Federal Ministry
of Education
and Research

THE NEW
HIGH-TECH
STRATEGY
Innovations for Germany

Action Plan Nanotechnology 2020

An inter-departmental strategy of the Federal Government

THE NEW HIGH-TECH STRATEGY

Innovations for Germany

Leading an innovative Germany

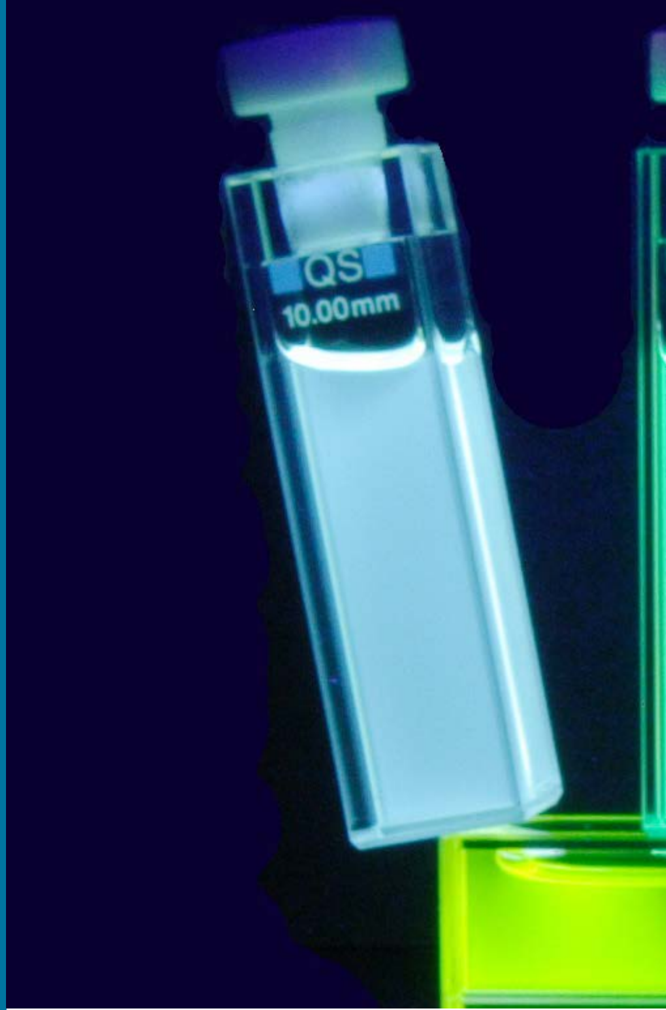
New products and services are developed from good ideas, made in Germany. They are in demand worldwide and safeguard our prosperity and our quality of life. Innovative solutions have already been found for many pressing issues and challenges for the future. In other fields, further research and experimentation will be necessary. That is where a new High-Tech Strategy begins: by systematically examining the entire innovation process – from the creative kernel to implementation in new products and services. The new High-Tech Strategy focuses on research topics that are of particular relevance for society, and for growth and prosperity:

- Information and communication technologies characterise almost all our life and business. But how do we want to live, learn and work in a digital world?
- How do we shape manufacture and consumption that respect resources, are more environmentally friendly, more socially acceptable and thus more sustainable?
- What is the future of work?
- How can we work towards achieving advances in health and wellbeing?
- How do we prevent disruptions or bottlenecks in energy supply, IT communication, mobility or logistics?

The new High-Tech Strategy brings together all the actors involved in innovation to combine forces and smooth the path from idea to application. They also ensure that conditions remain buoyant for innovation in Germany. For this, skilled professionals are just as necessary as better financing for innovation or research-friendly copyright law.

Find out more under
www.hightech-strategie.de/en

Table of Contents



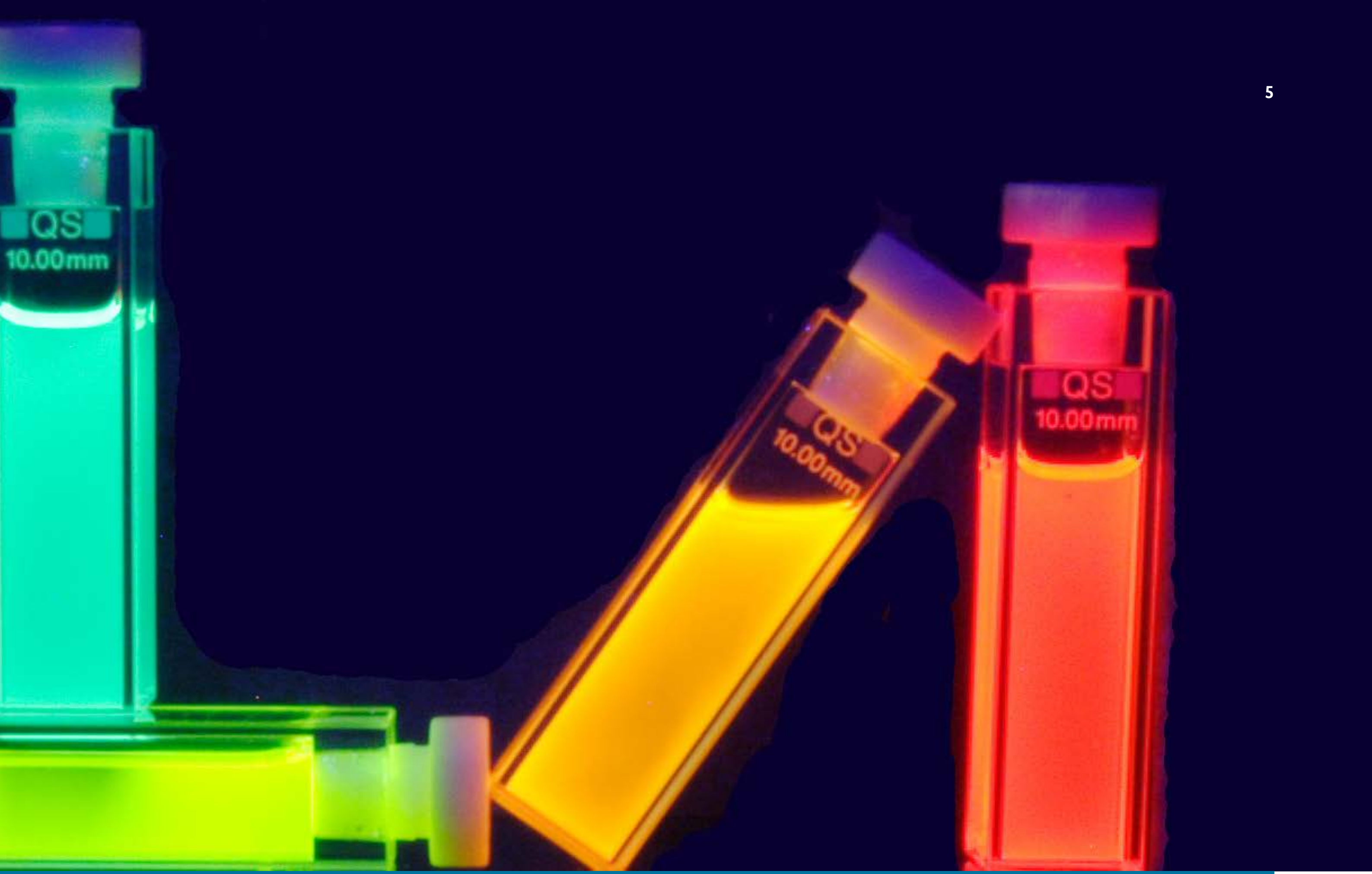
Foreword

Nanotechnology is playing a growing role in our everyday lives. Nanomaterials enable the targeted manufacture of innovative products with special properties. This will make it possible, for example, to produce the new high-performance battery storage systems and lightweight components which are so important for a mobile future and the energy revolution. Nanoelectronic components, for their part, allow fast data processing in Industry 4.0 applications. Nanotechnology is also facing high expectations in the area of health; for example in cancer therapy and diagnostics, where nanomaterials can be used to enable targeted drug delivery and enhance contrast agent uptake in tumours.

However, we can only develop the innovation potential of nanotechnology sustainably if we can guarantee its safe and environmentally compatible use. The Federal Government therefore attributes major significance to studies into the impact of nanomaterials on humans and the environment. A responsible innovation policy also involves cooperating on national and international standardisation and regulatory bodies, conducting international research networking activities and entering into a transparent dialogue with the public.

With the "Action Plan Nanotechnology 2020" we are presenting a new, inter-departmental approach based on the collaboration between seven Federal Ministries which already began in 2006. We are pooling previous findings in nanotechnology research and establishing new priorities in those areas where fine tuning is required. The Action Plan closely follows the objectives of the Federal Government's new High-Tech Strategy. We intend to open up new opportunities for society, which we will use responsibly.

Prof. Dr. Johanna Wanka
Federal Minister of Education and Research



1 Introduction

Applications based on nanotechnology have become ever more significant economically in the past few years. They have become commonplace in the everyday lives of workers and consumers. Nanotechnology-based product innovations play an increasingly important role in many areas of life, such as health and nutrition, the workplace, mobility and energy production. The Action Plan Nanotechnology 2020 introduces the Federal Government's inter-departmental support strategy for nanotechnology in the period 2016–2020. It thus pursues the objective of continuing to exploit the opportunities and potential of nanotechnology in Germany, without disregarding any potential risks to humans and the environment.

In order to accompany this development responsibly and play an active role in shaping it, the Federal Government has bundled its activities and measures for nanotechnology support into one inter-departmental approach, the so-called "Action Plan Nanotechnology 2020". Alongside exploitation of the opportunities from nanotechnological developments, its political activities are equally determined by safe and environmentally responsible application of this technology. Under the leadership of the Federal Ministry of Education and Research (BMBF), the Federal Ministry of Labour and Social Affairs (BMAS), the Federal Ministry of Food and Agriculture (BMEL), the Federal Ministry of Health (BMG), the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB), the Federal Ministry of Defence (BMVg) and the Federal Ministry for Economic Affairs and Energy (BMWi) are involved in the Action Plan Nanotechnology 2020.

This inter-ministerial cooperation in the field of nanotechnology reflects the aspiration for responsible government action. Sustainability, safety and the protection of humans and the environment are defined thereby as higher-level goals of a policy that is fundamentally related to mankind and the environment. The policy is required to create an appropriate regulatory framework based on the results of nanorisk research in order to guarantee the conditions for safe handling of nanomaterials, but without restricting innovations and the international competitiveness of industry more than is necessary. The Federal Government's coalition agreement from 2013 also assigns great potential to nanotechnology in the initiation of innovation processes. At the same time, the need for government-accompanied research into the impact of artificially manufactured nanomaterials on humans and the environment is to be considered as indispensable. Global challenges such as climate change, demographic development, the control of widespread diseases, ensuring the security of world nutrition and the finite nature of fossil raw materials and energy sources require forward-looking solutions, which can be advanced with the help of research, new technologies and the dissemination of innovations.

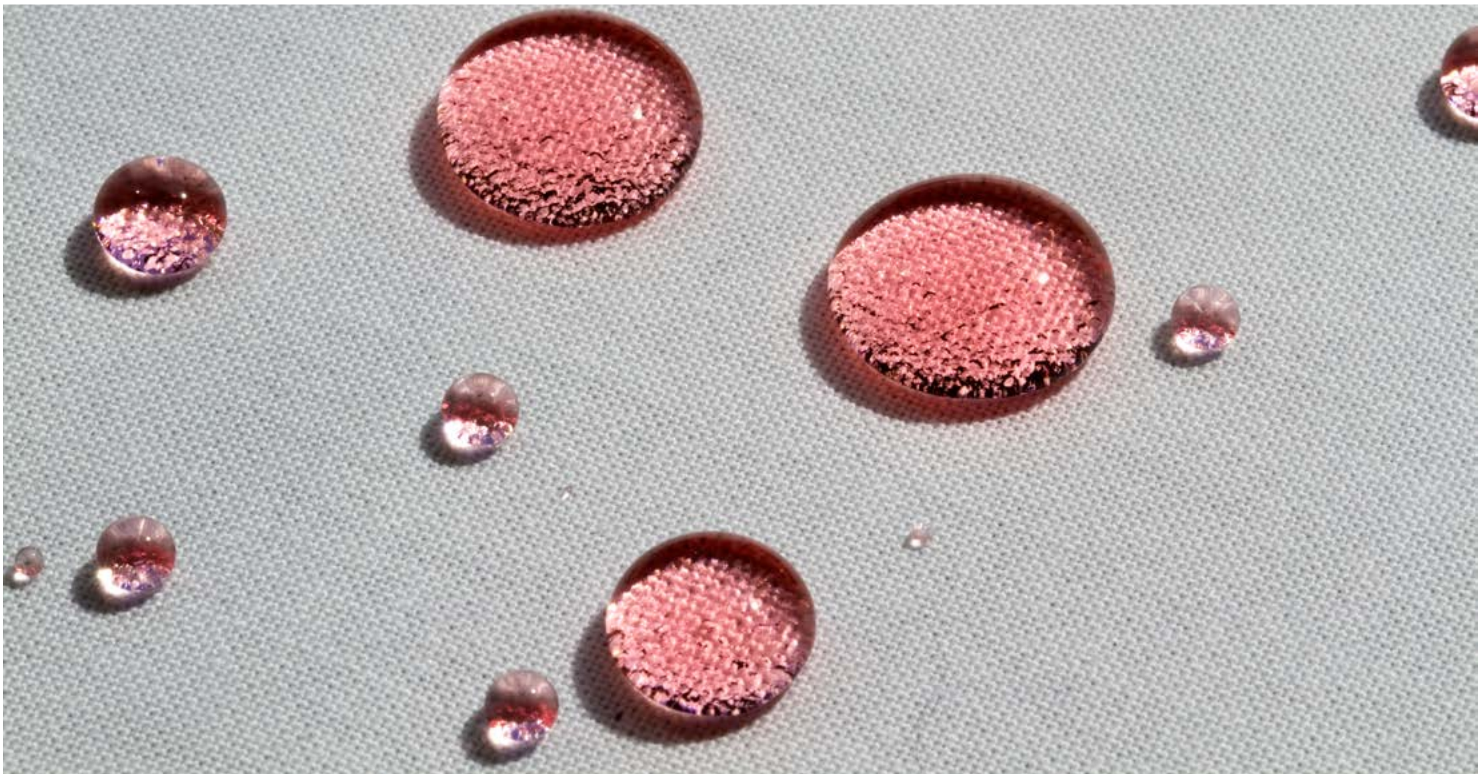
For this reason, the Federal Government consistently targets its innovation policy under its new High-Tech Strategy (HTS) towards central social challenges. Nanotechnology is regarded as having a great potential for solving the problems in the designated future fields. As in the case of other high technologies, in nanotechnology too it is valid to impose a responsible innovation policy at an early stage as well as coordinated collaboration amongst all stakeholders from research, education, economy, politics and society. As part of the new High-Tech Strategy, the existing potentials in the field of nanotechnology should be better utilised for Germany and the subsequent value chains should be aligned in an innovation-oriented manner.

