic developments, and indications of risks to human health and the environment from nanotechnology, it is essential that such risks be recognized and assessed. It is therefore necessary that manufacturers disclose the outcome of their risk assessment. Risk research in Germany and Europe should be stepped up, agreed test and assessment strategies – particularly within the OECD – should be developed and nano-specific requirements adopted in chemicals legislation and implementation guidelines.
3. For the purpose of enhanced transparency concerning nanomaterials in products, the Federal Environment Agency recommends introduction of obligatory registration. The German Chemicals Act allows for the introduction of obligatory registration in the case of preparations. To promote freedom of choice on the part of consumers, an appropriate labelling system should also be aimed for, which provides information without suggesting risk. Despite the increasing number of scientific investigations there are still considerable knowledge gaps and thus a need for specific research on risk assessment, which should be jointly financed by the industries involved.

The Federal Environment Agency assumes if nanomaterials are tightly bound to a product, no leaching will occur and such nanomaterials will not impair human health and the environment. Manufacturers should commit to assess exposure scenarios covering the complete life cycle of nanomaterial containing products. Based on the precautionary principle the application of products where potential leaching of nanomaterials is likely should be reduced or avoided until an in-depth assessment demonstrates the safe use. As long as the data required for conclusive assessment of products in not available, the Federal Environment Agency disapproves of awarding the "Blauer Engel" environmental label to products that contain nanomaterials.

7. Further Reading

Angrick, M. (2008): Ressourcenschutz für unseren Planeten. Metropolis-Verlag Marburg.

Bachmann, G. et al. (2007): Nanotechnologien für den Umweltschutz. Zukünftige Technologien Nr. 71.

Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, Bundesinstitut für Risikobewertung, Umweltbundesamt (2007). Nanotechnologie: Gesundheits- und Umweltrisiken von Nanomaterialien – Forschungsstrategie –. (http://www.umweltbundesamt.de/technik-verfahren-sicherheit/dokumente/forschungsstrategie.pdf)

Bundesinstitut für Risikobewertung (2008): Risikowahrnehmung beim Thema Nanotechnologie – Analyse der Medienberichterstattung. BfR-Wissenschaft 07/2008 vom 10.11.2008. (http://www.bfr.bund.de/cm/238/risikowahrnehmung_beim_thema_nanotechnologie.pdf)

Bundesinstitut für Risikobewertung (2008): Wahrnehmung der Nanotechnologie in der Bevölkerung. BfR-Wissenschaft 05/2008 vom 18.06.2008. (http://www.bfr.bund.de/cm/238/wahrnehmung_der_nanotechnologie_in_der_bevoelkerung.pdf)

Bundesministerium für Bildung und Forschung (Hrsg.)(2006): Nano-Initiative – Aktionsplan 2010.

Führ, M. et al. (2007): Rechtsgutachten Nanotechnologien – ReNaTe. Umweltbundesamt Texte 10/2007. (http://www.umweltdaten.de/publikationen/fpdf-l/3198.pdf)

Helland, A. et al. (2007): Reviewing the Environmental and Human Health Knowledge Base of Carbon Nanotubes. EHP 115(8): 1125-1131.

Hund-Rinke, K. et al. (2007): Technisches Vorgehen bei der Testung von Nanopartikeln. Abschlussbericht des Ufoplan-Projektes FKZ 206 61 203/03.

Hund-Rinke, K. et al. (2008): Beurteilung der Gesamtumweltexposition von Silberionen aus Biozid-Produkten. Umweltbundesamt Texte 43/2008. (http://www.umweltdaten.de/publikationen/fpdf-l/3673.pdf)

Kaegi, R. et al. (2008): Synthetic TiO2 nanoparticle emission from exterior facades into the aquatic environment. Environm Poll 156, 233-239.

Kreyling, W.G. et al. (2002): Translocation of ultrafine insoluble iridium particles from lung epithelium to extrapulmonary organs is size dependent but very low. J Toxicol Environ Health A.

Luther, W. et al. (2004): Nanotechnologie als wirtschaftlicher Wachstumsmarkt, Innovations- und Technikanalyse. Zukünftige Technologien Nr. 53, Düsseldorf.

Luther, W. et al, (2007): Zukunftsmarkt Nachhaltige Wasserwirtschaft und Nanotechnologie. In: Umwelt, Innovation, Beschäftigung (Hrsg.: BMU und UBA) 12/07. (http://www.umweltdaten.de/publikationen/fpdf-l/3454.pdf)

Malanowski, N. (2001): Vorstudie für eine Innovations- und Technikanalyse (ITA) Nanotechnologie. Zukünftige Technologien Nr. 35, Düsseldorf.

