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baua: Bundesanstalt für Arbeitsschutz und Arbeitsmedizin

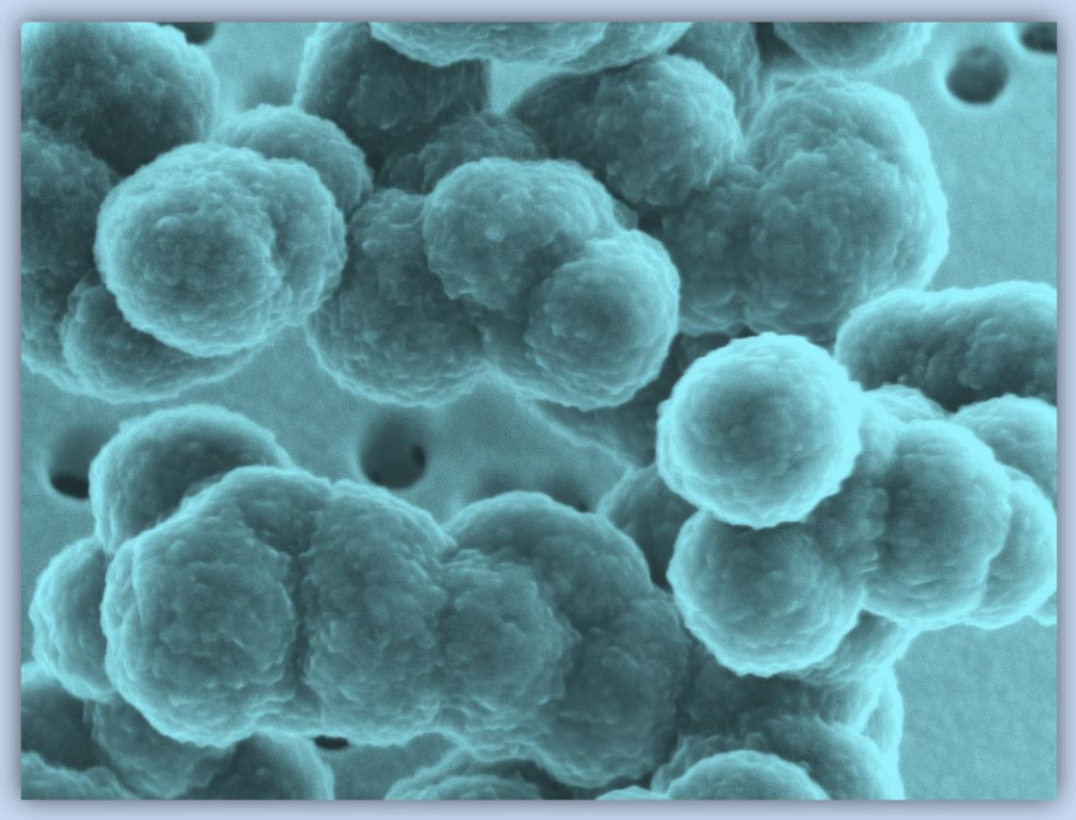
BfR Bundesinstitut für Risikobewertung

PTB Physikalisch-Technische Bundesanstalt Braunschweig und Berlin

Umwelt Bundesamt

Review of the joint research strategy of the higher federal authorities

Nanomaterials and other advanced materials: Application safety and environmental compatibility



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Cover Photo

Scanning electron microscopic image of an agglomerate of graphitized carbon particles, synthesized by chemical vapour deposition. The particles are located on a membrane with pores of 200 nanometres in diameter, giving an impression of the size scale.

Foreword

In a long-term research strategy, the German higher federal authorities responsible for human and environmental safety – the German Environment Agency (UBA), the Federal Institute for Risk Assessment (BfR), the Federal Institute for Occupational Safety and Health (BAuA), the Federal Institute for Materials Research and Testing (BAM) and the National Metrology Institute (PTB) – are accompanying the rapid pace of development of new materials from the points of view of occupational safety and health, consumer protection and environmental protection. The strategy is therefore closely linked with public funding programmes for research on nanomaterials and other advanced materials, such as those of the Federal Ministry of Education and Research (BMBF) ("From Material to Innovation") and the EU ("Horizon 2020").

The research strategy builds on the outcomes so far of the joint research strategy of the higher federal authorities launched in 2008 and first evaluated in 2013, "Nanotechnology: Health and Environmental Risks of Nanomaterials"[1], while additionally covering other advanced materials where these pose similar risks to humans and the environment or where such risks need to be studied. It also takes up the idea of application safety of chemical products[2] from the New Quality of Work (INQA) initiative of the Federal Ministry of Labour and Social Affairs (BMAS) and the concept of sustainable chemistry[3] endorsed by the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB). Application safety and environmental compatibility are aimed for advanced materials and derived products in order to largely rule out unacceptable risks to humans and the environment. This can be achieved by:

1. Using *safe materials* without hazardous properties for humans and the environment (direct application safety); or
2. *Product design* for low emissions and environmental compatibility over the entire product lifecycle (integrated application safety); or
3. Product stewardship, where producers support users in taking *technical, organisational and personal safety measures* for the safe use and disposal of products (supported application safety).

[1] http://www.baua.de/nn_47716/de/Themen-von-A-Z/Gefahrstoffe/Nanotechnologie/pdf/Forschungsstrategie.pdf

[2] http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/Nachhaltige-Chemie/Nachhaltige-Chemie.html

[3] http://www.umweltbundesamt.de/themen/chemikalien/chemikalien-management/nachhaltige-chemie

As a comprising part of the Federal Government's Nanotechnology Action Plan 2020, the update of the joint research strategy aims to contribute to governmental research in the following main areas:

- characterising and assessing the human and environmental risks of advanced materials
- Supporting research institutions and business enterprises
- Science-based revision of legal requirements and recommendations
- Public acceptance

The research strategy is to be implemented in projects and other research-related activities. These include governmental research, tendering and extramural research funding, and participation in mostly publicly supported projects with third-party funding. Additional activities will take place as part of policy advice and the ongoing work of the sovereign tasks of agencies involved. Interdisciplinary and transdisciplinary approaches will be used to better connect risk and safety research with innovation research and material development. In keeping up with the rapid pace of development, the time horizon for the research strategy is up to 2020. The research objectives address the research approaches likely to be actionable in this period. The research strategy will be supported by a working group and be evaluated and revised by the end of the Nanotechnology Action Plan 2020.

Research focus 1:
Ongoing development and scientific validation of test methods and approaches for characterizing and assessing in the human and environmental risks of advanced materials

Development of comprehensive approaches together with related test methods for characterising and assessing the risks for chemical substances and products for humans and the environment is the basis for chemical safety. Standardised testing and information obligations to address the risks of a chemical substance for humans and the environment are laid down in legislation such as the European chemical regulation, REACH[4]. With regard to advanced materials, however, there is the recurrent question of whether existing testing methods are applicable and adequate, and whether they will deliver scientifically robust findings for risk characterisation.