Even since 2006, seven Federal Ministries have been coordinating their work in the field of nanotechnology under the “Nano Initiative – Action Plan 2010” with the aim of jointly promoting national extension of this technology of the future. Various initiatives for supporting small and medium-sized enterprises (SMEs), for collaborative research, for nanorisk research and for promoting a transparent dialogue with the general public about the opportunities and implications of nanotechnology were combined.

At the beginning of 2011, this inter-departmental approach was extended for a further five years by the “Action Plan Nanotechnology 2015”. In doing this there was increasing focus on aspects of economic recovery, the responsible handling of materials and technology, improvement of the framework conditions for companies and public debate on the subject of nanotechnology.

The new High-Tech Strategy “Innovations for Germany” launched by the Federal Government in August 2014 focuses on six priority tasks for the future Digital Economy and Society, Sustainable Economy and Energy, Innovative Working Environment, Healthy Living, Intelligent Mobility and Civil Security. The breadth and complexity of the defined tasks for the future requires a strategic innovation policy that takes

Nanomaterials change the wetting properties of textiles.



into account both technological and social innovations.[1] This realignment of the High-Tech Strategy is taken into account in “Action Plan Nanotechnology 2020”. This Action Plan is seamlessly linked to Action Plan 2015 and demonstrates how nanotechnological processes and materials are useful for coping with the six future tasks.

This present brochure is intended as a further political contribution to the transparent dialogue with the public on the topic of nanotechnology. In addition to a description of the status quo of national nanotechnology, for the first time after 10 years of inter-ministerial cooperation a conclusion is drawn on the progress that has been achieved from the point of view of the participating ministries, where potential gaps can be identified and therefore the need for action is derived with respect to future activities.

The adhesive force of the gecko is based on nanostructures on its feet.

Definition

Nanotechnology covers such a wide range of different material properties and procedures that it is difficult to provide a straightforward definition. As a rule, therefore, a pragmatic approach is taken that is also the basis for this Action Plan:

“Nanotechnology deals with the controlled manufacture and use of materials and components with functionally relevant structure sizes below 100 nanometres in at least one dimension. New functionalities and properties therefore result from this nanoscale, which can contribute to the improvement of existing or to the development of new products and applications.”[2] These new functionalities and properties are on the one hand due to an extremely large surface area relative to their volume, by which nanoscale objects can interact with their environment. On the other hand, quantum effects may cause the properties of a material to change fundamentally, since the nanoscale structuring of a material provides its electrons freedom of movement. This makes targeted material developments possible, for example particle-size-dependent colour changes, an extreme increase in thermal and electrical conductivity or an increase in the reactivity of particle surfaces. Biological entities in the nanoscale, such as viruses or antibodies, are not covered by this definition.

The EU Commission (COM) has provided a broad definition recommendation for identifying nanomaterials in the legal sense.[3] According to that, nanomaterial consists of at least 50% of particles in the size range between 1 nm–100 nm. This includes also larger entities consisting of primary particles in the nanoscale. This recommendation expressly permits deviations in specific regulatory areas. The food and cosmetic sectors use their own definitions.

2 Strategic Goals of the Federal Government

A responsible innovation policy addresses both opportunity safeguarding and risk research. Close cooperation between politics, business, science and society is important for the success of such a sustainability-oriented strategy. Social acceptance of technology is only possible through transparent presentation of the findings of research into opportunities and risks and an intensive dialogue with the public.

A coordinated innovation policy serves the sustainable protection of international competitiveness in Germany. That is why the Federal Government's High-Tech Strategy was further developed into a comprehensive multidisciplinary innovation strategy. Innovations should thus solve global challenges and improve the quality of life of our citizens. This requires new concepts for the development of improved products, processes and services. The foundations for these can be created by the exploration of key technologies, such as nanotechnology. Nowadays many applications based on nanotechnology can be found in everyday life and consumer products, further innovations are on the way to open up new markets.

Superior knowledge in the high-technology sectors is particularly important for an export-oriented and natural resources poor country like Germany, whose competitiveness is closely linked to future markets. In order to remain competitive internationally also in the long term, the promotion of key technologies – like nanotechnology – is to be developed further as an integrated component of the new High-Tech Strategy.

The intention is to release synergies through interdisciplinary research, strengthen the innovation dynamics of the economy and improve the framework conditions for promising innovations. For this it is also necessary to promote dialogue within society and to initiate education programmes. The Federal Government will consistently pursue its previously successful inter-departmental approach towards coordinated research and innovation policy in the field of nanotechnology. This is how the high level of research achieved and the positive economic effects are to be further expanded and how the sustainability of innovations is to be supported through accompanying risk research and communication.

Nanotechnology is part of the Federal Government's new High-Tech Strategy.

The Federal Government has set itself the target of

- **aligning nanotechnology support to priority tasks for the future within the new High-Tech Strategy**
  The application of nanotechnology findings to the production of products with new functionality has already been accepted into numerous sectors. The future economic success of high-tech products will depend on whether advantage is consistently taken of new opportunities created by key technologies like nanotechnology. This also includes the assessment of possible risks from nanotechnology and ensuring safe use of nanomaterials in production processes and products. The research and development activities oriented towards responsible utilisation are focused on the future tasks named in the new High-Tech Strategy: Digital Economy and Society, Sustainable Economy and Energy, Innovative Working Environment, Healthy Living, Intelligent Mobility and Civil Security. By focusing its research support, the Federal Government is seeking to intensify economic and scientific collaboration, accelerate the extension of thematic strategic partnerships and to contribute to the prosperity and quality of life of our society through targeted transfer of results.

- **improving the competitiveness of German companies by more efficient implementation of results**
  Germany must constantly secure its competitiveness through new innovations. The proportion of research-intensive products in the value chain is therefore growing continuously. Growth and employment can only be achieved by successful transfer of established findings into applications. Production is increasingly organised in global value chains, applicable knowledge is characterised across disciplines and innovations are closely linked to the solution of societal challenges. Coordinated collaboration amongst the federal ministries involved is necessary, especially in areas such as nanotechnology. Science, economy and politics will work closely together in the established manner to ensure early networking of participants to accelerate the efficient implementation of research results into applications and services. To this end, small and medium-sized innovative companies in particular are to be supported by means of targeted measures, in order to transfer more quickly pre-competitive technology developments into marketable commercial products. The appropriate avenues of international cooperation will also be extended in order to be able to utilise the knowledge available globally.

- **ensuring responsible governance of nanotechnology as a contribution to sustainable development through accompanying risk research and communication**
  In addition to the perception of opportunities, there is also a need for public discussion on the potential risks of nanotechnology. Although nanoscale effects generate new functionalities, at the same time they pose questions about the effects on humans and the environment due to the development, production, use and disposal of nanotechnology products. As a consequence, fulfilment of the proper precautionary principle with still missing risk data and the sound scientific development of legislation and practice recommendations are also the focus of current ministerial activities. The Federal Government

is contributing to better assessment of the potential risks and the operation of differentiated risk management by means of research projects to identify ecological and human toxicological hazards, life cycle analysis and derivation of safe exposure scenarios. This should ensure the safe, environmentally friendly development of nanotechnology.
The ministerial research facilities of the Federal Institute for Occupational Safety and Health (BAuA), the German Federal Environment Agency (UBA), the Federal Institute for Risk Assessment (BfR), the Federal Institute for Materials Research and Testing (BAM), and the National Metrology Institute (PTB) pursue a common research strategy. This is aimed above all at safety in use and the environmentally-friendly development of new materials in an early phase of innovation. In addition, options for action and practical assistance with working, consumer and environmental protection measures for the entire life cycle, from manufacture to disposal are derived. With the increase in the use of nanomaterials also comes an increase in the associated waste-management challenges. The waste containing nanomaterials created during manufacture, as part of production processes and after the end of the use phase, requires special consideration in its recycling or environmentally acceptable disposal. There are still knowledge gaps in answer to the question whether and to what extent the disposal of waste containing nanomaterials can cause a hazard or harm to humans and the environment. Some of these are already the subject of research projects as well as various studies, in particular under the auspices of a working group of the Environment Directorate of the Organization for Economic Co-operation and Development (OECD).
Citizen and stakeholder dialogues, Internet platforms and consumer conferences are being used to transparently consider and discuss the investigation results and make them available to the public.

- **creating innovation-friendly framework conditions for sustainable management**
  A successful and sustainable transfer of results into innovative products and applications requires a responsible research and development policy and the creation of innovation-friendly framework conditions. The Federal Government supports both

Citizens dialogues are used for the transparent representation of the opportunities and risks of nanotechnology.

Determination of the patterns of dust generation from nanomaterials at a test bench of the Federal Institute for Occupational Safety and Health.

the generation of safe products as well as a culture of technological openness in the economy and society by means of fair competition conditions and transparent market situations, risk communication, financing options for SMEs and start-ups, the guarantee of qualified vocational training, measures for the protection of intellectual property rights and the development of internationally recognised norms and standards.

Well qualified specialists, sufficient new scientific talent and needs-oriented training and further education for workers in the field of nanotechnology are necessary for securing employment and corporate development. This also includes the creation of networks, overviews of options for training and further education, the implementation of industry dialogues as well as the provision of funding and capital for financing start-ups. Norms and standards can open up markets for innovative technologies and create market transparency. They contribute directly to improving the competitiveness and innovative strength of companies. In the field of nanotechnology, the increasing research activities, product developments and also regulatory measures require as much extensively harmonised definitions and terminology as possible, but also internationally coordinated, metrological test and measurement methods and processing procedures traceable to the International System of Units (SI). Concerning standardisation issues the International Organisation for Standardisation (ISO) and the OECD at international level together with the European Committee for Standardisation (CEN) at European level deal with the development of norms and standards. The Federal Government supports the active involvement of German experts in the respective committees. The international comparability of measurement results for significant measurement parameters are regularly checked and verified by means of a system of international comparative measurements organised and carried out by national metrology institutes (the PTB in Germany), and the designated institutions BAM, UBA and the Federal Office of Consumer Protection and Food Safety (BVL).

3 The Status Quo of Nanotechnology in Germany

Germany is one of the world leaders in an international comparison of research, development and marketing of nanotechnology, but also on issues relating to the potential risks for human health and the environment. The coordinated collaboration among seven federal ministries started in 2006 has made a significant contribution to the promotion of nanotechnology. Both the use of nanotechnology applications and the possible impact of nanomaterials on humans and the environment have been investigated under the umbrella of the Action Plan, in order to establish the basis for responsible use of nanotechnology.

3.1 Balancing National Funding

The establishment of a solid scientific basis for nanotechnology in Germany has been facilitated by two parallel developments. Firstly, the BMBF had already started promotion of research into nanotechnology at the beginning of the 1990s and has since continuously expanded it. Secondly, industry's interest in new technological breakthroughs has been steadily increasing.

The first publicly funded research projects were still predominantly fundamental in character. Economic use increasingly became the focus of these projects with the involvement of industrial partners within collaborative research. One central challenge of nanotechnology is the interdisciplinary association of scientific and engineering disciplines. Efficient networking of stakeholders is consequently required for implementing nanotechnology innovations. The BMBF had therefore started with the establishment of national competence centres as early as the end of the 1990s. Further initiatives and clusters followed at state and regional level, as a consequence of which a steering group was set up to better coordinate state activities with those at federal and municipal level.