Ministry for Environment and Water Conservation, Agriculture and Consumer Protection of Federal State North Rhine-Westphalia, Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, and Federal Environmental Agency (2006): Municipal Wastewater Treatment with Membrane Technology.

Nanoderm Abschlussbericht (2007): http://www.uni-leipzig.de/~nanoderm/Downloads/Nanoderm_Final_Report.pdf.

Nanokommission der deutschen Bundesregierung (2008): Verantwortlicher Umgang mit Nanotechnologien – Bericht und Empfehlungen der Nanokommission der deutschen Bundesregierung. (http://www.bmu.de/files/pdfs/allgemein/application/pdf/nanokomm_abschlussbericht_2008.pdf)

Oakdene Hollins (2007): Environmentally Beneficial Nanotechnologies – Barriers and Opportunities. A report for the Department for Environment, Food and Rural Affairs (UK).

Oberdörster, G. et al (2005): Nanotoxicology: An Emerging Discipline Evolving from Studies of Ultrafine Particles. Environmental Health Perspectives 113(7), 823-839.

OECD – Safety on Nanomaterials (http://www.oecd.org/env/nanosafety).

Paschen, H. et al. (2003): TA-Projekt Nanotechnologie. Arbeitsbericht Nr. 92. Berlin, Büro für Technikfolgen-Abschätzung beim Deutschen Bundestag (TAB).

Peters, A. et al. (2006): Translocation and potential neurological effects of fine and ultrafine particles a critical update. Part Fibre Toxicol 3: 13.

Poland, C. A. et al. (2008): Carbon nanotubes introduced into the abdominal cavity of mice show asbestos-like pathogenicity in a pilot study. Nat Nanotechnol. 3(7): 423-428.

Renn, O. und Roco, M (2006): Nanotechnology Risk Governance. International Risk Governance Council White Paper No. 2.

Roller, M. (2008): Untersuchungen zur krebserzeugenden Wirkung von Nanopartikeln und anderen Stäuben. Bundesanstalt für Arbeitsschutz und Arbeitsmedizin. Ref Type: Report.

Royal Commission on Environmental Pollution (2008): Novel Materials in the Environment: The case of nanotechnology.

Scientific Committee on Emerging and Newly Identified Health Risks – SCENIHR (2009): Risk assessment of Products of nanotechnologies. (http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_023.pdf)

Scientific Committee on Emerging and Newly Identified Health Risks – SCENIHR (2005): Opinion on The Appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies. European Commission SCENIHR/002/05.

Semmler-Behnke, M. et al. (2008): Biodistribution of 1.4- and 18-nm gold particles in rats. Small 4(12):2108-11.

Steinfeldt, M. et al (2004): Nachhaltigkeitseffekte durch Herstellung und Anwendung nanotechnologischer Produkte. Schriftreihe des IÖW 177/04.

Steinfeldt, M. et al.(2009): Entlastungseffekte für die Umwelt durch nanotechnische Verfahren und Produkte. Abschlussbericht FKZ des Umweltbundesamtes 20661203/02); Umweltbundesamt Texte 40/2009.

The Royal Society & The Royal Academy of Engineering (2004): Nanoscience and nanotechnologies: opportunities and uncertainties July 2004. (http://www.nanotec.org. /finalReport.htm)

U.S. Environmental Protection Agency (2005): External Review Draft: Nanotechnology White Paper.

VDI-Technologiezentrum: http://www.nanomap.de/ (retrieval on 06.03.2009).

Woodrow Wilson International Center for Scholars (2009): The Project on Emerging Nanotechnologies: (http://www.nanotechproject.org/inventories/consumer/analysis_draft/) (retrieval on 03.09.2009).

Annex

Activities of the German Federal Environment Agency

The German Federal Environment Agency intends to provide information on aspects of nanotechnology that are of relevance to the environment, fill gaps in knowledge and identify the need for further action. On the one hand it intends to support and encourage the positive effects of nanotechnology and ascertain environmental relief potentials; on the other hand it intends to identify risks for the environment and human health as well as to provide for their reduction.