As with most international activities in this connection, the research strategy pursued by the higher federal authorities in Germany concentrated on the applicability of and the need for adjustments to existing testing methods and approaches for characterising and assessing risks to humans and the environment. The main focus was on nanomaterials already marketed on an industrial scale. It soon became apparent that the existing toolbox was not enough for assessing the risks to health and the environment. Specific testing methods had to be added that addressed the special characteristics of nanomaterials and other advanced materials with regard to their behaviour and their effects on biological systems.

For occupational safety and health, the priority here is on health risks of biopersistent, respirable particles. Among these, particles that combine high biopersistence with asbestiform fibres are considered highly critical. The fibrous nature of such particles is far more significant than their nano scale. This created an urgent need also to characterise, classify and assess fibres that have diameters bigger than 100 nanometres but are still respirable.

The need to modify and add to environmental testing methods mostly arises due to the specific behaviour of nanomaterials and how they differ in this regard from regular organic chemicals. This includes standardised methods for determining dissolution, agglomeration, and abiotic degradation and transformation in the environment. Differences in the behaviour of nanomaterials compared with organic chemicals also affect the significance of other test systems for environmental behaviour and effects. There is a need for guidance on introducing nanomaterials into test systems, on the accompanying analytics, and on interpreting the results of studies on environmental effects and bioaccumulation.

[4] Regulation (EC) No 1907/2006. REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals.

There is still substantial need for research to obtain reliable analysis of nanomaterials in complex consumer product matrices and different environmental compartments. Further, information about nanomaterial consumer products on the market and about consumer behaviour in relation to such products need to be improved as a basis for exposure estimation and the development of exposure scenarios. Research is also needed to develop and validate exposure estimation models. Special challenges are posed by unknown unknowns: entirely new risks that existing test methods and approaches are not (yet) able to identify. These call for ongoing prospective research based of mode of action hypotheses, experimental testing of such hypotheses, and screening instruments. Governmental research can contribute significantly here.

Test methods for risk characterisation of nanomaterials require elaborate equipment, extensive interdisciplinary expertise and many years of experience. Over time, research institutes, universities and other laboratories have compiled in-house procedures and work instructions based on good laboratory practice. However, the diversity of approaches impairs comparison between results and hence the ability to enforce legal requirements. Harmonisation requires precise specification of processes, parameters and procedures and extensive round robin tests to ensure comparability and reproducibility in procedures and work instructions. In the German research landscape, there is no provision for funding major round robin tests. The only channels for efforts to harmonise guidelines and procedures are therefore voluntary programmes (OECD-WPMN), standardisation (ISO) and legislation (such as REACH). Governmental research contributes suitable approaches here. The participating higher federal authorities also aim at greater involvement in and support for large-scale round robin tests to evaluate new testing methods by virtue of their special role at the interface between science and policy advice for progress of legislation. The provision of sufficient human and material resources is essential in order to keep up with the rapid rate of development.

a. Physicochemical characterisation

Nanotechnology is used to deliberately modify chemical substances and mixtures in order to achieve desired material properties. According to the definition proposed by the European Commission[5], nanomaterials are materials with structural elements smaller than 100 nanometres. The morphology of such materials can also be influenced in diverse ways. The interaction of chemical and morphological properties responsible for achieving desired material properties can affect the nature and magnitude of the risks for humans and the environment. Comprising and reliable physicochemical characterisation of the materials studied is therefore the basis for all risk research on nanomaterials.

With regard to released fibres, for example, fibre rigidity is now thought to be a significant factor in risk assessment for occupational safety and health purposes. In order to pick out

[5] http://nano.dguv.de/fileadmin/user_upload/documents/textfiles/Grundlagen/2011_696_EU.pdf

asbestiform fibres from the many different types of fibre on the market and in development, methods need to be developed that measure the rigidity of released fibres as a material property.

In the case of biopersistent granular particles, the lung-deposited volume of agglomerates or aggregates affects their toxicity. Agglomerated particles based on nanomaterials might be ascribed an ‘apparent density’ that is significantly lower than the density of compact particles (‘popcorn’ versus ‘sweetcorn’) and can result in higher toxicological potency. Methods to measure the apparent density of airborne particles, such as from combustion processes, already exist and need to be adapted to the specific properties of manufactured nanomaterials.

Like viruses, nanomaterials can be transported by endocytosis into cells, where they can cause acute or long-term harm. Major progress has been made in recent years in the quantitative and qualitative detection of nanomaterials in cells, but further research is needed. Notable challenges for the years ahead consist of localisation, visualisation and dose measurement in cells. Due to the complex conditions of biological milieus and interactions with biological matrices, nanoparticles are exposed to diverse influences that can result in physiochemical changes. Quantitative analysis of nanoparticles in biological systems is therefore insufficient. Visual imaging techniques have to be used as well in order to learn about where particles end up (such as translocation into secondary organs) and about their state (such as solubility and shape). Such techniques are so far only available to a limited extent.

A further core focus of governmental research is on reducing measurement uncertainty and on the traceability of measurement parameters to physical standards. Various measurement techniques in the nanoscale range are now so far developed that work can begin on traceability. This notably applies to the measurement of particle number concentrations and particle size distributions.

Information about morphology (particle size distribution; crystal structure) and surface properties (specific surface area; surface chemistry; charge) is also needed in order to properly interpret the behaviour and effects of nanomaterials in the environment. Environmental behaviour and bioavailability are additionally influenced by characteristics of the environmental compartments themselves (such as pH, salinity and naturally occurring organic compounds).

Important factors for the characterisation of nanomaterials from consumer products include measurement in the product and the demonstration of any release of nanomaterials through the intended use of the product. Nanomaterials in food contact materials, cosmetics and biocides are currently subject to different legal definitions and testing requirements. The definition applied in the risk assessment of cosmetics, for example, only covers insoluble or biopersistent industrially manufactured nanomaterials. The assessment of emulsions and very lipid-rich creams (such as sunscreens) is challenging, including for official inspectorates. While current work on the development of methodology focuses on inorganic nanoparticles, the characterisation of organic nanoparticles (such as pigments) will be a future challenge.