Potential gaps in BMBF research funding were addressed by new instruments in order to continuously adapt the funding portfolio to the needs of different nanotechnology target groups. Thematically focussed calls are regularly published, accompanied by structural support measures and innovation-related promotional activities. In addition to classical joint project funding, for example, key innovations were developed as instruments for strategic research cooperation in order to secure existing market potential and develop new fields of growth in strong German industries such as the automotive industry and the chemical and optical industries. Innovation alliances consisting of representatives from science, business and politics addressed areas with global market perspective and targeted substantial economic leverage. A number of specific BMBF funding measures such as SME-innovative were established with the aim of supporting SMEs with cutting-edge research specifically for the implementation of research and development (R&D). Measures for the promotion of young scientists were also introduced. Excellent post-doctoral students are supported in building up their own research teams under the NanoMatFutur talent-development programme. The BMBF funding portfolio was also extended to include leading-edge clusters and clusters of excellence, which partly address nanotechnological issues.

Starting in 2002, the BMBF established a National Contact Point (NCP) for nanotechnology, which facilitates German applicants from research and industry in gaining access to European research funding. To this end, a wide range of consultancy services in the form of information days, cooperation exchanges, individual interviews and web-based seminars is available to all interested partners.

The classical joint research of the BMBF was continuously augmented by a series of specific accompanying measures. Already in the 1990s, activities were carried out for the early recognition of technology, for innovation and technology analyses as well as for measures accompanying innovation. The “nanoTruck” that

The nanoTruck provided information about the applications of nanotechnology.

travelled on German roads until 2015 can be seen as a successful example of public information on nanotechnology: Numerous students and interested lay people have experienced practical applications of nanotechnology in the mobile hands-on laboratory and have learned about the opportunities and the potential of this technology via interactive teaching materials. Easy to understand BMBF brochures, Internet-based information portals or even expert discussions with citizens regularly convey knowledge about current trends and developments, but also the opportunities and risks of nanotechnology.[4]

Nanorisk research has been established as a funding priority in its own right since 2006. Interdisciplinary teams from research institutes, federal authorities, universities and industry work together to explore the impact of nanomaterials on humans and the environment. Numerous projects to investigate the behaviour of synthetic nanomaterials were also started under the NanoCare and NanoNature funding measures. As examples, the main topics are long-term effects due to inhalation, toxicity mechanisms, material design, possible grouping strategies and measuring methods. The projects also deal with the discharge of nanomaterials into the environment and their continuance. The topics safety and environmental compatibility are currently covered by the BMBF funding programme “From Material to Innovation”. In addition, findings made under the national funding activity flow into the expertise of the OECD Working Party on Manufactured Nanomaterials (WPMN) for risk research on nanomaterials. Since nanotechnology applications are increasingly advancing into different areas of people’s lives, alongside health and ecological also ethical, legal and socio-economic issues must be better taken into account at all stages of the innovation chain – over the entire life cycle of nanoproducts. The principle of responsible research and innovation is also becoming ever more important in the context of nanotechnology and is shaping current scientific policy debates. Reliable national and international data and research results on the safety of nanomaterials are being made available via the BMBF project “DaNa – Data and Knowledge on Nanomaterials”[5]. In addition to providing easily comprehensible information about materials and products, DaNa also enables exchange with highly qualified scientists.

The total sum attributed to nanotechnology funding by the public sector is currently more than 600 million euros per year[6]. Included in this are the funding activities of the federal ministries, institutional support and that of the federal states. Around 10% of finance by federal ministries is invested in pre-cautionary and risk research and associated measures. Alongside German funding measures, the expiring activities of the 7th Framework Research Programme (7th FRP) by the EU and current funding measures under Horizon 2020 are a further important source of funding for German applicants.

3.2 Nanotechnology Players in Germany

An analysis of the national research and industrial landscape shows that the number of companies and research institutes involved with nanotechnology in Germany is continuing to grow. There are now some 2200 organisations from the fields of industry, services, research and associations registered in the BMBF Nanotechnology Competence Map[7]. Networking amongst the nanotechnology institutions is also developing further. These include research networks in the German research community and the institutional research facilities, activities for technology transfer at regional and state level as well as cross-cutting initiatives for bundling of nanotechnology skills at the federal level.

Nanotechnology is steadily increasing in importance within the national research landscape. Almost all institutional and university research facilities with technical-scientific orientation exhibit research activities with regard to nanotechnology. Numerous study and further training courses have been developed to prepare suitable personnel for research, development and product manufacture. Essential basic scientific knowledge is being compiled in particular as part of the support measures of the German Research Foundation (DFG) and research activities of the Max Planck Society (MPG), the Helmholtz Association of German Research Centres (HGF), the Fraunhofer Society (FhG), the Leibniz Association (WGL) and of ministerial research facilities and universities.

Networked participants from industry and research are the basis for nanotechnical innovations.

There are currently also some 1100 companies in Germany engaged with the use of nanotechnology in the fields of research and development as well as the marketing of commercial products and services. The proportion of SMEs is around 75%. The Federal Government supports R&D measures and activities for standardisation and legislation. Internationally recognised product and safety standards are being prepared in cooperation with the EU-wide and international organisations responsible for these tasks, the EU Commission and the European Chemicals Agency (ECHA), OECD, CEN, ISO, and the World Health Organization (WHO) in order to ensure a healthy and environmentally sound use of nanotechnology. Also the development of procedures for exposure assessment, strict worker protection measures and independent risk research by the German Statutory Accident Insurance Association (DGUV) is extending companies level of knowledge about occupational health and safety in the fields of nanotechnology and nanomaterials in the workplace.[8]

4 Contributing to the Future Tasks of the High-Tech Strategy

Key technologies such as nanotechnology will provide the basis for new products, processes and services for the future tasks described in the Federal Government's new High-Tech Strategy. Research thus contributes to the solution of urgent social problems and central challenges and promotes the prosperity and quality of life of our citizens. It is important therefore to seize the opportunities and carefully consider the implications of nanotechnological innovations. During the transfer of scientific knowledge into business applications, it is necessary to ensure that aspects of economic use are combined with approaches to good governance and to derive the necessary regulatory measures.

4.1 Digital Economy and Society

Our modern industrial society is permeated by digital techniques. Many areas of life and work processes would be inconceivable nowadays without digital support. Intelligent networks and complex software control enable numerous applications in the fields of mobility, health and energy, but also in research, education and public administration. At the same time, in the course of these developments there are always new questions being raised about data security or possible social effects. Traditional jobs are being changed or replaced through the use of robots, for example, yet on the other hand new occupational profiles are emerging. Thanks to electronic services medical care for patients is improving and the pressure on medical staff is being relieved, intelligent energy is being distributed and it is clear that fully automated vehicles will be transporting goods and people in the future. Fundamental changes in industry are expected due to the digital networking of machinery. These should lead to intelligent production within the framework of Industry 4.0.

Information and communication technologies are the basis for the digitisation of our everyday and working lives. Innovations in the fields of micro- and nanoelectronics are a prerequisite for the underlying technical developments. Processors and memory are the core elements of electronic components. Only through the use of nanotechnological processes and new material developments have transistor density and memory capacity on computer chips increased within a few years, such that current systems achieve maximum computing performance at controllable energy consumption, data storage systems manage massive amounts of data and fastest transfer rates are available for data transfer. In order to be able to master the challenges of digital transformation in industry and society in the future, there is a need for further R&D efforts in the improvement of micro- and nanoelectronic components and the development of materials for semiconductor and chip technology. There are also special requirements with regard to IT security. Here there are research approaches that are dealing with the development of secure encryption and signature procedures by means of quantum information technologies.

In addition to adequate availability of raw materials, their safety for humans and the environment play a decisive role in the use of new materials.

4.2 Sustainable Economy and Energy

As a key and cross-sectional technology, nanotechnology can make important contributions to environmental and climate protection. It enables innovations in processing and remediation, in sensor systems and in the efficient use of resources. For example, nanofunctionalised polymers and ceramic membranes are used for drinking and process water preparation, highly selective sensor layers for the detection of contaminants, or nanoscale materials to reduce the need for scarce raw materials. Nanostructured catalysts convert the climate-damaging carbon dioxide CO_2 into fuel or plastics and thus help save oil. Coatings with nanomaterials can contribute to dirt repellent and antimicrobial surface properties and thus complement cleaning and disinfection procedures. However, these surfaces can also release nanomaterials within their life cycle and thus contribute to an occurrence of nanomaterials in the environment.

Nanotechnology is opening up opportunities for improvements in the production, storage and efficient use of energy. Nanoscale materials, thin layers, processes and suitable manufacturing procedures are important components in the optimisation of batteries, fuel cells, photovoltaic elements or for energy saving through lightweight materials, thermal insulation or improved anti-friction properties. Batteries with high energy density, inexpensive solar cells with a high energy conversion performance or efficient fuel cells are only economically viable through the use of nanomaterials.

Numerous energy and resource saving applications with potential for the future can also be found in the construction sector. For example, multi-functional glass façades are being considered, which feature dirt-repellent properties and optimal light and heat permeability due to their nanostructured surface or can be used for direct energy generation when configured with transparent photovoltaic layers. Building materials such as concrete can obtain special static and constructive qualities by means of nanofibres. Nanomaterials also allow the properties of paints, lacquers or varnishes to be modified in a variety of ways.

Nanolayers optimise the efficiency of photovoltaic modules.

Nanotechnology approaches for sustainable management are also being applied in agriculture and the food industry. The use of nanotechnological processes should reduce the amount of active ingredients in fertilizers and allow more precise diagnosis of plant diseases. Hygienic surfaces can support cleaning and disinfection measures in food processing. Nanomaterials can improve the mechanical and thermal properties in food packaging, protect food against UV light or indicate that the cold chain has been interrupted or that the expiry date has been exceeded.

Many of the applications mentioned above may also involve the release of nanomaterials, so that a careful risk-benefit assessment should be conducted. Concomitant risk research is examining the possible effects of the use of nanomaterials on humans and the environment, in order to ensure safe development of the procedures.

4.3 Innovative Working Environment

Nanotechnology exhibits a high degree of interdisciplinarity. Biologists, chemists, physicists, doctors and engineers contribute their experiences and ideas to generate innovative applications and products for society. This requires intensive collaboration based on division of labour and a high level of understanding of other disciplines. The Federal Government therefore supports the efforts of universities to stimulate interested interdisciplinary talent and nanospecific training opportunities. The internet platform werkstofftechnologien.de clearly displays the existing education and training opportunities for both nanotechnology and materials research in Germany. Portraits of individual study programmes make the choice of study easier for interested young talent. SMEs without major research departments are especially reliant on the graduates of such educational opportunities designed for future skills requirements. Higher education also has a key role to play in familiarising budding scientists and engineers with methods of risk assessment, the relevant regulations and the possibilities for safe application and environmentally compatible creation of material innovations.

Excellent young talent is of high importance to Germany as a location for nanotechnology.

The funding of excellent young scientists is of central importance to Germany as a location for nanotechnology, since creative ideas contribute to the success of companies. However, factors such as demographic change and increasing global competition for the best brains make it more difficult to recruit highly-qualified young scientific staff. For this reason, the BMBF supports qualified up-and-coming talent in particular. As part of ministerial research, the Federal Government also supports the qualification of young scientists and researchers in the field of risk research.

Nanotechnological products and processes are also changing working conditions in many companies. Here it is not only important to avoid the negative effects, for example from particulate pollution at the workplace, but also to exploit the various opportunities of innovative technologies to create humane working conditions. The first major challenge is to place employees in a position to keep pace with the innovations. One interesting approach is provided by the DGUV nanoramas.[9] “Nanorama” – a word created from the combination of “nano” and “panorama” – is an innovative e-learning application. Nanomaterials and nanotechnologies that are now typical in industry can be viewed in 360° panorama. The objective is to convey knowledge and any necessary occupational safety measures via the applications.

4.4 Healthy Living

Those who are healthy would like to remain so, and those who are sick would like to be healthy again soon or at least experience a reduction in their complaints. Innovative preventive and therapeutic approaches in medicine play a growing role against this background, with the increase in the number of diseases such as cardiovascular disease or diabetes and an ageing society. Nanotechnological applications can contribute to such innovations: In the last two decades therefore in the area of materials science, considerable progress has been made in the manufacture of nanoscale materials. At the same time there was an enormous growth in medical findings. Both trends have facilitated the introduction of nanotechnological innovations in the field of medicine. Meanwhile the inclusion of nanotechnological processes and of nanomaterials represents an important engine for the research and development of new drugs, diagnostic and medical products and imaging procedures. Material developers, chemists, physicists and biologists are working closely together with pharmacists, clinical researchers, doctors and the manufacturers of medical devices and pharmaceuticals in order to bring demand-oriented nanotechnological innovations that are safe for patients onto the market. In doing so, they can consult at an early stage with the competent medicines evaluation agencies. Such successful collaborations are inter alia realised within the German Centres for Health Research.