Main emphases of future activities of the German Federal Environment Agency related to nanotechnology

The main emphasis of future Federal Environment Agency activities remains the assessment of eco- and ecotoxicological risks emanating from nanomaterials. For this purpose, the Agency is involved up to the end of the year 2010 in Phase 1 of the OECD Sponsorship Programme for compilation of complete data sets for several nanomaterials (general co-ordination in the case of titanium dioxide and responsibility for silver). From 2011, the Federal Environment Agency will participate in Phase 2 of the OECD Sponsorship Programme, in which, among other things, in-depth tests of additional endpoints and validation of test methods should be undertaken on the basis of experience gained in the initial phase. In connection with the OECD Sponsorship Programme, the Federal Environment Agency is preparing the carrying out of research projects concerned with the environmental behaviour and ecotoxicological short- and long-term effects of the nanomaterials titanium dioxide and silver. In addition, the Agency is involved in a research network of the Federal Ministry for Education and Research, whose task it is to gain insights into the behaviour, fate and effect of nanoscale silver in products. Within the framework of SKEP the Agency is supervising a research project on future developments and environmental effects of nanotechnology in convergence with other technologies of the future. A particular focal point will continue to be the adaptation of statutory regulations to the demands of nanotechnology. Agency activities concerning REACH and the Biocidal Products Directive will be continued.

The assessment of nanotechnical processes and products has to be enhanced. For this purpose, the Federal Environment Agency urgently requires an assessment instrument for nanotechnical processes and products regarding their advantages and disadvantages for the environment compared to conventional alternatives. In addition, it requires instruments for the assessment of nanotechnical developments that open up new functionalities, for which there are no conventional alternatives. Within the scope of this core area, the Federal Environment Agency plays a part in working groups of the OECD (Working Party on Manufactured Nanomaterials "Potential Environmental Benefits of Nanotechnology") and in the "NanoDialog"“ of the German Federal Government.

Research projects, expert reports, involvement in committees, publications and contributions to conferences

Summaries of research projects and expert reports on the topic (Table 1), involvement in committees as well as co-operative activities of the Federal Environment Agency (Table 2) are to be found below (for detailed descriptions of individual activities see Chapter 5).

Table 1: Research projects and advisory reports on the topic of nanotechnology commissioned by the Federal Environment Agency

Research projects / Expert reports	Period	Brief description
Legal Appraisal of Nanotechnologies – Rechtsgutachten Nanotechnologien (2007)	2007	In their Legal Appraisal of Nanotechnologies, Ökoinstitut – Institute for Applied Ecology and sofia – Society for Institutional Analysis addressed the need for regulation and the possibilities for regulation of nanotechnology within the existing statutory framework at a national and EU level. http://www.umweltdaten.de/publikationen/fpdf-l/3198.pdf
Technical procedure for the testing of nanoparticles – (Technisches Vorgehen bei der Testung von Nanopartikeln (2007)	2007	On the basis of evaluation of relevant literature on the environmental behaviour and ecotoxicology of nanomaterials, recommendations were made concerning the technical procedure to be followed in the testing of nanomaterials as well as the information that should be covered by the documentation obligation. http://www.umweltdaten.de/publikationen/fpdf-l/3484.pdf
Sustainable water management and nanotechnology – market of the future – Zukunftsmarkt nachhaltige Wasserwirtschaft und Nanotechnologie (2007)	2006-2007	The study investigates the technological development dynamics, economic potential and productive performance of the most important countries for nanotechnical products in the power supply industry. http://www.umweltdaten.de/publikationen/fpdf-l/3455.pdf
Assessment of the total environmental exposure of silver ions from biocidal products – Beurteilung der Gesamtumweltexposition von Silberionen aus Biozid-Produkten (2008)	2008	The risk of the release of silver into the environment had to be estimated. In addition, information was gathered on products containing silver and the quantities of silver employed, the fate and behaviour of silver in the environment, as well as ecotoxicological data on silver compounds and silver nanoparticles. On the basis of this data, the experts carried out risk estimation and highlighted gaps in knowledge http://www.umweltdaten.de/publikationen/fpdf-l/3673.pdf
Environmental relief effects through nanotechnical processes and products Entlastungseffekte für die Umwelt durch nanotechnische Verfahren und Produkte (2009)	2006-2008	The study identifies, on the basis of case studies, positive effects on the environment through the application of nanotechnology compared to conventional product solutions.
Investigations into the application of nanomaterials in environmental protection – Untersuchungen des Einsatzes von Nanomaterialien im Umweltschutz (2009)	2007-2008	The study investigates the opportunities and risks of nanotechnical products and processes in environmental protection.
Specific identification of synthetic nanoparticles in the air – Spezifische Identifizierung künstlicher Nanopartikel in der Luft (2009)	2007-2008	The study had the objective of describing the technical possibilities of identification of synthetic particles in air samples. Sources of nanoparticles of relevance to the air were identified, as well as their physiochemical properties and the release paths of nanoparticles from products. The report is supplemented with a survey of currently available analytical methods for the characterization of airborne nanoparticles and the technical possibilities for specific identification of synthetic nanoparticles.
Analysis of the toxicokinetics of nanoparticles in vivo – Untersuchung zur Toxikokinetik von Nanopartikeln in vivo (2009) 2007-2009	2007-2009	In the research project, the distribution of radioactively marked titania nanoparticles in rats was investigated following one-off inhalational exposure by means of quantitative, biokinetic analysis.
Study on the emission of nanoparticles during the life-cycle of selected products – Studie zur Emission von Nanopartikeln aus ausgewählten Produkten in ihrem Lebenszyklus (2010)	2008-2009	The aim of the study is estimation of the exposure of humans and the environment to synthetic manufactured nanomaterials during the life-cycle of selected examples, as well as of the possible effect on the environment.
Internal research: Measurement of abrasion particles from textiles		Investigation, by means of specific abrasion tests, into the influence of textiles of varied used and wear, which have been treated with titania nanoparticles, on the release of such particles.