Research objectives

- Development of measurement techniques to determine the rigidity of released fibres as a material property
- Development of methods to determine the (apparent) density of nanomaterials and other advanced materials
- Development of a tiered strategy for material characterisation using simple, cost-effective testing methods to determine whether there is a need for more elaborate methods such as for toxicological studies
- Development of application-oriented reference nanoparticles and reference aerosols to improve the traceability and comparability of the measurement techniques used to characterise nanotechnology products
- Standardisation of dose determination and aerosol characterisation for toxicological testing methods (in-vivo and in-vitro)
- Evaluation and development of measurement techniques for material characterisation in the research sector with special focus on cost savings and on measurement comparability
- Development of measuring techniques for the characterisation of nanomaterials in order to improve the identification of their functionally relevant properties
- Evaluation and further development of visualisation methods for nanoparticles in in-vitro and in-vivo studies
- Development of standardised test guidelines for the determination of selected physicochemical properties of nanomaterials
- Chemical characterisation of the surfaces and composition of particles released from advanced materials
- Initialisation of and targeted support for round robin tests on the validation and comparability of existing and new testing methods for the characterisation of nanomaterials. Different legal requirements, such as food contact materials, cosmetics and biocides should be considered.

b. Hazardous properties; toxicological and ecotoxicological characterisation

The scientific knowledge available so far on the effects of nanomaterials and other advanced substances on humans and the environment relates to substances that have been on the market for some time and in some cases in large quantities. These include among others nano titanium dioxide, nanosilver and carbon black. However, large numbers of other materials are close to market launch. Among these are nanomaterials made of hitherto little-studied chemical substances (such as rare earth compounds) and materials with novel structures, surface modifications and dopings. Hazardous properties must be identified here reliably and as early as possible.

The toxicological characterisation hypotheses formulated under the previous research strategy need to be verified and ranked in targeted animal studies. This will make it possible to provide information on specific materials, and in particular on their carcinogenic effects. The studies are to be used to derive exposure-response relationships that provide the scientific basis for threshold and guiding values for occupational safety and health and consumer protection purposes (see C1). The development and standardisation of cost-effective screening methods without animal testing should also be vigorously pursued as a form of early warning system in which animal experiments are reduced in future to a necessary minimum. It is also essential for OECD test guidelines to be adapted to the specific requirements of nanomaterials and other advanced materials, for example with regard to the type of application, sample preparation and the selection of suitable measurement methods for determining concentrations.

The test guidelines on the determination of ecotoxicological effects also need to be specifically adapted for nanomaterials. Testing procedures currently allow a degree of leeway that can result in poor comparability of results when it comes to nanomaterials. It is necessary to identify where such leeway exists and to eliminate it by providing more precise guidance. This relates to instructions for introducing nanomaterials into test systems, the accompanying analytics, and interpretation and documentation of the results.

Research objectives: toxicity studies

- Animal studies on the chronic inhalation toxicity, carcinogenicity, and translocation of nanoscale, granular, biopersistent particles, such as nano cerium dioxide.
- Animal studies on the chronic toxicity and carcinogenicity of selected nanocarbons and comparison with screening instruments

Research objectives: Analysis of action mechanisms; methodology development

- Mobile screening techniques to detect indications of potential cell toxicity at an early stage in the material innovation process
- Identification of material properties determining toxicity (such as solubility, biopersistence and shape) and cell and tissue effects of nanomaterials in consumer applications
- Studies on the toxicological relevance of nanoforms with specific morphology (fibres, plates, etc.) or differing isomer characteristics
- Transcriptome, proteome and metabolome analyses to study the cellular changes induced by nanoparticles in order to screen for nanospecific effects and for early detection of hitherto unknown action profiles
- Development and validation of testing procedures for determining the biopersistence of granular particles
- Preliminary work towards semiempirical computational models (in silico) based on the generation of reference data and identification of relevant parameters

- Adaptation of OECD test guidelines on toxicology to the requirements of nanomaterials
- Methodology development and round robin tests to study the toxic effects of nanomaterials using in-vitro methods, and in particular methods to determine genotoxicity, oxidative stress and inflammatory effects
- Study of nanoparticle-induced cell death mechanisms (apoptosis and necrosis) for nanosilver using a flow cytometry method
- Development of comprehensive guidance with recommendations for properly carrying out aquatic ecotoxicological tests and ecotoxicological sediment tests with nanomaterials in accordance with OECD test guidelines

c. Release, exposure measurement and environmental behaviour

An important way of avoiding known and hitherto unknown risks is by minimising the exposure of humans and the environment to new materials. With no exposure, a hazardous property of a material cannot turn into a risk. Determination and estimation of exposure is therefore a further pivotal area in the development of methods for risk assessment. This not only relates to intended or unintended release during the use of the finished product. Suitable methods are also needed to measure exposure in the handling of the raw material, in the processing and handling of composite materials made from it, and in its use as an additive in composite materials (interactions with non-particulate additives such as catalysts). The manufacturing process (e.g. drilling or grinding) and the tools used are not the only decisive factors here. Particles can also be released during the intended use of a product (such as through diffusion or soaking) and through interaction with light. Processes that materials undergo at the end of the lifecycle are also important in exposure assessment. These include both recycling and complex environmentally degradation processes during disposal at landfills.

With regard to occupational safety and health in activities involving nanomaterials, exposure through inhalation has proved especially relevant for risk characterisation. The respirability of inhaled particles is very much more significant than their nano scale. Approaches to determining exposure in this connection focus on the measurement and morphological characterisation of respirable particulate fractions with particle sizes of up to about three micrometres. Traditional measurement methods for respirable particulates are mass-based and do not allow further morphological characterisation of the particles. A wide variety of particle-based measurement methods have been added in recent years. These range from direct display measurement devices showing particle number concentrations to breath collectors that allow the chemical and morphological characterisation of inhaled particles with the aid of electron microscopy. The various techniques have been incorporated in the meantime in an OECD-published strategy on exposure assessment for nanomaterials. However, the occupational safety and health stipulations based on a grouping approach create further requirements for governmental research. Studies are needed to determine what measurement methods can be used to test for the criterion, set by Committee on Hazardous Substances (AGS) assessment, of 0.5 mg/m3 for occupational exposure of granular biopersistent particulates consisting of manufactured nanomaterials, and to evaluate the importance of particle-number-based optical measurement methods. The meas-

urement strategy for respirable fibres that has been developed for asbestos must also be adapted for the correct detection of other types of fibre.

When it comes to consumer protection, not only inhalation but also the ingestion of particles is relevant for risk assessment, for example with regard to food safety. For consumer protection purposes, market analyses and surveys need to be carried out in order to obtain better data on exposed the section of the population due to the use of products featuring nanomaterials. Consumer behaviour surveys are to be conducted in order to derive and establish standard exposure scenarios. This relates among other things to the release of nanomaterials from textiles. Efforts are also underway to develop, adapt and validate quantitative exposure assessment models for consumers, as most available models were not specifically developed for exposure to nanomaterials. Since 2015, a model specially developed for modelling consumer exposure to nanomaterials in spray products has been available in the form of ConsExpo nano (https://www.consexponano.nl/). Such models are lacking for other routes of exposure. The scientific basis for determining internal exposure also needs to be improved, considering aspects such as absorption, distribution, metabolism and elimination. Statutory testing requirements also need to be adapted for food contact materials.