Nanomaterials are also used in the development of new medicines to encapsulate active ingredients in order to protect them against premature degradation and achieve targeted release only in the desired tissue (so-called drug delivery). Nanoscale polymers can be modified and be functionalised so that they contribute to an improvement or extension of the application and performance of medicinal products and medical devices. Regenerative medicine represents a field of the future: An example here is the research into optimisation of implant coatings and innovative procedures, which allow re-generative tissues and organs to heal or by means of which these can be replaced. One day, for instance, person-specific implants with functionalised surfaces for the regeneration of body tissues could be manufactured by three-dimensional printing (3D printing) of appropriate nanomaterials.

At the BMBF symposium "ProMatLife", Stefan Müller (Parliamentary State Secretary to the Federal Minister of Education and Research) obtains information on the possibilities of manufacturing tissue for regenerative medicine in bioreactors.

Nanotechnological approaches are also increasingly being used in diagnosis. Modern imaging methods allow research into new approaches for the early detection and localisation of tumours, for example. Here nanomaterials introduced into the body are used to increase the detection limit for the start of tumour development and improved spatial resolution for tumour location.

Nanotechnology-based applications are also increasingly being used in the analysis of body fluids such as blood or saliva. Measurable molecules such as gene or metabolic products or the presence of pathogenic agents can thus be studied. Analysis of these molecules, also known as biomarkers, allows early and accurate diagnosis of diseases, development of optimised therapies whilst avoiding undesirable effects and ongoing control of therapeutic success, as well as also providing prognostic statements on the course of the disease. The results of such analyses could in future also have an increasing influence in so-called individualised medicine, where the attempt is to make customised prevention or treatment decisions on the basis of the individual requirements and needs of a patient.

In the field of nutrition, nanomaterials also contribute to an optimised diet and better quality of food products. Through nanoencapsulation of bioactive substances, the aim among other things is for increased stability of the bioactive substances in the food matrix, the masking of undesirable aromas like those of omega-3 fatty acids for instance, their delayed or controlled release and improved transport through the wall of the intestine. By means of encapsulation or size reduction in the nanoscale, food can be produced with a lower salt, sugar or fat content without the taste being affected.

4.5 Intelligent Mobility

Innovative mobility concepts are the basis for the economy and production, but also for prosperity and quality of life. Sustainable mobility requires traffic and transport concepts that are efficient, resource-conserving and low in emissions. At the same time, transport systems should be fast, safe and comfortable.

Nanotechnology-based innovations have great potential in the medical field.

The growing political and public interest in alternative vehicle propulsion systems is essentially due to rising CO_2 emissions, the dependence on oil and air pollution. Technical successes in battery technologies, in power electronics, in lightweight construction, in the development of fuel cells or in hydrogen storage also contribute to this awareness. Progress in these areas has been supported by nanotechnological processes and the use of nanomaterials.

A core task in electric mobility is the provision of safe batteries with a high energy density and as low a weight as possible for a large range and dynamic driveability. Especially lithium-based high-performance cells are therefore currently favoured as the batteries to power electric vehicles. Nanoscale materials and new nanocomposites play an essential role in the optimisation of electrodes and battery cell components. Nanoscale molecular structures are crucial for the operating safety of such batteries. For example, so-called super capacitors can be used in addition to the battery storage system in order to have sufficient energy available in acceleration phases. Their high power densities can only be achieved through the installation of nanomaterials and nanostructured system components. The current disadvantages of modern battery technologies, in comparison with conventional energy sources such as petrol, are lower energy density and the resulting short range and long recharge time.

In relation to alternative powertrains, the automotive industry is also working on fuel cell concepts. Fuel cells generate electricity directly from energy-containing gases such as hydrogen or methane. This conversion is carried out with a high degree of efficiency. Among other things, nanostructured surfaces based on carbon and the installation of nanomaterials are being studied to improve the performance of membrane layers, electrodes and catalytic converters. Nanoporous carbon systems and metallic framework structures are inter alia being explored for hydrogen storage.

Energy-saving options result from the use of nanomaterials in lightweight materials. Energy efficiency can be optimised by innovative nanoelectronic system components for the electric motor and drive train. New wear-resistant nanocoatings lead to reduced friction and thus contribute to reducing the energy or fuel consumption. Modern anti-corrosion protection layers enable resource savings due to the longer life of components. Furthermore, catalytically acting nanomaterials in the exhaust pipe are being explored in order to reduce emissions.

As mobility technologies are associated with a high use of materials and broad diversity, the accompanying risk research and the development of safe and environmentally friendly products is of special importance here. The Federal Government supports the intensive investigation of the scientific basis for a differentiated risk assessment and regulation.

4.6 Civil Security

The area of civil security includes measures taken for the protection of people, infrastructure or organisations against criminal or terrorist activities, in the event of catastrophes, but also in the event of an accident in both private or public life. This includes digital communication and intelligent information management systems, navigation, observation and tracking technologies, sensors for the detection of hazardous substances and protection technology and equipment.

Nanostructured materials improve the security and energy density of batteries used in electric vehicles, for example.

Nanostructuring can make electronic systems more powerful, allowing data and information to be recorded, transmitted and evaluated more quickly. Nanoelectronic components allow energy-saving operation of mobile communications systems, ultra-precise optical camera systems help in the automatic detection of potential hazards and quantum cryptographic encryption provides secure data transfer. Mobile or stationary detection systems based on functionalised nanoscale materials are used for detection of dangerous or prohibited substances. Contributions from nanotechnology especially influence the further development of miniaturised, autonomously operating sensors for the detection of hazardous chemical or biological substances. The long-term goal is to develop multisensory, miniaturised detection systems that have a wide range of use and are durable and robust.

The objective of R&D activities is also the improvement of personal protective equipment for rescue and emergency personnel. These include inter alia filters and decontamination technologies. Custom filter systems for hazardous chemical, biological and nuclear substances are being studied, for example. Self-cleaning nanostructured surfaces with integrated catalytic materials can also contribute to decontamination of dangerous chemical or biological agents. Carbon-based polymer nanocomposites are suitable for the manufacture of shot and stab resistant vests for the police. Material-related approaches for multi-functional vests are being realised in the combined use of nanofluids for heat protection and automated sensor systems for hazardous substance detection or location.

The use of nanomaterials also enables document security and protection against plagiarism by the identification of documents or products with tamper-proof security features. To this end, nanostructured interference layers, quantum dots or infra-red pigments can be applied for the optical encoding. Alternatively, specific proteins or DNA can be used as the marking materials.

Nanomaterials make it possible to produce multifunctional protective suits.

5 Creation of Value Added Research and Funding Programmes

Due to the cross-cutting nature of nanotechnology, its research funding in Germany is anchored in various specialist programmes of the Federal Government and is partly promoted as part of inter-ministerial support frameworks. In addition, there is complementary funding by the federal ministries in synergy with the activities of institutional research funding.

Basic research findings are as a rule the starting point for value creation-oriented innovation processes. The early stages of the innovation chain are largely covered by the funding activities of the German Research Foundation (DFG) and of the large German research organisations. If research topics with application potential are identified and the conceptual orientation of the research work is determined, the objective of the different promoters is to identify the participants necessary for the entire chain and involve them at an early stage in the R&D activities. The R&D work is conducted with a view to opportunities for future exploitation.

Activities such as the development of networks, risk research, training and further education, public relations, dialogue processes with citizens and representatives of interest groups or even required regulatory steps are included in the strategic innovation policy as part of the support measures. For practical implementation of the R&D findings into applications there is collaboration with national and international bodies for norms and standards, or such cooperation is supported.

5.1 Specialist Federal Government Programmes

Nanotechnology references can be found in numerous specialist programmes of various federal ministries, whereas the BMBF launches a wide range of thematic research and innovation activities. In addition, the BMWi, BMUB, BMEL, BMG, BMAS and BMVI also support nanotechnology oriented activities in the context of research and development.

Bioeconomy (BMBF, BMEL)
The "National Research Strategy BioEconomy 2030" is pursuing new approaches to the use of natural resources as raw materials of the future. Its objective is the structural change from industry based on crude oil to biological industry for the sustainable production and processing of chemicals, materials and fuels. Nanocatalytic converters, functional coatings or nanomembranes are useful technological elements in this.

Electromobility (BMWi, BMBF, BMVI, BMUB)
Researchers, car manufacturers and suppliers are working closely together for an electromobile future within the Federal Government's national development plan

for electric mobility. The BMBF is involved in battery research among other things via the material research programme, where nanomaterials are of significance. Findings from nanotechnology also assist in lightweight vehicle concepts, mobile storage technologies and plans for the development of new powertrains.

Energy research (BMWi, BMBF, BMEL, BMVI)

The BMBF is involved with basic research work for energy efficiency and renewable energies via the Federal Government's 6th Energy Research Programme. Nanomaterials and modern methods of nanotechnology are applied in energy generation, storage and use.

Human-technology interaction (BMBF)

People interact more and more in everyday life with their technical environment, be it through communications, medical diagnosis or in the use of means of transport. In so doing, the use of nanoscale functional materials in intelligent, innovative assistance systems is constantly increasing. The study of human and technological interaction is the content of the "Bringing Technology to the People" research programme.

Health (BMBF, BMG)

The priorities of the Federal Government's framework programme for health research are on the study of widespread diseases, care provision and prevention, individualised therapy approaches and the health economy. Here nanotechnology research provides suggested technological approaches, for example for long-lasting implants, improved medical imaging, more sensitive diagnostic procedures, new active substances and active substance carriers.

Information and communication technologies (BMBF)

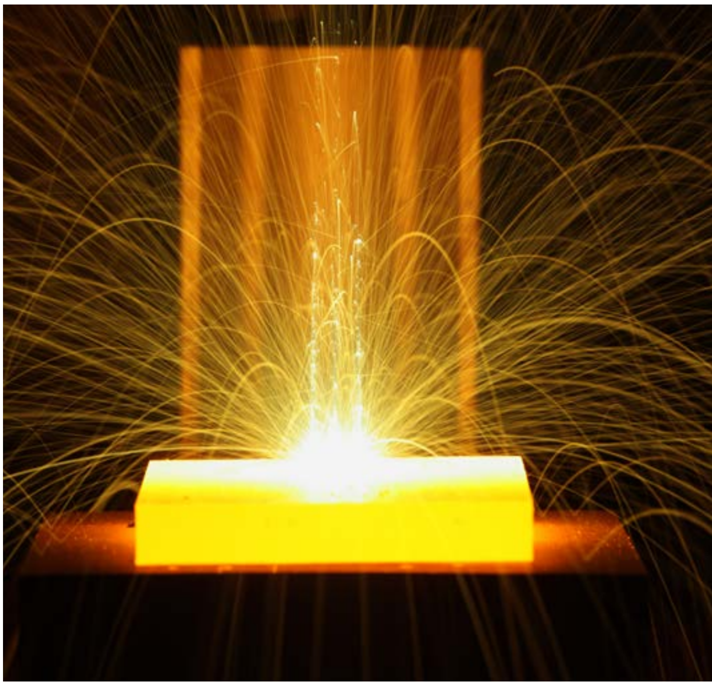
Parts of the ICT 2020 Programme are related to nanotechnology in the case of manufacturing of machinery and equipment for the production of electronic circuits, or of automotive electronics. Also the new Federal Government framework programme "Microelectronics from Germany – Driver of Innovation for the Digital Economy" uses nanotechnological findings for the production of highly complex electronic systems.

Materials research (BMBF)

Innovations in the field of materials research are closely linked with our understanding of the atomic and molecular structure of matter and how functional

Functional materials are becoming increasingly important for man-machine interactions.

The materials research programme constitutes the framework for the study of nanomaterials.



materials and components can be created by means of targeted design using these building blocks of matter. The framework programme for the promotion of materials research "From Material to Innovation" is closely associated with branches of nanotechnology research. This is therefore the first time that nanomaterial-specific elements will be integrated into the material research programme.


Functional layers are used in photonics.

Sustainable development (BMBF)
The framework programme "Research for Sustainable Developments" was launched to deal with climate research and conservation of resources. Its objectives are inter alia to contribute towards more intelligent and more efficient use of raw materials and Germany's sustainable and secure supply of raw materials. The material use of CO_2 as a chemical raw material is also part of the programme-specific support measures.

Photonics research (BMBF)
Agenda Photonics 2020 is focused on the alignment of photonics research with application markets such as lighting, displays, optics or sensors, but also with generative manufacturing and material processing. Photonic process chains are determined significantly by innovative production processes as well as the availability of materials with adjustable optical properties.

Production research (BMBF)
The BMBF programme "Innovations for Tommorow´s Production, Services and Work" supports the development of new production technologies and systems for customer-tailored, resource-friendly and reliable production in Germany. Innovations developed within the framework of Industry 4.0 will be used along the entire value chain and for procedures and equipment with which higher-performance products can be manufactured from nanoscale particles, fibres and coatings.

Security research (BMBF, BMEL)
The framework programme "Research for Civil Security" pursues technological solutions to protect people against threats in all situations. Nanotechnology findings are also fundamental to it. Research activities on the safety of material innovations in the food sector are also conducted in the BMEL ministerial research area by the Federal Research Institute for Nutrition and Food – Max Rubner Institute (MRI) and the Federal Institute for Risk Assessment (BfR).