Table 2: Involvement in national and international committees and co-operation

National and international committees and co-operation	Brief description
Research strategy of German federal superior authorities (with BAuA (general co-ordinator) and BfR)	In the joint research strategy entitled "Nanotechnology: health and environmental risks of nanomaterials" prioritized research topics were identified for risk assessment for the protection of humans and the environment.
"NanoDialog" of the German Federal Government (2006-2008; continued 2009-2010, with representatives of NGOs, industry, national research institutions and public authorities)	Participation in Working Group 1: "Opportunities for the environment and human health – efficient handling of resources and health protection" and Working Group 2: "Risks and safety for the environment and human health"
OECD Working Party on Manufactured Nanomaterials (WPMN) 2006-2012	Participation in the development and supervision of the "OECD Database on Research into the Safety of Manufactured Nanomaterials"; putting forward the research strategy of German federal superior authorities and national research projects. Participation in the OECD Sponsorship Programme (2006-2012) for the testing of 14 manufactured nanomaterials. Prime responsibility for titanium dioxide, partial responsibility for nanosilver and involvement with 4 other nanomaterials. Since March 2009 the Federal Environment Agency provides one of the vice-presidents of the WPMN. Participation in the "Steering Committee" for the "OECD Conference on Potential Environmental Benefits of Nanotechnology".
European network: Scientific Knowledge for Environmental Protection (ERA SKEP)	Participation in the joint European invitation to tender for a research project entitled "Opportunities and Impacts of Emerging Technologies for Environmental Regulation". Within the ERA SKEP network a "Technical Working Group" is responsible for the development of specific objectives and research issues.
DECHEMA/VCI Working Group "“Responsible Production and Use of Nanomaterials"	Involvement in the working group with the aim of supporting the economically and technically successful application of nanotechnology, taking account of ethical, ecological, societal and economic aspects.
National and international standardization	Informal participation in DIN NA 062-08-17 AA "Nanotechnologies" with four working groups: "Terminology and Nomenclature"“, "Measurement and Characterization", "Health, Safety and Environment" and "Material Specifications“, and in the ISO/TC 229 Task Group on Nanotechnologies and Sustainability.
Nanomaterials under REACH	The Federal Environment Agency is working closely in the area of implementation and adaptation of REACH to nanomaterials with other authorities concerned with risk assessment (BAuA, BFR) as well as the Federal Office for Chemicals and the European Chemicals Agency ECHA. An EU working group (Subgroup on Nanomaterials from the Meetings of REACH and CLP Competent Authorities) is working on concepts for the treatment of nanomaterials under the REACH Regulation. The Federal Environment Agency participates in discussions of this working group through the BAuA, which is responsible for general co-ordination for Germany.
Biocidal Products Directive	The Federal Environment Agency participates in discussions on the amendment of the Biocidal Products Directive, and advocates that biocidal active substances composed of nanomaterials, due to their particular properties, be treated as independent active substances with their own identity.

Bibliography

Umweltbundesamt (2006): "Nanotechnik: Chancen und Risiken für Mensch und Umwelt" Hintergrundpapier August 2006.

Becker, H. (2007): Gesundheitliche Risiken technisch hergestellter Nanopartikel. UMID 2/2007 S. 24-27.

Dubbert, W. und Rappolder, M. (2007): Nationale und internationale Aktivitäten zu den Chancen und Risiken der Nanotechnik im Umweltbereich. UMID 2/2007 S. 20-23.