The relevant pathways into the environment must be identified in order to determine environmental exposure. This requires adequate knowledge about the manufacture, use, recycling and disposal of nanomaterials in products and applications and about the possibilities of release along the way. Entry into environmental compartments is possible e.g. via applications that are intentionally open to the environment or via improper disposal of nanomaterial products, respectively. Point discharges of nanomaterials may occur in wastewater treatment plants. Nanomaterials may be released during the use of a product by wear or product ageing (such as via weathering or leaching). The current challenge in this regard is to develop specific detection methods for nanomaterials that allow qualitative and quantitative analysis of environmental releases. Current research activities focus on studying the complex processes to which nanomaterials are exposed in the environment and which influence their properties and behaviour. Nanomaterials differ in environmental behaviour from regular organic chemicals. There is therefore a need to adapt and supplement exposure assessment models and test methods for determining the environmental behaviour, bioaccumulation, transformation and ageing of nanomaterials in relation to ambient environmental parameters.

Research objectives: occupational safety and health

- Testing and standardisation of personal monitors and breath collection systems for workplace particulate exposure and for consumer protection
- Determination of the dustiness and morphology of selected nanocarbons
- Development and validation of strategies to measure workplace inhalation exposure to fibrous nanomaterials
- Development of systematic approaches for the characterisation of different morphologies of workplace fibrous material aerosols

- Evaluation of optical instruments for measuring hazardous materials in the workplace

Research objectives: consumer protection and food safety

- Market analyses and surveys to obtain better data on the section of the population potentially exposed due to the use of nanomaterial products
- Development and establishment of standard exposure scenarios for consumer protection over the lifecycle of nanomaterials
- Studies on the release of nanomaterials from foods and composites in consumer products such as food contact materials and textiles
- Release and migration of nanoparticles from composite materials by ageing or abrasion, and validation of modelling approaches for release behaviour
- Chemical characterisation and source identification of interior and workplace air (including on the basis of indirect indicators such as household dust). This notably requires the refinement and validation of techniques for the chemical characterisation of airborne nanomaterials

Research objectives: environmental protection

- Development of methods for the study of transformation and ageing processes for nanomaterials in the environment
- Development of a standardised test guideline (OECD) for description of agglomeration and the agglomeration behaviour of nanomaterials in aquatic media
- Verification of the suitability of methods for routine detection (qualitative/quantitative) of nanomaterials in the environment
- Development of a decision tree to investigate the environmental behaviour of nanomaterials based on dissolution and agglomeration behaviour in relation to various environmental parameters
- Development of a test protocol for the investigation of of bioaccumulation of manufactured nanomaterials in filtering organisms
- Closing of knowledge gaps with regard to disposal of waste containing nanomaterials: Studies on the disposal in waste treatment plants of waste containing nanomaterials
- Closing of knowledge gaps with regard to disposal of waste containing nanomaterials: Studies on release of nanomaterials in connection with landfilling and soil spreading of waste
- Closing of knowledge gaps with regard to disposal of waste containing nanomaterials: Disposal of carbon-fibre-reinforced plastic waste using thermal processes

- Study of the dissolution and retention of inorganic nanoparticles in soil (bank filtration): Influence of natural organic coatings and the role of velocities in transport behaviour

Research focus 2:
Supporting research institutions and business enterprises in the development of advanced materials and derived products on the basis of application safety and environmental compatibility

Under applicable law, manufacturers and distributors have a statutory duty to identify inherent hazardous properties of chemical substances and products using international testing standards. The European chemical regulation, REACH, for example, provides for a testing programme that is tiered according to production quantities. For low tonnages, the regulation primarily requires tests for acute effects on humans and the environment. For the characterisation of long-term effects on human health and the environment, however, more elaborate studies are generally needed in order to obtain findings that can be relied on for regulatory purposes. These are therefore only required under REACH for higher tonnages, although other legislation such as the European Plant Protection Products Regulation and the EU Biocidal Products Regulation demand them regardless of production quantity. The testing and information obligations under these legislations, however, focus on well-known modes of action, and endpoints, of chemical substances; they do not include the information requirements needed in order to adequately describe the effects and behaviour of nanomaterials and other advanced materials.

If significant hazardous properties of advanced materials only emerge long after market entry, the consequences can be fatal. Hazardous properties of very high concern – such as carcinogenic, mutagenic or reprotoxic (CMR) properties – invoke serious statutory consequences that restrict the ability of products to be placed on the market and brought into use. Governmental research activities are also called for here in instances where advanced materials are financially supported by public funding programmes such as those of the BMBF or the EU. Early identification of the risks of new technologies for humans and the environment in ongoing and well-resourced prospective research is therefore one of the most important tasks of governmental research. This includes the ongoing development of existing test methods together with risk research carried out in parallel with innovation activities. Such research should test known modes of action on new materials while also looking to identify previously unknown risks and scientifically verify new mode of action hypotheses. The goal is to promote advanced materials on the basis of application safety and environmental compatibility and to avoid misallocation of public and private sector investment spending together with the social follow-up costs.

Research on nanomaterials to date has shown – among other things by the example of the potential health risks of carbon nanotubes – that scientific insights into the potential risks and proportionate risk management are possible early in the material innovation cycle. The Committee on Hazardous Substances (AGS) thus now distinguishes in its occupational safety and health recommendations between rigid and non-rigid forms of nanomaterials. Frequently, however, the necessary knowledge of methods and evaluation findings is restricted to scientists who study human and environmental effects. The cooperation of material scientists with experts from risk and safety research should therefore be supported to pursue responsibility with regard to the safe development. Knowledge in relation to material

and product design on the basis of application safety and environmental compatibility must be incorporated into the innovation process from an early stage.

a. Design criteria for application safety and environmental compatibility in advanced materials

The approaches and testing methods for the early detection of health and environmental risks set out in Section A can be used to develop and test designs of advanced materials and derived products which feature both application safety and environmental compatibility. This requires analysis of research findings to identify material modifications that avoid risks to health and the environment. A well-known and successful example from the late-1990s was the substitution of biopersistent mineral wool with biosoluble products that largely rule out any cancer risk. It is necessary to investigate whether similar design criteria can be derived for other new materials. With regard to human health, for example, the possibility of using in-vitro and in-vivo methods should be assessed for determining the biosolubility of granular and fibrous materials and their relationship to response and potency in the human organism. Methods to measure dustiness can be used to identify low-emission forms of new materials or deliberately to create such forms by modifications to the materials. This provides starting points towards an integrated application safety approach that uses good product design to prevent significant releases of and human and environmental exposure to hazardous substances over the product lifecycle. With regard to the environment, criteria and properties need to be identified that allow corresponding conclusions to be made in relation to ecotoxicological endpoints.

An additional aspect is the improvement of technical processes for the manufacture of nanomaterial products. Release of materials during production and use should be avoided. The same goes for disposal and recycling processes applied to nanomaterial products. It must be ensured in such processes that no hazardous concentrations of nanomaterial constituents can be released and enter exhaust air or waste water.