Risk research (BMUB, BMBF)
Concrete questions on the health and environmental risks of nanomaterials are pursued as part of the BMUB ministerial research plan. The results are included in the discussions and activities of the European and international bodies (EU, ECHA and OECD). Basic research results on potential risks relating to the use of nanomaterials are also incorporated into the BMBF materials research programme.

European Metrology Programme for Innovation and Research EMPIR[10] (BMWi, European Commission)
The European metrology institutes provide their joint contribution to the fulfilment of the requirements that metrology faces from new technologies through transnational cooperation under the umbrella of the European Metrology Programme for Innovation and Research (EMPIR) coordinated by the European Association of National Metrology Institutes (EURAMET)[11] and the designated institutes. Germany is primarily involved in specific challenges in the area of nanometrology via the work undertaken in the PTB or BAM

5.2 Funding Structures, Research Organisations and Departmental Research Institutes

Funding structures and research organisations

The funding activities of the DFG as well as the research of the Max Planck Society (MPG), the Helmholtz Association of German Research Centres (HGF), the Leibniz Association (WGL), the Fraunhofer Society (FhG) and at the institutes of the DGUV are crucial to the development of basic scientific knowledge.

German Research Foundation (DFG)

Using funds from the Federal Government and the federal states, the DFG promotes aspects of nanotechnology, but not as an autonomous funding area. Yet relevant projects can be found in the fields of natural, life and engineering sciences. In the context of these science areas, there exists a wide range of review boards that deal with nanotechnology issues. Scientific issues related to nanotechnology are studied alongside individual funding within coordinated programmes – including in priority programmes, research training groups, collaborative research centres and in research units. In addition, the DFG promotes graduate schools and clusters of excellence under the Excellence Initiative of the Federal and individual states Governments.

Max Planck Society (MPG)

14 of the current total of 82 Max Planck institutes deal with the thematic fields of solid state research and material sciences. In particular the Institutes for Polymer Research, Colloids and Interfaces Research, Solid State Research, Intelligent Systems, Coal Research, Iron Research or Microstructure Physics address nanotechnology-related research.

Helmholtz Association of German Research Centres (HGF)

The Helmholtz Association is Germany's largest scientific organisation and operates 18 research centres. Nanotechnology is primarily pursued by the HGF in the key technologies research area, in support of government programmes in the High-Tech Strategy. Fundamental nanorelated questions for future applications are being addressed, especially in the HGF programme "Science and Technology of Nano Systems". The main centres dealing with nanotechnology are located in Karlsruhe (KIT), Jülich (Research Centre Jülich), Geesthacht (HZG), Berlin (MDC) and Dresden (HZDR).

Leibniz Association (WGL)

In the Leibniz Association there are currently 89 Leibniz institutions working with different areas of specialist focus. Materials with special physical and chemical properties are studied in the materials and nanotechnology research focus. Ten institutions are involved in this focus. The Leibniz Research Alliance Nanosafety, under the coordination of the Institute for New Materials (INM) together with five other institutions, is investigating how nanomaterials can be used safely. Furthermore, the competencies of 14 institutes are bundled into the Leibniz Nano-Network.

Fraunhofer Society (FhG)

The FhG is the largest application-oriented research organisation in Europe. It comprises 67 institutes and research facilities that deal with nanotechnology topics at numerous locations. The Fraunhofer Nanotechnology Alliance works with a total of 19 FhG institutes across industries in almost all fields of nanotechnology and covers the transfer of results along the entire value added chain from application-oriented basic research to industrial implementation.

German Statutory Accident Insurance (DGUV)

The accident insurance agencies have been represented by their joint umbrella organisation the DGUV[12] since 2007. The DGUV also advises on the topic of nanotechnology and promotes research projects by its members as well as external bodies in the fields of prevention, occupational diseases and rehabilitation.

Federal Government departmental research

The departmental research of the appropriate federal authorities has a key function in the safe application and environmentally sound development, use and disposal of material innovations. Among other things, the Federal Government is financing investigations into the responsible use of nanomaterials in the agricultural and food sector. Departmental research uses proactive initial research to contribute as early as possible to detection and prevention of relevant risks for humans and the environment. Here it is also valid to consider the resources and energy efficiency of nanotechnological products and applications. Departmental research provides targeted scientific findings and analyses based on a scientific foundation, also as a basis for political and administrative decision-making processes, for national protection purposes as well as for the provision of technical infrastructure.

Since 2008 the BAuA, UBA, BfR, BAM and PTB have pursued a strategy of joint research into the safety of nanomaterials for man and the environment. Their activities are conducted under the title “Nanomaterials and other advanced materials: safe to use and environmentally compatible” in the context of this Action Plan.

The **Federal Institute for Occupational Safety and Health (BAuA)** researches and develops in the field of safety and health at work, promotes the transfer of knowledge into practice, advises on policy and fulfils its official duties. Risk research into nanomaterials has been anchored in the BAuA working programme since 2007 and builds on many years of research activities on respirable particles and fibres. The research projects under this Action Plan focus on issues of risk assessment and the design of safe fibrous materials as well as the integration of a suitable information and testing strategy for respirable particles and fibres into the European regulations for the safety of chemicals.

The German **Federal Environment Agency (UBA)** is the central environmental authority in Germany. The task of the UBA is to collect data on the state of the environment, to explore relationships, produce forecasts for the future and with this knowledge to advise the Federal Government, such as the BMUB, in relation to policy decisions. In addition, the UBA executes environmental laws and puts them into practice. It is meant to serve as an early warning system that identifies possible future impairments of mankind and the environment in a timely fashion, assesses them and proposes workable solutions. It is also active in public relations work. In the context of this Action Plan, the UBA focuses on questions relating to risk assessment of the environmentally compatible design of products and applications containing nanomaterials as well as the integration of a customised information and testing strategy for nanomaterials into the European regulations on safety of chemicals.

The **Federal Institute for Risk Assessment (BfR)** produces expert opinions and position statements on questions of food and feed safety and on the safety of chemicals and products. The institute works on the basis of internationally recognised scientific evaluation criteria and is independent in its scientific evaluation and research. Risk communication is a further task of the BfR. With regard to nanomaterials, the institute is involved in numerous national and international research projects. Its priorities are the development of more sensitive detection methods, investigations into bioavailability as well as the development of the basis for grouping approaches.

The **Federal Institute for Materials Research and Testing (BAM)** makes important contributions to nanotechnology, as part of its “Safety in Technology and Chemistry” task, by developing testing methods and reference materials, contributing its scientific expertise to standardisation and thus progressing quality assurance. Safety and reliability in the use of nanomaterials are in the foreground for the BAM. It is also involved in a number of research activities and projects into material science-related issues, the development of measurement and testing methods, chemical nanoanalytics or nanoscale reference materials.

The Federal Institute for Occupational Safety and Health is conducting research into potential risks posed by nanomaterials.

The **Physikalisch-Technische Bundesanstalt (PTB)** functions as the national metrology institute for the uniformity of metrology in Germany. It ensures the traceability of measurement results to the International System of Units (SI) through the development of measurement methods and devices as well as regular participation in international comparison measurements. In the field of nanotechnology, the PTB thus works inter alia on research projects for the quantitative characterisation of reference materials and the functional properties of nanomaterials and nanoscale structures as well as being involved in the relevant standardisation bodies.

The **Max Rubner Institute (MRI)**, Federal Research Institute for Nutrition and Food, examines nanoscale carrier systems for bioactive substances and their behaviour during food processing, the influence of nanomaterials on food-related microorganisms and intestinal flora agents, the migration of nanoparticles from materials in contact with food, the influence of particle size on bioavailability, the interaction of nanomaterials with components of the food matrix, methods for the detection and characterisation of nanomaterials in food as well as the use of nanotechnology for the enhancement of quality, safety and durability of food.

The **Paul Ehrlich Institute (PEI)**, Federal Institute for Vaccines and Biomedicines, is responsible as an international drug approval authority for the approval and batch release of vaccines and biomedicines. As a research institute, the PEI examines important questions on the mode of action, safety and efficacy of these products. This increasingly includes nanomaterials, which are used for example as stabilisers, auxiliary materials or active ingredient carriers and thus have a significant impact on the safety and efficacy profile of the therapeutic agent. Moreover, biomedical drugs are increasingly present in forms with nanotechnological properties (such as in encapsulations), which raises new questions as to the bioavailability and the interaction of these products with the organism. The PEI consequently conducts important biological distribution studies in this area, to assess the efficacy and safety of these products.

The **Federal Institute for Drugs and Medical Devices (BfArM)** is responsible for the approval and improvement in the safety of medicines, as well as the risk assessment and evaluation of medical devices. The primary objective of all measures is the improvement in safety of medicinal products and thereby patient safety. In this way the BfArM makes an important contribution to the prevention of health risks for our citizens. In the field of nanomedicine, the BfArM has combined institute-internal and interdisciplinary expertise in order to guarantee proper handling in the processing of tasks relating to pharmaceutical and medical products and to be able to provide scientific and regulatory advice to pharmaceutical companies and medical device manufacturers. The BfArM is involved in the harmonisation of requirements in the field of nanotechnology through the creation of framework conditions for European drug approvals.

5.3 Funding Open to Technology

Nanotechnology research and development is also promoted through a variety of Federal Government programmes open to technology and industry.

The **Central Innovation Programme for SMEs (ZIM)** is open to all technologies and is used by the BMWi to promote demanding, market-oriented R&D projects of small and medium-sized enterprises. The companies determine the topics themselves and can conduct their projects as individual projects, as cooperation projects with research institutes or with other companies or in the context of innovative networks.

The gap between fundamental research and economic application is filled by the BMWi **"Programme for promoting industrial collective research (IGF)"**. This programme prepares new technologies for entire economic sectors or across all industries. Companies, the majority of them SMEs, steer the research activities, so that they are geared towards their needs and interests. Only research associations that are members of the German **Federation of Industrial Research Associations (AiF)** can apply for funding under the IGF. The AiF is an association of around 100 non-profit research associations from trade and industry, which represents some 50,000 SMEs. The involvement of research associations aims to provide a preliminary review and boost quality. The results, however, are freely open to all interested companies – irrespective of AiF membership – and represent the precursor for company-specific developments.

As part of the BMWi, the **High-Tech Gründerfonds (HTGF)** invests in technology-oriented start-ups and young companies, which on the one hand have particularly high market opportunities, and on the other, also have considerable technical risks. Alongside venture capital, the HTGF also provides management supervision and support.

Innovations for new products and services are the driving force behind the success of the German economy. **WIPANO** is the German abbreviation for **"knowledge and technology transfer via patents and standards"** and the WIPANO programme is used by the BMWi to fund public research and companies in the patenting and exploitation of their ideas and supports innovative (research) projects dealing with standardisation.

The BMBF funding instrument **"Validation of technological and social innovation potential of scientific research – VIP+"** addresses scientists who wish to commercially exploit their research results or apply them in society. This creates the prerequisites for new products, processes or services.

The BMWi funding programme **EXIST** supports scientists and students in the preparation of their technology-oriented and knowledge-based start-ups. Another aim of the programme is improvement of the entrepreneurial culture at universities.

Under the funding initiative **SME-innovative**, the BMBF supports small and medium-sized enterprises to establish new products and procedures with a more promising foothold in the market. This funding is aimed at issues with great application potential and high technological risk. The funding instrument "SME-innovative: Materials Research" involves issues of nanotechnology in particular.

In the context of the new conception plan **"Priority for SMEs – the ten-point programme of the BMBF for more innovation in small and medium-sized enterprises"**, a number of new open-topic measures have been launched, in which SMEs together with partners develop and implement innovative ideas, for example as part of innovation forums.

Various Federal Ministries support young entrepreneurs also in the nanotechnology sector.

The BMBF's **Leading-Edge Cluster Competition** focuses on the networking activities of research and industry to create higher-performance, more innovative clusters. This funding activity should firstly create both growth and jobs and then make contributions to the major societal and economic challenges. In addition, the BMBF measure "Internationalisation of top clusters" will also make the globally available knowledge accessible to future projects and similar networks, in order to strengthen the competitiveness of the companies involved.

With the funding initiative **"Research campus – public-private partnership for innovation"**, the BMBF supports nine partnerships between science and industry in which at least one university and non-university research institutes and commercial companies conduct a jointly-established research programme for up to 15 years. It promotes research fields with high research risk and specific potential for leap innovations.

5.4 Innovation Accompanying Measures

The tasks of a strategic innovation policy include the networking of science and industry, the support of innovative SMEs, the promotion of training of professionals, the more rapid dissemination of new technologies, the target-oriented coordination of activities and the strengthening of public perception. Suggested solution approaches are especially necessary in new cross-sector, interdisciplinary technology fields such as nanotechnology. To make the most of the potential of nanotechnology and realise it in a targeted manner in new products, applications and social benefits, it is necessary to implement specific innovation support measures that extend significantly beyond direct project and research support, and circumscribe these in the main areas for action.