BAuA-UBA-BfR (2007): "Nanotechnologie": Gesundheits- und Umweltrisiken von Nanomaterialien – Forschungsstrategie.

Bendisch, B. und Leuschner, C (2008): "Untersuchungsbedarf für Zwerge" – Testverfahren für Nanomaterialien bedürfen weiterer Entwicklung. Umwelt 9/2008 S. 485-486.

Conference contributions / lectures / posters

Dubbert, W., Märkel K., Rappolder M.: „Nanotechnologie, kleine Probleme – große Wirkung?, UBA-Kolloquium, 22.05.2006.

Rappolder, M.: „Nanotechnologie – eine Herausforderung für die regulatorische Ökotoxikologie", SETAC GLB, Landau, 05.09.2006.

Rappolder, M.: „Nanotechnologie: Kleine Teilchen – Große Wirkung", Tagung der KNU (Koordinierung Normungsarbeit der Umweltverbände) 28.09.2006.

Rappolder, M., Dubbert, W.: "The German Research Strategy", Treffen des Council for Science and Innovation (CST) UK im BMU, Berlin, 10.11.06.

Rappolder, M.: Nanotechnologien in vielen Lebensbereichen – Lassen sich die positiven und negativen Folgen für die Umwelt abschätzen? Tagung Ev. Akademie, BUND, Iserlohn, 05.05.2007.

Rappolder, M.: "Nanotechnology – The German Research Strategy for Environment and Health". SETAC Europe Porto, 20.-24.05. 2007.

Becker, H.: „Wirkungsbezogene Beurteilung von Nanopartikeln", SETAC GLB, Helmholtzzentrum für Umweltforschung - UFZ Leipzig, 12.-14.09.2007.

Rappolder M.: „Nanotechnologie – Chancen und Risiken für Mensch und Umwelt", Umweltkolloquium Landesumweltamt, Güstrow, 15.11.2007.

Leuschner, C. und Rappolder, M.: "Einsatz von Nanomaterialien – Untersuchungsbedarf zum Schutz der Umwelt", Workshop Photokatalyse Fraunhofer IME, Schmallenberg, 13.03.2008.

Hund-Rinke, K., Herrchen, M., Leuschner, C., Rappolder, M.: "Testing fate and effect of nanomaterials needs harmonized methodology to achieve – maximum synergism of results in this new area", SETAC Europe 2008, Warschau, 25.-29.05.2008.

Leuschner, C. und Aust, N.: "Untersuchungsbedarf zum Schutz der Umwelt – Nano-Silber in Alltagsprodukten", Evangelische Akademie, Villingst, 30.05.2008.

Rappolder M., Leuschner C., Dubbert, W.: "Nano-Silber in der Anwendung –Einschätzung im Umweltbundesamtes". Veranstaltung des Hessischen Ministeriums für Wirtschaft, Verkehr und Landesentwicklung und VCI-DECHEMA „ NanoSilber – Einsatzmöglichkeiten, Nutzen und Wirkmechanismen antimikrobieller Anwendungen. Frankfurt, 16. Juni 2008.

v. Gleich, A. (Uni Bremen) und Dubbert, W.: UBA-Projekt "Entlastungseffekte für die Umwelt durch nanotechnische Verfahren und Produkte", DECHEMA/VCI, Frankfurt am Main, 17.06.2008.

Leuschner, C.: "Untersuchungsbedarf zum Schutz der Umwelt – Aktivitäten des Umweltbundesamtes zur Nanotechnik", DECHEMA NanoNature Workshop, Frankfurt am Main, 26.08.2008.

Martens, S. (Golder Associates) und Dubbert, W.: UBA-Projekt "Untersuchung des Einsatzes von Nanomaterialien im Umweltschutz", DECHEMA/VCI, Frankfurt am Main, 13.10.2008.

Leuschner, C.: "Untersuchungsbedarf für Nanomaterialien – zum Schutz der Umwelt", Workshop ‚Nanotechnologie in der Landwirtschaft' Julius Kühn Institut, Kleinmachnow, 21.10.2008.

Dubbert, W. und Leuschner, C.: "Nationale und internationale Aktivitäten des Umweltbundesamtes zur Nanotechnik", 3. Symposium "Nanotechnology and Toxicology in Environment and Health", Helmholtzzentrum für Umweltforschung - UFZ, Leipzig, 18./19.03.2009.

Dubbert, W.: "Nanotechnology and its Potential Benefits for the Environment"=, ACHEMA 2009, Frankfurt am Main, 14.05.2009.