Alongside these risk-related aspects, consideration should also be given in design to the potential benefits of using nanomaterials. Factors to be taken into account when modelling environmental benefits of nano-enabled applications and products have to include additional criteria such as reductions in resource consumption (energy, water and raw materials), avoidance of greenhouse gas emissions and other environmentally harmful emissions, and reductions in the quantity and hazardousness of waste. Other aspects requiring consideration are benefits to the consumer (improved product utility/safety in use) and benefits to employers and workers (improved handling/safety; workplace health improvements).

Research objectives

- Development of a ‘pre-REACH’ testing strategy for risk characterisation and assessment of new materials at early stages of the innovation cycle
- Identification and establishment of criteria for the design of manufactured nanomaterials on the basis of application safety and environmental compatibility

- Development of assessment criteria and standardised test methods for low-emission material design
- Industry dialogue on environmental analysis of smart and active packaging with regard to recyclability
- Derivation of a risk matrix as a basis for the design of nanocarbons to ensure application safety
- Derivation of environmentally compatible nanomaterials by means of comparative long-term studies of the aquatic ecotoxicology of different forms of selected nanomaterials

b. Increasing awareness and improving the knowledge base among researchers and business enterprises with regard to application safety and environmental compatibility in the use and design of material innovation

Research institutions and university spinoffs play a key role in the development of new materials on the basis of application safety. Experience over many years show that technically oriented institutions especially tend to lack occupational safety and health expertise that goes beyond minimum standards of laboratory safety and promotes the safe design of material innovation. ‘Safe by design’ criteria must be made an integral part of operational innovation management. Medium-sized and large enterprises use a stage-gate model for this purpose, with defined multidisciplinary work phases (stages) and decision points (gates).

This established approach needs to be supplemented by integrating tiered, proportionate, pre-regulatory requirements for a test strategy that cover human and environmental safety aspects. In collaboration with interested institutions and business enterprises, private-public governance networks are to be established or linked into existing networks in order to develop and disseminate design approaches for new materials based on application safety and environmental compatibility. The establishment of such networks will be supported and evaluated in the launch phase by governmental research institutions. The goal is a strategic approach that, for example, the Federal Government can make use of in the context of innovation funding in order to better link up material development with occupational health and safety, consumer protection and environmental protection concerns.

A further objective is to raise awareness among aspiring researchers and product developers for occupational safety and health issues and for application safety and environmental compatibility in the design of new materials and products. The Federal Institute for Occupational Safety and Health (BAuA), for example, provides course offerings to this end for students at an advanced stage of a bachelor’s or master’s degree in the natural sciences at the Technical University of Dortmund.

Research objectives

- Development of model governance networks with research institutions and start-ups in Germany to support application safety in the design of advanced materials
- Practical guidance on safe and environment-friendly practice in working with materials in laboratories, pilot plants and start-ups
- Sample lectures on the legal framework, occupational safety and health measures and application safety in the design of nanomaterials and other advanced materials

Research focus 3: Science-based revision of legal requirements and recommendations ensuring safety and environmental compatibility over the entire lifecycle of advanced materials

Nanomaterials, other advanced materials and products based on them must meet the requirements of European statutory provisions related to chemical and product safety. Occupational health and safety law, consumer protection and environmental protection rules may additionally apply. Before they can be placed on the market, substances and mixtures must be classified and labelled with regard to any hazardous properties in accordance with best available knowledge. A safety data sheet must be provided for commercial customers. Certain product groups such as biocides are subject to authorisation obligations. In addition, require a labelling for nanoscale constituents exists. Labelling requirement must also be noted for consumer information purposes in the case of cosmetics and food additives. The testing and information requirements under the various areas of legislation also stipulate the standardised tests that applicants and registrants must perform for risk characterisation. As noted in Section A, however, there are significant gaps in those requirements with regard to advanced materials These relate to description of the identity of the substance, exposure assessment, and the determination of hazardous properties and risks. An example is the potential risks to workers from respirable biopersistent particulates released by nanomaterials and other advanced materials.

Governmental research is required to generate a high-quality scientific basis so that ministries can be provided with well-founded advice on the revision of existing legislation while keeping up with the major and rapid progress in material development. Testing and assessment methods have to be adapted or even newly developed in a short period of time.

a. Integration of transparency and specific testing, risk assessment and information requirements in existing rules and regulations governing chemical safety, occupational safety and health, environmental protection and consumer protection.

The testing and information requirements under statutory provisions relating to chemical and product safety legislation do not yet adequately cover a number of risks to humans and the environment that can arise from nanomaterials and other advanced materials. The higher federal authorities in charge of chemical safety in Germany (UBA, BfR and BAuA) consequently formulated recommendations as early as 2012 for additions to the testing and

information requirements for nanomaterials under REACH as a contribution to the European debate.[6]

Given the large number of nanomaterials and other advanced materials, however, individual testing and assessment involves enormous effort and expense. Established approaches exist for grouping chemical substances into substance groups. The objective of substance grouping and analogy concepts is to predict physicochemical, toxicological and behavioural properties of chemical substances on the basis of structural similarity. Given sufficient arguments in favour of grouping, this allows available data, for example on the hazardous properties of a substance, to be read across from that substance to another. The established approaches do not yet include specific procedures for nanomaterials, however. Criteria allowing groups to be derived grouping and data to be read across between nanomaterials have yet to be developed. This requires the identification of parameters that determine the comparability of nanomaterials or nanoforms.

Grouping approaches have already been successfully derived for nanomaterials on the basis of findings from risk research, although so far solely in relation to workplace hazards. A focus of the present research strategy is the development of grouping approaches specifically for risk assessment in other areas of concern, such as environmental protection.

Significant risks for occupational safety and health include the health risks of inhaling biopersistent particles which primarily accumulate in the lungs and whose long-term toxicity in many cases has not yet even been identified and classified. Such risks can therefore be highly important for risk management with regard both to nanomaterials and to other materials that do not fall under the EU definition of nanomaterials. Special attention should be paid to fibrous particles. It cannot be ruled out that a number of such materials pose risks similar to asbestos that cannot be reliably identified with the current testing requirements under REACH. To clarify the occupational safety and health requirements in Germany, the Committee on Hazardous Substances (AGS) has classified manufactured nanomaterials in an announcement (BekGS 527) into four groups, each with health-based assessment criteria for workplace exposure. These group-based parameters can be revised if material-specific testing data are established or can be read across from similar materials. In addition, to minimise hitherto entirely unknown risks, all chemical substances are subject to the application of minimum standards involving simple measures to prevent high exposures in general.