SMEs are of great significance for Germany as a business location and for the creation of new jobs in nanotechnology. It is therefore extremely important for SMEs to obtain facilitated access to research findings. The Federal Government thus promotes the innovative power of SMEs through targeted measures and reduces existing barriers to innovation. The BMBF supports the online portal nano-map.de[13], which provides an interactive map of the participants from science and industry to aid in the search for cooperation partners. Technology discussions and dialogue events are also held in order to address sector-specific problems at an early stage and actively support the diffusion of new application options into commercial practice.

Activities for the marketing of Germany as a location for nanotechnology include trade fair presentations and conference appearances, which support companies in the initiation of international cooperation. German SMEs and research associations, but also to some extent large companies, often face the problem of establishing innovative ideas, research results and products in international growth markets, particularly in Asia and Latin America. Potential strategic partners for scientific and technical cooperation are addressed at an early stage through the selection of international trade fair locations, associated with the accompanying evaluation of scientific and economic performance of the respective target region. Here the BMWi and BMBF support interested companies with advice and the organisation of states stands and German Pavilions.

The targeted promotion of young scientists by the BMBF contributes to sustainable assurance of well-trained, skilled workers for jobs in the field of nanotechnology. This generation of scientific talent begins with the organisation of holiday internships in cooperation with renowned research institutes. In addition, the internet portal nano-bildungslandschaften.de[14] provides information about training and eduction options.

Young scientists should find good starting conditions in Germany at the beginning of their careers. This is particularly true for top talent that is strongly courted internationally. Already since 2002, the BMBF has supported excellent junior researchers in the field of nanotechnology via the “NanoFutur” competition. Since 2013 followed promotion in materials research via the “NanoMatFutur” talent competition, with a broad inclusive approach that includes nanotechnological aspects. Selected winners have the opportunity to build their own research group and to use an ambitious research topic to qualify for a scientific career. Young scientists and engineers are trained in these junior research groups for an academic or industrial career.

Even since 2006 the German Government has accompanied its funding activities with various civil dialogue formats to provide the interested public with information about the current trends and developments, potentials, opportunities and risks of nanotechnology. The commercial success of nanotechnology is directly dependent on the social attitude toward this technology. The potential risks of nanotechnology in the areas of consumer, occupational and environmental protection can be a serious innovation barrier to the marketing of nanotechnology products. Involvement of the various participants and social interest representatives in expert committees and dialogue events will make a contribution to transparency and the objective of social risk discourse. In order to close any potential public information gaps in a targeted manner, research findings will be conveyed to citizens in the context of the “Citizens meet Experts” event format at different locations in Germany and there will be open discussions about the opportunities and risks.

Joint international stands generate interest in German nano products.

6 Identifying Nanomaterial Risks for Humans and the Environment – Making Innovations Sustainable

The further development of test and measuring methods for risk characterisation, the support of research institutes and companies in the safe application and environmentally compatible development of material innovations, the derivation of courses of action for risk management and the further optimisation of risk communication are the focus of this Action Plan. They are supported by a common research strategy "Nanomaterials and other innovative materials: Application safety and environmental compatibility" of the federal authorities BAuA, BfR, UBA, BAM and PTB.

In the last 10 years considerable efforts have been made to establish and continuously improve the scientific basis for assessment of potential risks from nanomaterials for humans and the environment. The results of a number of research projects show that nanomaterials are not per se linked with a risk for people and the environment. Nor have new effects of nanomaterials on human health been described to date.

Although it is becoming increasingly clear that even in the "new guise" of nanomaterials, known effects of substances, particles and fibres can still occur. Some nanomaterials release respirable fibrous particles that may have a carcinogenic effect due to their long retention time in the body (biopersistence). This is not, however, limited to nanomaterials. The Action Plan therefore provides a framework for risk research that also includes, if required, further advanced materials with comparable risks to man and the environment. Examination is also required to find out whether and how the tools of risk assessment must be adapted. In the interests of sustainable development, the activities should contribute to detecting the risks for mankind and the environment at an early stage of innovation and to establishing opportunities for the safe application and environmentally compatible development of new materials.

6.1 Early Detection and Assessment of Risks

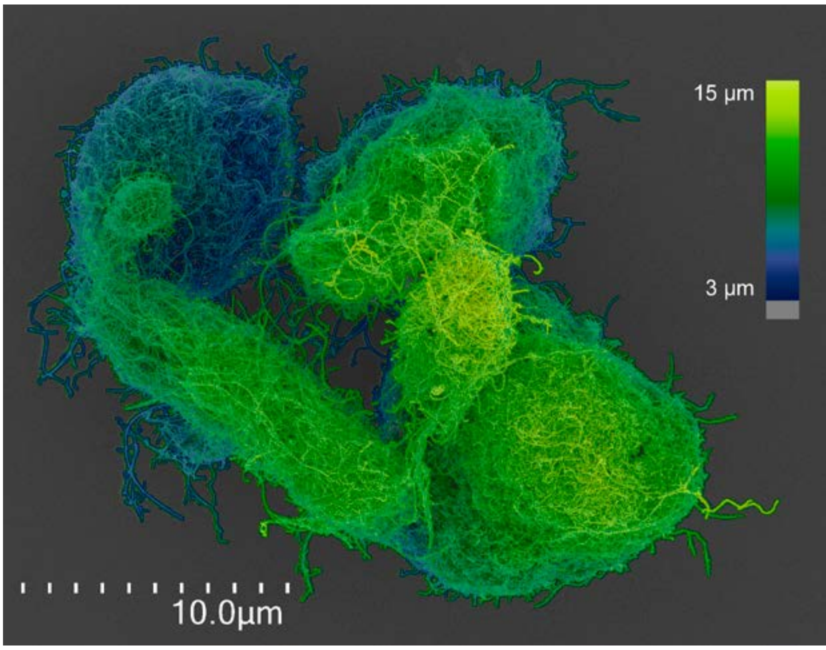
A number of research projects have assessed the applicability and relevance of established testing methods and concepts for evaluation of the risks of industrial chemicals to humans and the environment. These focused mainly on nanomaterials already manufactured industrially on a larger scale, such as nanotitanium dioxide, industrial soot (carbon black), nanosilica, nanosilver and other nanoscale pigments. Here the need for further development and specific adjustment of test procedures often became clear. Moreover, the increasing diversity and complexity of new nanomaterials that are on the threshold of application and marketing are a challenge for risk research.

At the forefront of hazards for occupational safety is the inhalation of respirable and biopersistent dusts. This is especially critical if the dust particles are fibrous. In addition, surface modifications and the release of ions influence the toxicity of less biopersistent materials. The well-known nanomaterials were therefore assigned into the groups “granular biopersistent particles (GBP)”, “biopersistent respirable fibres” and “specific toxicity”. The group assignment addresses different, but already established, testing and protection strategies that can also be applied to nanomaterials in a modified form, if required. In the case of respirable fibres, a carcinogenic effect can be characterised by the influencing factors “fibre shape”, “critical length”, “critical diameter” and “biopersistence”. The critical fibre dimensions relate to fibre lengths between 5 and 100 microns and fibre diameters of less than 3 microns.

The most recent research findings suggest that for a carcinogenic effect the fibre must be sufficiently rigid and thus must exhibit a minimum diameter. This would explain why large differences in the characteristics of the toxic effects were observed with different carbon nanotubes. Test procedures should therefore be developed or adapted as part of the Action Plan in order to determine the release, the morphology, in particular the rigidity and the biopersistence of fibres. This will create a basis for a differentiated risk assessment of nanohydrocarbons and other fibrous materials.

Little attention has been paid so far to the evaluation of the dust explosion behaviour of nanoscale particles. There is a need for action in particular for industrial processing. A determination is required as to how the chemical composition, flow behaviour and dust extraction influence explosion behaviour.

The sensitive detection and characterisation of nanomaterials and the investigation of potential release in the life cycle of nanotechnology-based products is of central importance to consumer protection. A variety of detection methods and reference materials is now available, but these are often too time consuming for routine application by companies and the supervisory authorities and therefore can only be used to a limited extent. This concerns for example characterisations



High-resolution, false colour representation of a cluster of carbon nanotubes taken with a scanning electron microscope.

relating to labelling requirements for food and cosmetics, if complex matrices are to be analysed using highly sensitive measuring devices. This is where the departmental research facilities make a substantial contribution by the further development of material characterisation procedures and making available the know-how for interpretation of the measurement results as well as reference methods and materials.

For food items, the possible inclusion of nanomaterials through the digestive tract is significant for the applicable, legally prescribed risk assessment and authorisation before they are placed on the market. If nanoparticles were to be absorbed into the body via the intestinal barrier, they could potentially accumulate in different organs. Questions as to the toxicity and degradation of the particles would also have to be taken into account alongside bioavailability and accumulation before any authorisation can be given. One possible example for the use of nanomaterials in food are encapsulations of vitamins and trace elements from organic systems.

According to the current state of knowledge, the diffusion of nanoparticles from food wrappers onto food is very low. In the event of abrasive conditions, however, a transition to the food cannot be completely excluded. This knowledge gap should be closed by the use of sensitive detection procedures.

The current procedures for risk assessment are suitable for the approval of medicines in order to detect any risks from nanoscale materials for people and animals and to enable a robust risk-benefit analysis. Here too, the advances in science should be carefully monitored so that the assessment procedures can be further developed.

In the very material-intensive construction sector there are many application possibilities for nanomaterials, which can improve and optimise the specific characteristics of construction products, for example as a concrete additive or for surface protection against weathering, ageing processes or mechanical influences. These often consumer-oriented applications require a sound risk assessment of the potential effects on human health or the environment in the event of release into the building's surroundings. According to state building regulations, buildings are to be constructed such that life, health and the natural foundations of life are not jeopardised. That is why the Federal Government is committed to working with the states at an early stage in order to find solutions for the evaluation of construction products manufactured using nanomaterials and to initiate and support the development of more appropriate evaluation procedures.

It is also evident in environmental protection that the nanoscale of a substance alone does not automatically indicate a hazard potential. In reality the potentially harmful effect of a nanomaterial is determined alongside its chemical composition by properties such as its size, geometry, crystal structure and surface properties (charge, structure and surface chemistry). In addition, environmental parameters (pH-value, salt content, content of natural organic substances) influence the mobility, bioavailability and toxic effects of nanomaterials in the environment. Reliable data have been generated in the last few years for the assessment of the environmental effects on organisms. These should now be used to extend and adapt the instruments for environmental hazard assessment.

Although risk assessment for the protection of the environment also requires the determination of potential environmental exposure. Missing here are both robust

Nanomaterials in construction products have to be investigated with respect to their risk on release into the environment.

assessment models and the necessary data on production quantities, areas of application and any possible sources of release. Measuring methods are currently being evaluated and standardised to provide reliable statements on the release of nanomaterials from products and applications and to generate qualitative and quantitative evidence in the various environmental compartments.

Previous exposure assessment models are based on thermodynamic processes in which a distribution between the various environmental compartments is adopted to reach a concentration balance. Behaviour and persistence of nanomaterials in the environment, however, are primarily subject to kinetic processes such as agglomeration and sedimentation. Nanomaterials can also adhere to existing particulate materials in the environmental compartments. Biological degradation, as an important parameter for determining the environmental exposure of many substances, is however not relevant for many inorganic nanomaterials. Although what are important are abiotic changes through chemical transformation due to loss of surface coatings or by binding of other substances.

It is important for all protection objectives that reliable regulatory statements about the risks to man and the environment are not only obtained for individual materials. Effect hypotheses should rather be derived and reviewed, which could enable a transfer of the knowledge gained to other substances. The aim is to develop concepts that allow sufficient assessment of nanomaterials with regard to their exposure, yet avoid the need for individual tests of a large number of different types. The studies should also lead to meaningful dose-response relationships, which are required as a scientific basis for the limit and guide values in occupational, environmental and consumer protection. Although the development of animal-free test procedures and simple methods should also be further promoted as an "early warning system".

6.2 Making Material Innovations Safe to Use and Environmentally Compatible

A large number of other materials is at the threshold from application research to market entry. This also includes nanomaterials produced from chemical substances that have not yet been sufficiently evaluated (e.g. rare earth compounds). In addition there are materials whose physiochemical properties have been purposefully and extensively altered for certain purposes, for example by surface functionalisation or doping.

The Nano Action Plan should support research institutes and companies to undertake activities with advanced materials in a safe manner, even if essential data for risk assessment are not yet available. Alongside the derivation of preliminary occupational protection measures, on the basis of the precautionary principle it is of vital importance that the previous grouping approach is sufficient or else it must be further developed. Fundamentally new patterns of risk, which have not yet been observed in the nanomaterials previously considered, can only be detected through continuous

Suitable extraction equipment has to be used in the case of nanomaterials that create dust.

Findings on patterns of dust generation when working with nanomaterials are of great significance to occupational safety measures.

basic research and the awareness of all those involved in the innovation process.

Nanomaterials and other advanced materials are subject to the relevant European test and information obligations for chemical safety. Albeit these only relate to already known and scientifically well described hazards and often only when an innovative material is placed on the market in large quantities. The tonnage-dependent test obligations mask the danger that the long-term effects of an innovative substance or material on man and the environment can only be detected decades after market entry. The early detection of potential risks from nanomaterials for man and the environment and the application of the precautionary principle in order to avoid or reduce the negative environmental and health effects therefore belong to the central concerns of this Action Plan. This requires the continuous development of existing test methods and innovation accompanying risk research. These should test known effect principles in new materials, but also have a view towards hazards that have not yet been recognised. This is how safe to use and environmentally compatible material innovations are to be promoted, in order to prevent the failure of entrepreneurial investment and severe social ramifications.

The approaches and methods established for early detection of health and environmental risks can therefore be a guideline for safe and environmentally compatible development of advanced materials and their secondary products. The scientific findings must be evaluated to the extent that material modifications allow, in order to minimise or eliminate risks to health and the environment from the outset. The patterns of dust generation from nanomaterials and other advanced materials should be systematically investigated to discover low-emission forms of use, relationships with material structure and processing methods.

The application safety and environmental compatibility of material innovations should be promoted by improving cooperation between product engineers, materials scientists and experts from risk and safety research. In a model project of the BAuA under the Action Plan, public-private governance networks are to be established with research institutes and companies in order to develop and disseminate safe to use and environmentally compatible development concepts for new materials.

6.3 Creating Sustainable Product Life Cycles

Due to their special properties, nanomaterials offer great potential to provide energy-efficient and resource-saving products. Although the effects of the product on human health and the environment must thereby be considered whilst taking the entire life cycle into account. Several billion tonnes of materials are installed and dismantled in Germany every year, for example. Risk assessments must therefore take possible exposure during the use phase into account when assessing the risk from the formation of dust during deconstruction and the introduction of problematic substances in materials cycles. Aspects of information and knowledge management are also important here, such as the collection, provision, retention and distribution of risk information from the planning stage to realisation, use and demolition of a building.

The assessment of the opportunities and risks of new product innovations must be conducted on a sound scientific basis. Instruments for the ecobalancing reflection on products containing nanomaterials have already been developed, but so far only a few products have a qualitative and quantitative analysis of their environmental and sustainability potential. Furthermore, nanotechnology products and applications are often still in an early stage of application and it must be assumed that key parameters can still significantly change, for instance through more efficient production processes.

Manufacturers and importers are responsible for ensuring that advanced materials and the products manufactured from them meet the legal requirements of European chemical safety. There are also the requirements under European and national rules and regulations for occupational, consumer and environmental protection. Before being placed on the market, substances and mixtures must be classified according to present findings and be supplied with a hazard label. A safety data sheet must be produced for commercial customers. Approval and registration obligations apply to certain product groups like food, cosmetics and biocides or additional labelling requirements for consumer information must be observed. To ensure sustainable protection of man and the environment it is essential that regulations keep pace with the rapid and significant progress in material development. The testing and information requirements specified in the chemical and product safety regulations do not yet adequately cover some risks to man and the environment that can be released by nanomaterials and other advanced materials. Currently the sole responsibility for material and product safety and compliance with the relevant safety objectives thus lies with the manufacturer or importer. It is therefore necessary, particularly from the point of view of the consumer and environmental protection, to bear in mind the life cycle of relevant materials and corresponding products with regard to traceability.

There are also open questions on the risk assessment for man and the environment relating to the processing of composite materials, which contain nanomaterials and other advanced materials as a permanent component. Here processing procedures, method of use and ageing have a decisive influence on possible release during the life cycle. Criteria for low-emission products and processing procedures are to be derived as part of the Nano Action Plan. In the case of composites, as well as the patterns of dust generation consideration must also be given to a possible concentration of nanomaterials on the surface of the processed or aged material. This is also to include activities at the end of the life cycle in the event of recycling and disposal.

There are also open questions on the assessment of the risk from nanomaterials for man and the environment when it comes to recycling.

6.4 Intensifying the Communication of Risk

The high dynamics in material development, but also in the generation of risk and scientific data relevant to measures, necessitates special efforts to keep all relevant target groups up to date and ready to act. The development of the competence needed requires long-term vocational and further training opportunities for experts in risk and safety research. In addition, prospective scientists and product developers should be made aware of occupational, environmental and consumer protection issues as well as the development of safe to use and environmentally compatible new materials and products. This is to be achieved through enhanced cooperation between materials scientists and experts in risk and safety research, for which corresponding training and study opportunities are to be created in further education colleges and universities.

The by now world-wide harmonised hazard labelling using pictograms, hazard and precautionary statements is the most important instrument for risk communication for those involved in the supply chain for substances and mixtures. Commercial customers also receive a comprehensive safety data sheet from suppliers. This is also the employer's central source of information for the legally prescribed risk assessment in the workplace and for the selection of occupational protection measures. Hazards due to the release of respirable, biopersistent particles inter alia are not yet adequately covered by hazard labelling and the information obligations. The declaration of potential hazards from composite materials, such as a release of reactive or biopersistent particles during processing, use or at the end of their life cycle, is still not satisfactorily resolved. The Federal Government will continue to advocate the achievement of optimal and proportionate transparency and communication of risks and measures with respect to nanomaterials and other materials innovations. Safety data sheets must enable employers to conduct a robust risk assessment and therefore must contain precise information as to the material characterisation, the physiochemical, toxicological and ecotoxicological properties and the necessary protection measures. There are still considerable deficits here. Reliable manufacturer information is also required in order to duly consider nanomaterials in consumer information.

Investigations in 2012 showed that there are in principle no major concerns within the population as regards nanomaterials[15]. Albeit their use in products that come into close contact with the human body is viewed rather more critically. The representative population surveys and media analyses as to the perception of nanotechnology in the population are to be continued. One focus is the manner of representation of nanotechnology in the media. Target-group-oriented risk communication strategies are to be derived from the results so that ongoing progress in the description of the risk can be announced in a transparent and comprehensible way to the technical community and other interested groups. Accompanying studies are to evaluate whether the communication of these findings leads to changes in risk perception. The growing importance of social networks is also to be taken into account.

Transparent transfer of knowledge about nanotechnology is a prerequisite for technological acceptance and trust in nano products.

7 Creating the Framework Conditions for Sustainable Innovations

The objective of all statutory framework conditions and regulatory efforts on the part of the Federal Government is to use the commercial, sociological and ecological potential of nanotechnology in a controlled manner and to avert potential risks. The necessary regulatory measures and reliable norms and standards must therefore likewise be further developed.

7.1 Legislation and Regulation

Chemicals legislation

European chemicals legislation, especially the European REACH regulations and the regulation on classification, labelling and packaging of substances and mixtures (CLP)[16], alongside the specific provisions such as for cosmetics or food, currently form the most important framework of legal principles for placing chemical substances on the market, this also includes those at nanoscale.

All substances above a certain quantity threshold (1 tonne/year) are always covered under REACH. The Federal Government accepts that the provisions of REACH are in principle well suited to include the detection of risks from nanoscale forms in the substances to be registered. Although the regulation still has to be adapted to the findings on nanomaterials gained from risk research in the interim. The Federal Government is in discussion with European partners about a comprehensive conception plan as to how nanomaterials can be regulated under REACH. It provides for additions to the provisions, in particular the introduction of a definition of nanomaterials, the inclusion of additional tests for the characterisation of nanomaterials and a modification of the standard test programme to account for the special properties of nanomaterials. With these changes and the already existing instruments in REACH for risk assessment and risk management, nanotechnology can meet the requirements of occupational, environmental and consumer protection.

The European Commission (COM) has announced the adaptation of the annexes of the EU REACH chemicals regulation in terms of nanomaterials (such as adaptation of definitions or modified tests).[17] The Federal Government has already decided upon constructive support of this regulatory process in the Nano Action Plan 2015. It asked the federal authorities to submit a specific text proposal to the COM as a basis for discussion. This occurred in 2013. Since then the Commission has not put forward an official proposal. A legally binding regulation for the third registration phase ending 31 May 2018 can no longer be expected. The Federal Government confirms its commitment to continue in a constructive process to ensure that the European Commission supplements REACH with the findings from risk research into nanomaterials and closes any existing gaps in the protection of human health and the environment.

A safety data sheet must be produced for industrial and commercial customers. This is to contain important information on the identity of the product, expected hazards, safe handling and measures for prevention and hazardous events. The aim is that these will in future also contain further safety-related information for nanomaterials, such as on patterns of dust generation.

The European regulations on classification and labelling (GHS/CLP – Globally Harmonised System/Regulation on Classification, Labelling and Packaging of Substances and Mixtures) are effective without any tonnage threshold. The manufacturer or importer therefore has the obligation to evaluate the hazard characteristics for all substances and mixtures placed on the market. A working group of the UN is currently checking whether the existing GHS classification criteria are applicable to nanomaterials. Since the form of a substance has to be considered during classification, data must be used that was collected taking into account specific requirements for the investigation of nanomaterials.

Food

The general statutory food regulations are applicable to food that contains technically produced nanomaterials[18]. Accordingly, only safe food may be produced and placed on the market. Furthermore, specific regulations are relevant depending on the nature of the food: If substances in nanoscale dimensions are to be used as food additives, i.e. used for technological purposes in food, they are subject to authorisation requirements.[19] Authorisation will only be granted if the health assessment by the European Food Safety Authority raises no objections to the intended use. If nanoparticulate materials are to be used for other purposes (e.g. for nutritional-physiological purposes), then a safety assessment and authorisation are required prior to placement on the market if the food has experienced a significant change in its composition or structure due to the use of a previously "non-standard" manufacturing process.[20]

For the information of consumers, a requirement for the labelling of food ingredients produced from manufactured nanomaterials was also introduced throughout the EU.[21] These must accordingly be supplemented with the wording "nano" in brackets in the list of ingredients. The regulation on the labelling obligation also contains a definition of what is to be understood under "manufactured nanomaterials".

Operating instructions are to describe the hazards and workplace protection measures required.

Food that contains nanomaterials is subject to an EU-wide labelling obligation.

Foodstuff commodities

Foodstuff commodities – irrespective of the method of production and the particle size of the materials used for their manufacture – must satisfy the general requirements of the framework regulation for foodstuff commodities/food contact materials.[22] The companies responsible must thereby ensure that human health is not at risk. There are also additional, specific requirements for the use of certain substances. For instance the EU plastics regulation[23] includes an approval obligation for nanomaterials. Such approval follows on the basis of a health assessment by the European Food Safety Authority. At national level, a regulation with special provisions for the printing of foodstuff commodities is currently being drafted. This is also to include provisions for the use of nanomaterials.

Biocidal products

Biocide law[24] regulates the formal and substantive testing and licensing regulations and also addresses the potential nanoscale properties of biocides. A separate risk assessment must be carried out if nanomaterials are used in a biocidal product. This requires specifications to be developed on specific data requirements in terms of physiochemical properties for risk assessment. Furthermore, the law explicitly provides that the applicability of the specified toxicological test methods must be checked on nanoscale products on a case-by-case basis. The marking of nanoscale ingredients on the label is mandatory

Plant protection products

Plant protection products are subject to an authorisation requirement.[25] It is important to ensure that application does not have any harmful effects on human and animal health and on groundwater or any unacceptable effects on the balance of nature. This also applies to nanoscale ingredients within plant protection products.

Cosmetics

The regulation on cosmetic products[26] contains specific provisions concerning the use of nanomaterials. This regulation basically stipulates a requirement to notify nanomaterials in cosmetic products to the European Commission. Approval is also required for nanoscale UV filters, dyes and preservatives. The addition of "nano" in labelling is moreover mandatory for nanoscale components in cosmetics.

Medicines and medicinal products

Medicines for humans[27] and animals[28] are subject to approval by the competent authorities. The application for approval must include information on quality, efficacy and harmlessness from laboratory tests and clinical studies in humans or field studies in the target species. The balance between benefit and risk, which also includes an assessment of environmental aspects, is an important part of the authorisation decision.

Similarly as for medicines, it deals with medicinal products containing nanomaterials. They are to be classified into three risk classes according to the future (still to be adopted) European Directive on Medicinal Products[29] in relation to the extent of the exposure to nanomaterials in the human body. This risk-based classification is important because it directly determines the nature and scope of the conformity assessment procedure for attaining marketability (comparable with the authorisation procedure in the case of medicinal products).

Transparency concerning nanomaterials in products

The European Commission is currently planning to introduce an instrument to increase the transparency concerning products on the European market that contain nanomaterials. It establishes an ECHA monitoring centre. The Federal Government will strongly advocate for this instrument to achieve the objective of transparency concerning the type, quantity and applications of nanomaterials on the European market. One prerequisite for this is the appropriate adaptation of the statutory chemical regulations.

Occupational protection

Nanomaterials are chemical substances and therefore fall under the provisions of the European Agents Directive[30] and its implementation in the Ordinance on Hazardous Substances (GefStoffV). The GefStoffV stipulation for occupational protection when handling hazardous particulate substances[31] also applies to activities involving nanomaterials if these can lead to exposure to respirable dusts. In that event the Committee on Hazardous Substances (Ausschuss für Gefahrstoffe – AGS) recommends that the risk assessment is conducted on the basis of a grouping approach[32] and describes the criteria for assessing air concentrations in the workplace, especially for biopersistent dusts produced from nanomaterials.[33]

Findings from risk research enable commensurate occupational safety measures.