The grouping approaches for derivation of workplace hazards common to multiple substances can be used to derive targeted testing and information requirements. For the determination of biopersistence and carcinogenicity of respirable fibres, for example, there are specific toxicological test designs which close the gaps in the standard test strategy. So far, however, these have only been incorporated into EU law in the case of mineral wools. In addition to the recommendations already formulated for revision of the REACH requirements, the higher federal authorities are preparing further specific testing and information

[6] https://www.umweltbundesamt.de/publikationen/nanomaterials-reach

requirements for comprehensive protection against respirable biopersistent particulates. A central element of these consists of mandatory dustiness tests whose results provide the basis for the remaining testing requirements.

The nanomaterial testing and information requirements formulated by the higher federal authorities are provided with further scientific underpinning by subjecting selected nanomaterials to substance evaluation under REACH. Experience is also analysed from other regulatory areas where specific evaluation of nanomaterials is already mandatory by law, such as for biocides. The higher federal authorities also participate in the development and adaptation of guidances for nanomaterial risk assessment issued by European authorities such as the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA). A further focus of the higher federal authorities is on the development and evaluation of in-vitro test systems that in the medium term will supersede the animal studies generally required today, or at least that can be used for screening and hence to limit the need for further testing. Work is underway in parallel on the transferability of toxicological data from animal studies to humans and on adequate handling of the uncertainties by the development of corresponding guidelines. Generally, toxicity in animals is tested for a limited range of potential effects and a limited exposure period. When transferring findings to humans, the effect of interspecies and intraspecies differences in susceptibility and to the potential existence of highly sensitive subpopulations needs to be considered.. If there is a difference in timeframe between toxicological testing and predicted exposure, it is necessary to extrapolate accordingly at both the qualitative and the quantitative level. It is also frequently unclear whether a toxicologically tested nanoform is identical with the form to which the subject is exposed during the lifecycle of a nanomaterial and whether differences in particle size, surface properties and reactivity significantly affect the (eco)toxicological potential.

Inadequate testing and information requirements in chemical legislation can have a very large impact on consumer and environmental protection objectives. In the absence of specific rules, such as those which apply in occupational safety and health, the fulfillment of protection objectives is solely determined by the manufacturer’s or importer’s responsibility for substance and protect safety. From a consumer and environmental protection perspective, the data gaps that remain to be filled make it necessary to keep in focus the lifecycle of relevant materials and related products with a view to traceability.

Research objectives

- Evaluation of standardised dustiness tests as a future basic requirement for REACH registration of poorly soluble solids
- Development of methods for the morphological characterisation of biopersistent particles (notably fibres) in the context of REACH registration
- Development of an enforceable procedure for testing and assessing the rigidity, biopersistence and carcinogenicity of respirable fibrous particulates
- Development of test methods for biopersistent granular fibrous particles for the inference of material-specific health-based limits and reference values, e.g. DNEL

- Grouping of nanomaterials for a joint assessment of environmental fate and effects for regulatory purposes
- Specification of criteria for grouping nanomaterials with regard to superordinate risk grouping taking into account hazard and exposure potential for humans and the environment
- Application of nanomaterial grouping with regard to physicochemical properties and toxicity testing, including consideration of toxicity mechanisms
- Improvement of the available data on nanomaterial consumer products in the market; analysis of market overviews and national product registers; use of labelling requirements; market information request among manufacturers
- Incorporation in risk assessment of information and data on solubility/(bio)degradation of nanomaterials and released particulates, taking into account surface specifications (stabilisation layer; surface modification) and internal particle components (particle core)

The research activities set out above are closely bound up with scientific policy advice by the higher federal authorities for evolution of the legal framework and with testing and evaluation responsibilities under chemical and product safety law. This notably includes:

- Evaluation of available testing data and preparation of a dossier for harmonised classification of carcinogenic forms of carbon nanotubes under the EU Regulation on Classification, Labelling and Packaging of Substances and Mixtures (the CLP Regulation)
- Participation in the European Chemicals Agency (ECHA) Nanomaterial Working Group (NMWG). The NMWG is made up of representatives of competent authorities in EU member states and observers from industry and non-governmental organisations. It is tasked with nanomaterial-related issues of regulatory relevance and with advising the ECHA in areas such as the development of guidance clarifying the requirements under REACH. Key aspects include physicochemical characterisation, information requirements and analogy concepts (grouping, categorisation and read-across)
- REACH substance evaluation of nano cerium dioxide, multiwall carbon nanotubes and nano zinc oxide
- Involvement in risk assessment of nanoscale amorphous synthetic silicon dioxide (SAS) and products with nanoscale constituents under the EU Biocides Regulation
- Participation in the Competent Authority Sub-Group on Nanomaterials (CASG Nano), a subgroup of CARACAL (Competent Authorities for REACH and CLP). The objective of the subgroup is exchange on regulatory issues concerning nanomaterials in relation to the CLP Regulation and REACH. CASG Nano discusses the adaptation of REACH for nanomaterials and other regulatory aspects such as the EU definition of nanomaterials and a register of nanomaterial products

- Participation in the European Food Safety Authority (EFSA) Scientific Network on Risk Assessment of Nanotechnologies in Food and Feed and in the EFSA Steering Committee Working Group (EFSA SC WG) on guidance on the human, animal and environmental risk assessment of the application of nanoscience and nanotechnologies in agro/food/feed
- Activities in the Working Party on Manufactured Nanomaterials (WPMN) and the Working Group of the National Coordinators of the Test Guideline Programme (WNT) of the OECD Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology, adaptation of OECD test methods and guidelines, and refinement of risk assessment instruments. The objective of the WPMN is to address safety issues relating to nanomaterials in international collaboration. The WPMN is made up of over 100 experts representing stakeholders from OECD member states and non-member states, along with experts from international organisations (UNEP, WHO, ISO, BIAC and TUAC). A key thematic area is the systematic identification of suitable parameters for grouping and read-across.
- Involvement in the scientific committees on consumer protection of the European Commission Directorate General for Health and Food Safety
- Participation in working groups of the Committee on Hazardous Substances (AGS) on approaches for the grouping of nanomaterials, the derivation of assessment criteria and workplace limit values, and the recommendation of suitable occupational safety and health measures
- Involvement in the DIN Committee on Nanotechnologies (mirror committee to the ISO Committee on Nanotechnologies)
- Secondment of an expert to the World Health Organization (WHO) guideline development group, WHO Guidelines on Nanomaterials and Workers' Health, which has the aim of producing international evidence-based occupational safety and health recommendations for activities involving manufactured nanomaterials

b. Good practice for safety to human health and the environment in production, use and disposal

The well-proven occupational safety and health measures required in the Particulate Hazardous Substances section of the Annex to the Hazardous Substances Ordinance (GefStoffV) are sufficient and effective with regard for activities involving nanomaterials. Announcement 527, "Manufactured Nanomaterials", published in 2013 by the Committee on Hazardous Substances (AGS) clarifies those measures on the basis of grouping with health and risk-based assessment criteria. These assessment criteria also make it possible for the Easy-to-Use Workplace Control Scheme for Hazardous Substances (EMKG) – Federal Institute for Occupational Safety and Health (BAuA) guidance on risk assessment in small and medium-sized enterprises – to be applied to various activities involving nanomaterials. Two-page control guidance sheets provide specific information on safe working practices. In 2011, BAuA began systematic evaluation of EMKG control guidance sheets using systematic measurement of hazardous substance concentrations at affected workplaces. The first project focused on filling processes for solvents. The second is to address

the handling of dust-generating solids. This includes activities involving nanomaterials. As an outcome, the control guidance sheets will be brought into line with best available technology with the addition of video sequences for workers showing the right and wrong way to apply the protective measures.

It has proven harder in research conducted so far to derive occupational safety and health, environmental protection and consumer protection measures for the processing of composite materials in which new materials are integral constituents. Both the type of processing and the resulting exposures as well as the nature of the composite material, its constituents and method of production are important for risk assessment here. Further research aims to derive requirements for low-emission processing methods that can be used, for example, as a basis for clarification of requirements under European law on machine and equipment safety and the applicable standards. Research will also look into whether and how the resulting knowledge can be applied to activities at the end of the lifecycle of composite materials, such as in recycling or disposal.

With regard to the environment-friendly manufacture of products, too, the aim is to continuously adapt and refine production processes in line with best available technology in order to reduce environmentally harmful emissions and make more efficient use of valuable resources. In implementation of the Industrial Emissions Directive (2010/75/EU), for example, BAT reference documents[7] are compiled that reflect the performance of systems and technologies with regard to emissions and resource, water and energy consumption. Applications involving nanomaterials will play an increasing role in this regard.

Research objectives

- Evaluation and updating of EMKG control guidance sheets for activities involving dust-generating materials at work using field studies; production of video sequences for worker instruction
- Continued development of the Nano to Go (www.baua.de/nanoToGo) guideline with training material on occupational safety and health and on safe material design for research institutions and business enterprises
- Derivation of recommendations on low-emission processes for composite materials containing nanocarbons

[7] BAT: Best available technique

Research focus 4: Formulation of recommendations for risk communication to promote public acceptance of nanotechnology and material innovations

Good governance with regard to nanomaterials and other advanced materials includes the ongoing revision of laws and recommendations to take into account the outcomes of risk research and assessment together with the formulation of strategies for appropriate risk communication. A wide spectrum of scientific knowledge is now available to confirm the picture of a highly complex risk map that is far more nuanced than the 'nanoconcern' that came before. For effective, participative risk communication, it is necessary to survey current risk-benefit perceptions in the general public and the media. Existing information, communication and consultation offers are to be evaluated in order to further improve target group-specific communication of chances and risks. A key factor here is the provision of readily understandable safety and environment information along the advanced material supply chain.

a. Investigation of public and media perceptions of risk

Research is to be conducted to determine whether the more nuanced 'risk map' for nanomaterials has led to change in public risk perceptions and media presentation. This research will also take into consideration the growth of online social networks.

Research objectives

- Conduct of representative public surveys on perceptions of nanotechnology and its applications
- Conduct of focus groups with subgroups of the population on selected issues in connection with nanotechnology and its applications
- Analysis of communication about nanotechnology and its applications in social media (including chats, blogs and Internet forums)
- Analysis of coverage in print and online media about nanotechnology and its applications

b. Development of target group-specific risk communication strategies

Both material innovation and the generation of scientific data relevant for risks and risk management measures proceed at a rapid pace. Because of this, special efforts are needed to ensure that all relevant target groups are able to act on current information. The German Federal Government's NanoDialogue makes a key contribution in this regard, as do other activities such as those of the federal states and accident insurance providers.

These activities are to be subjected to academic evaluation in order to further improve and sustain target group-specific risk communication. A campaign planned for 2018/19 by the European Agency for Safety and Health at Work (EU-OSHA) to boost prevention in the production and use of chemical substance will also be used to improve risk communication on advanced materials.

Research objectives

- Evaluation of existing information, communication and dialogue activities on nanotechnology
- Development of target group-specific visualisation tools to increase awareness and understanding of nanotechnology and the chances and risks of nanotechnology applications
- Conduct of dialogue processes with various stakeholder groups on chances and risks of nanotechnology and its applications
- Preparation of activities for research institutions and startups in the development of material for the European Agency for Safety and Health at Work campaign 2018/19 on “Establishing a Prevention Culture on Dangerous Substances while Targeting Specific Groups of Workers”.

c. Improvement of safety and environment information along the supply chain of advanced materials

Hazard labelling of chemical substance and mixtures is now globally standardised with pictograms and risk and safety phrases, and is the most important risk communication tool along the supply chain. Suppliers additionally provide commercial customers with a comprehensive safety data sheet. This is also the central source of information for employers in the conduct of statutory workplace risk assessments and the choice of occupational safety and health measures. Further labelling and information requirements apply for specific product groups, for example to provide consumers with information about the ingredients of cosmetics or foods. How to attain transparency and appropriate communication of risk and risk management measures with regard to nanomaterials and other advanced materials is currently a subject of expert debate. This applies most of all to substances and mixtures for which there is not yet adequate scientific data for risk assessment. A satisfactory solution has yet to be found for indicating the presence of potential hazards in composite materials such as the release of reactive or biopersistent particles in the processing or use of such materials or in recycling or disposal at the end of their lifecycle. The use of nanomaterials in products and materials can also lead to contamination of recycled material, making it difficult to perform high-quality recycling and close material cycles for the purposes of the Federal Act to promote closed cycle waste management and environmentally sustainable waste disposal (Kreislaufwirtschaftsgesetz).

REACH requirements have led to a significant increase in the extent of information of safety data sheets for registered substances, however. For SMEs especially, this makes it harder to use the information, for example in workplace risk assessment. One solution

could be EU-coordinated control banding approaches where the wide variety of risk management measures are covered in a small number of control strategies that are clarified for frequently encountered activities in standardised, brief control guidance sheets.

Research objectives

- Use of control banding approaches to simplify supply chain communication on chemical substances and mixtures
- Production of video sequences clearly demonstrating the safe handling of dust-generating materials for worker instruction
- Industry dialogue on environmental analysis of smart and active packaging with regard to recyclability and dialogue with stakeholders from disposal and manufacturing industries

Profiles of the participating higher federal authorities

a. Federal Institute for Occupational Safety and Health (BAuA)

Safe and healthy working conditions mean social progress and a competitive economy. The Federal Institute for Occupational Safety and Health (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin/BAuA) conducts research and development in the field of safety and health at work, promotes the transfer of knowledge into practice, advises policymakers and performs sovereign functions – under hazardous substances law, in product safety and with the health data archive. The BAuA is a governmental research institution within the purview of the Federal Ministry of Labour and Social Affairs (BMAS).

The Federal Institute for Occupational Safety and Health (BAuA), as Federal Office for Chemicals, is responsible for the implementation of legislation aimed at protecting people and the environment from hazardous substances. It performs statutory tasks with international activities in the field of regulation of industrial chemicals and the authorisation and evaluation of biocidal products. In the process, it acts as a national and international interface.

Division 4 is responsible for improving the protection of employees working with hazardous substances and biological agents (pathogens). It describes their risks, evaluates them and suggests measures to lower the risks for the employees to an acceptable level. This work is based on results from research and development (R&D) as well as many years of experience with legal obligations and political consulting.

In research and development, the BAuA has extended its focus beyond nanomaterials to other newly developed materials (advanced materials). The BAuA refines measurement and testing methods and conducts morphological and toxicological studies to generate a sound basis for the assessment of potential workplace health risks. Attention currently centres on studies on dust generation from substances, the shapes, surfaces and size distribution of released particles, and their biopersistence and cell toxicity as indications of potential risks. The medium-term goal of these activities is the coherent integration of protection against respirable particulates and fibres in EU chemical safety regulations. In addition, the BAuA aims to establish governance networks enabling research institutions and business startups to detect risks to humans and the environment as early as possible. This will promote design on the basis of application safety and the safe use of advanced materials.

b. German Environment Agency (UBA)

The mission statement of the German Environment Agency (Umweltbundesamt/UBA) is “For our environment” (“Für Mensch und Umwelt”). Founded in 1974, UBA is Germany’s central environment agency within the purview of the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB). Its main statutory responsibilities are as follows:

- Scientific support for the Federal Government (including the ministries responsible for the environment, health, research, transport, building and urban development)
- Enforcement of environmental law (such as on emissions trading, authorisation of chemicals, biocides, pharmaceuticals and plant protection products)
- Protection of human health from environmental pollution, and health-related environmental monitoring
- Public information on environmental protection

Identifying tomorrow's problems today: The UBA regards itself as an early warning system that provides timely detection of potential future impacts on humans and the environment, assesses them and proposes practicable solutions with the objective of sustainable development. For this purpose, UBA experts carry out research in the agency's own laboratories and award research contracts to scientific institutions in Germany and abroad. The UBA acts as partner and Germany`s focal point to numerous international organisations such as the WHO. It works closely together with global bodies, institutions and state entities, for example in Europe, the USA and Asia (among them the United States EPA, the Center for Disease Control and Prevention, the OECD and UNEP).

Organised in five divisions and a general services division, the UBA employs a staff of some 1,500 at 13 locations, including seven stations in its air quality monitoring network. Over 900 members of staff work at the headquarters in Dessau-Roßlau.

The UBA actively contributes towards providing information about environmental and health aspects of nanotechnology, closing knowledge gaps and identifying further needs for action. It supports the responsible use of nanomaterials by taking an active part in discussions on the considerations of the special features of nanomaterials in national, European and international chemical safety law.

c. Federal Institute for Risk Assessment (BfR)

The Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung/BfR) bases its work in the field of consumer health protection on the guiding principle of "Identify Risks – Protect Health". BfR was set up in November 2002 to strengthen consumer health protection and reports to the Federal Ministry of Food and Agriculture (BMEL). It is the scientific agency of the Federal Republic of Germany responsible for preparing expert reports and opinions on food and feed safety and on the safety of chemicals and products. The Institute thus plays an important role in improving consumer protection and food safety. It is independent with regard to its scientific assessments and research.

Its tasks include assessing existing and identifying new health risks, drawing up recommendations on risk reduction, and the communication of this process. BfR is mandated to conduct research in relation to its activities. The results of its work serve as the basis for scientific advice to the relevant federal ministries and other agencies such as the Federal Office of Consumer Protection and Food Safety (BVL) and the Federal Institute for Occupational Safety and Health (BAuA). In its assessments and recommendations, BfR is not influenced by any economic, political or social interests. The Institute works on the basis of

internationally recognised scientific assessment criteria. A scientific advisory council and several expert committees support BfR in its work. A further focus of its work is cooperation with the European Food Safety Authority, EFSA, for which purposes BfR is the national EFSA Focal Point. BfR also works closely with other national and international bodies.

The tasks of BfR include risk assessment of nanomaterials in consumer products, foodstuffs, feeds, chemicals and pesticides, together with related risk communication. In relation to these topics, the Institute has a part in a large number of national and international research projects, with areas of focus comprising the development of sensitive detection methods, studies on bioavailability, and the development of the scientific basis for grouping approaches.

d. Federal Institute for Materials Research and Testing (BAM)

The Federal Institute for Materials Research and Testing (Bundesanstalt für Materialforschung und -prüfung/BAM) combines research, assessment and advice in technology and chemistry under a single roof. It makes important contributions with regard to nanotechnology in line with its mission of “safety in technology and chemistry” by developing test methods and reference materials, contributing its scientific expertise in standardisation and thus furthering quality assurance. BAM places the focus with regard to the use of nanomaterials on safety and reliability. It is also involved in a wide range of research activities and projects on material science questions and in the development of measurement and testing methods, chemical nanoanalytics and nanoscale reference materials.

e. National Metrology Institute (PTB)

The German National Metrology Institute (Physikalisch-Technische Bundesanstalt/PTB) is a higher federal authority and research institute for science and technology under the Federal Ministry for Economic Affairs and Energy (BMWi). The PTB is based in Braunschweig and Berlin. It consists of 10 divisions and employs a staff of some 1,950 at its two locations.

The core competence of the PTB is metrology – the science of measurement and its application. Its tasks include fundamental research and development in metrology as the basis for all other statutory tasks, notably to lay the foundations and create the infrastructure for meeting future requirements demanded of metrological services. Research and development work amounts to about two thirds of all of PTB's activities.

Its work is focused on the following areas:

1. Fundamentals of Metrology: Realization, maintenance and dissemination of the SI units (Systeme International d’unités, the global system of units for physical quantities such as second, metre, kilogram etc.). Research accounts for a major share of work in this core thematic area and covers substantial areas of modern natural and engineering sciences.
2. Metrology for industry: A highly developed metrological infrastructure and the availability of top-level metrological expertise to support the development of new technologies is essential to an export-driven economy. By developing standards, refer-

ence measurement methods and approved measurement processes, the PTB provides the basis for precise and reliable measurement and testing in trade and industry while ensuring the necessary knowledge transfer.

3. Metrology for society: In broad areas of public life, there is strong interest in correct measurements and reliable measuring instruments covered by legal metrology. For this purpose, the PTB carries out type examinations and conformity assessment of measurement devices in the context of national and European legislation.
4. International issues: The PTB's tasks include contributing to internationally uniform metrology and hence combating non-tariff barriers to trade. This includes collaboration with other national metrology institutes, playing a major role in international bodies and technical and economic cooperation with developing and emerging countries. Through its involvement in standardisation, quality assurance and testing, including accreditation and certification, the PTB serves export-driven German industry.