7.2 Metrology and Standardisation

Metrology as the science of measurement and its application has been understood as an international task since the founding of the Metre Convention in 1875. Its objective is to ensure world-wide comparability of the calibrations of the national metrology institutes within their respective measurement uncertainties. The PTB takes this responsibility in Germany in cooperation with the designated institutes of the BAM, UBA and BVL. The comparability and measuring performance of the national metrology institutes are continuously reviewed and documented in a system of regular international comparison measurements. This also applies to the area of nanoscale measurement objects.

The traceability of measurement results secured by metrology to the international system of units contributes directly to increase international competitiveness and innovative strength of the company involved. Regulatory and legal certainty in the use of nanotechnology also require internationally harmonised definitions, a uniform terminology and internationally comparable characterisation procedures. It provides the opportunity to integrate standardisation aspects already established by R&D work on nanotechnology in order to further improve the framework conditions for the successful transfer of R&D results into innovative products and services. The awareness of standardisation as a transfer instrument for innovations can be raised and the effectiveness of public and private R&D funding can be increased by taking the relevance of standardisation into account.

German participation in international standardisation activities

In Germany, in particular the German Institute for Standardisation (DIN), the German Association for Electrical, Electronic & Information Technologies (DKE) and the Association of German Engineers (VDI) coordinate the development of standards and guidelines. They exercise the mandate of the European Commission for Europe-wide, harmonised standards and work with the European standardisation organisations Comité Européen de Normalisation (CEN), Comité Européen de Normalisation Électrotechnique (CENELEC), and the European Telecommunications Standards Institute (ETSI) to develop the corresponding standards[34]. German institutes and industry are engaged in the standardisation of nanotechnology at international level via the ISO and International Electrotechnical Commission (IEC). At the European level (CEN, CENELEC) and national level (DIN, DKE)[35] there are corresponding mirror bodies that work in close cooperation with the ISO/IEC committees and introduce the appropriate European or national interests into international committees.

The international standardisation activities in nanotechnologies are undertaken especially in the three ISO or IEC bodies ISO/TC 229 Nanotechnologies, ISO/TC 24 Particle characterization including sieving and IEC/TC 113 Nanotechnology Standardisation for

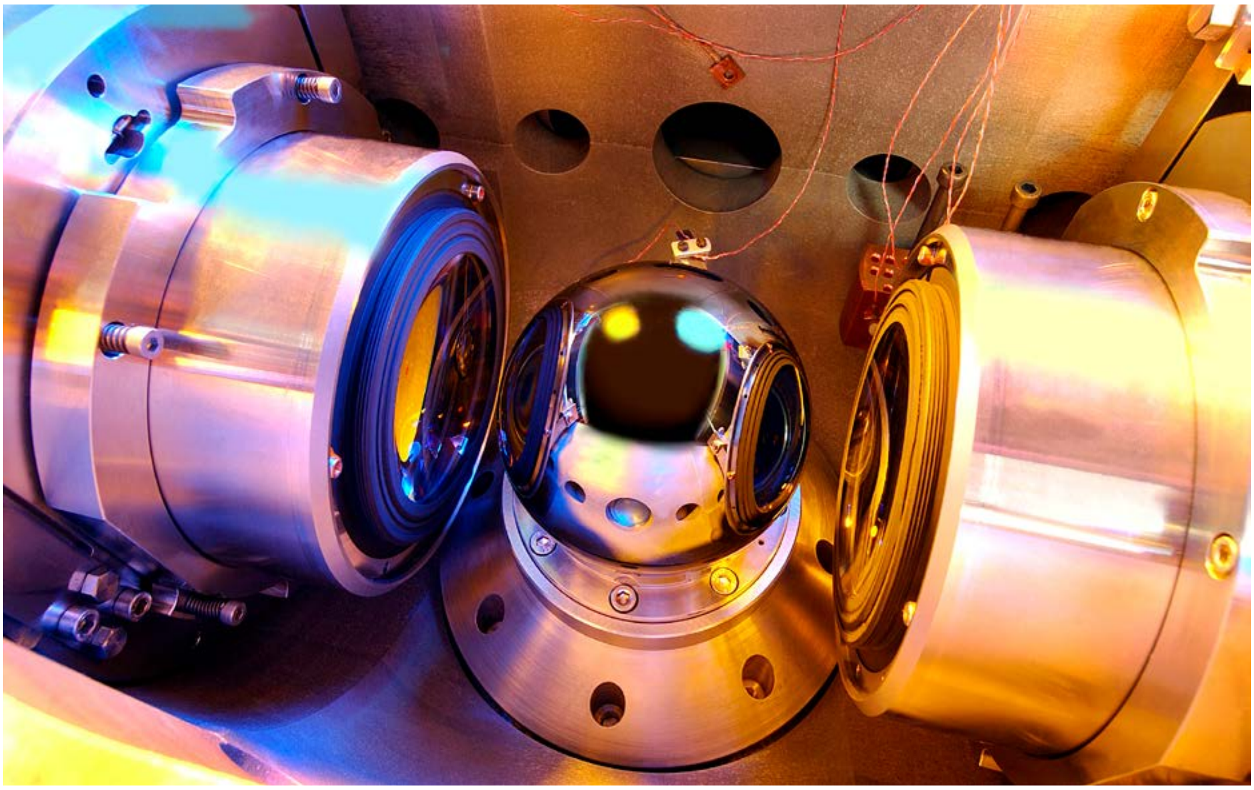
Electrical and Electronic Products and Systems as well as the European body CEN/TC 352 Nanotechnologies. ISO/TC 229 is currently dealing with more than 70 standardisation projects in parallel. The European CEN/TC 352 is processing eight of its own standardisation projects and handles many of the ISO/TC 229 projects in its work programme.

Germany chairs the secretariat of IEC/TC 113, where 40 standardisation projects are being handled. This is a position that can be used to help shape the standardisation of nanotechnological solutions in an international manner. It also provides the opportunity for international dissemination of German occupational protection solutions, which inter alia are laid down in the Technical Rules for Hazardous Substances. The Commission for Occupational Health and Safety and Standardisation is therefore producing a report that investigates the relationship between current standardisation activities and aspects of occupational protection.

The standardisation of nanomaterials is still in a dynamic phase. ISO Committee ISO/TC 229 has already drawn up 46 standards and rules, including the definition of nanomaterials. This definition is however too imprecise for regulatory and toxicological aspects on the one hand and often insufficient in terms of the biological field on the other. Efforts are therefore being made at EU level to firm up this definition for regulatory purposes. Although the definition is pushing at the limits of metrology, which are mainly standardised in ISO/TC 24. The planned EU definition will be difficult to enforce without increased efforts in research into metrology (process development as well as improved and correct application of the procedures).

In parallel to the standardisation activities in CEN/ISO/DIN there are normative activities in the areas of environment and toxicology, which are addressed by the OECD. The activities with respect to nanomaterials are concentrated in the body "Working Party on Manufactured Nanomaterials" (WPMN), which is attempting to standardise the complexity of the issue in guidance documents in close coordination with the ISO, stakeholders and the ECHA.

The nanometre-precise silicon sphere manufactured at the National Metrology Institute will significantly help to redefine the kilogramme.



Participation in standardisation bodies is the basis for safe use of nanomaterials.

Test guidelines and guidance

A series of standardised, internationally harmonised and accepted models, test guidelines and guidances are used for the reproducible and comparable testing of chemicals[36]. These have primarily been developed for soluble and organic chemicals.

In 2007, the OECD launched the so-called Sponsorship Programmes (2009–2014) within the framework of WPMN, in which originally 14 representative nanomaterials were to be tested[37]. One of its functions was to check whether the existing OECD test guidelines for the examination of chemicals are also applicable for nanomaterials or whether adaptation or supplement is needed. The programme resulted in confirmation that the existing test guidelines are generally applicable. There is nevertheless a requirement for adaptation and supplement. Inter alia in various expert meetings of the OECD, therefore, various selected OECD test guidelines were discussed with regard to their applicability for the investigation of nanomaterials and recommendations were produced.

Alongside the adaptation of existing OECD test guidelines on (eco)toxicology and the development of new test guidelines for environmental behaviour, what is important for an adequate risk assessment of nanomaterials is the specific description of the properties of nanomaterials to be examined, such as particle size and distribution, surface and surface chemistry and charge. The development of specific OECD test guidelines for characterising the physiochemical properties of nanomaterials is thus of key importance.

8 Implementing Transparent and Open Communication

The Federal Government considers dialogue with the public as an integral part of its innovation policy. Dialogue formats are therefore being made available through which citizens receive factual information on the potential, prospects and risks of nanotechnological innovations and products and suggestions for the further alignment of this field of technology are made.

8.1 Expanding Information Platforms

DaNa – Data and knowledge on nanomaterials

The Internet based information platform DaNa2.0 builds on the results of the project funded by the BMBF since 2009 called "DaNa – Data and knowledge on nanomaterials". DaNa uses the interdisciplinary knowledge of human toxicologists, ecotoxicologists, biologists, physicists, chemists and pharmacists to provide research results into nanomaterials and their impact on man and the environment for interested laymen[38]. The DaNa knowledge platform currently provides information on 25 materials that are used in the most common consumer-oriented applications. Short texts as well as detailed articles inform not only on the properties of coarse-grained and nanoscale materials, but also whether and how nanomaterials can be released and what the impact is to man and the environment. It also presents the scientific findings of the BMBF funding measures NanoNature and NanoCare. Its high degree of recognition is documented by the large number of around 100,000 visitors in 2015.

"nanoTruck" – Meeting Place Nanoworlds

As part of the Federal Government's High-Tech Strategy, the BMBF "nanoTruck" initiative has concentrated in the last ten years on generally intelligible, appealing communication of directly usable information about the basics, application areas, opportunities and potential risks of nanotechnology. In various theme worlds and event formats, visitors to the "nanoTruck" – the particular target groups were pupils, students and the general public – were able to get to grips with the status quo and the future of nanotechnology research and practice. The double-decker exhibition vehicle provided the perfect frame with interactive exhibits, a laboratory area for workshops and practical courses, multimedia terminals for individual research and a nano-cinema. Until the end of its operations in 2015, the "nanoTruck" reached approximately 100,000 people per year in school courtyards and in city centres, during technology days and science evenings, at educational and trade fairs and at industry events and conventions. On up to 220 operating days it was the guest at more than 80 venues in Germany. In future the spectrum of topics for the "nanoTruck" will be expanded and made accessible to the public under the motto "InnoTruck".

Further information platforms

The federal authorities BAuA[39], BfR[40], UBA[41] and DGUV[42] have their own websites for providing information on their activities and the results of risk research into nanomaterials, but also on issues and positions on regulatory aspects as well as recommendations for action.

The website of the working group on nanomedicine is where the BfArM[43] provides information on its activities with regard to medicinal products and medical devices that are developed through the use of nanomaterials and nanotechnology. The European Medicines Agency EMA[44] in London also provides information about nanomaterials and nanotechnology in relation to medicines on its website.

8.2 Continuing Dialogue Processes

The Federal Government's NanoDialogue

Since 2006, under the leadership of the BMUB a unique, Europe-wide stakeholder dialogue has been conducted with the motto "Sustainable use of Nanotechnologies". It involves non-governmental organisations, industry, science and public authorities at federal and state level. More than 300 experts share opportunities and potential risks on a continuous basis. The approach of considering opportunities and risks at the same time has led to high acceptance of the NanoDialogue on all sides. This has created a forum where even opposing positions can be discussed in a respectful and open manner. Understanding and trust has been fostered between the different participants and this has contributed to the success of this new technology. The NanoDialogue will therefore be continued.[45]

The theme worlds explored in the nanoTruck demonstrated numerous application possibilities for nanotechnology.

Technology discussions with citizens

These are discussions where citizens come into direct contact with experts, open active communication paths for well-founded discussion of the different facets of nanotechnology, gain insights and acquire an overview of the research field. Citizens should be informed at an early stage, heard and encouraged to express their fears and hopes and ask questions in order to reach an informed opinion.

Within this format, twice a year at alternating locations in Germany, the BMBF holds moderated dialogue events under the motto "Citizens meet Experts", which give an interested audience the opportunity to talk with experts from science, industry, administration and consumer protection on the opportunities, risks and perspectives of nanotechnology. These citizen discussions are supported locally by regional cooperation partners that are not necessarily from the scientific environment, but come from different areas of society.

Technology discussions with societal participants

The BMBF also conducts regular technology discussions with interest group representatives. In this case, societal stakeholders and non-governmental organisations obtain a generally comprehensible overview of risk research findings and about current developments in the field of nanotechnology. The objective here is to promote an open and transparent social dialogue based on the latest scientific findings.

9 Alignment of International Activities

International cooperation in research, development, standardisation and regulation are of crucial importance for Germany. It is also valid for nanotechnology that science is conducted in global cooperation, value chains extend across different countries, quality and functional comparisons can only be carried out following international norms and standards and the effective protection of human health and the environment can only be achieved by regulations that reach across national boundaries.

With a view to the future innovation power of companies and the sustainable protection of jobs in Germany, it is necessary to better apply the knowledge available worldwide for domestic development. International collaborations enable the use of know-how available outside Germany for the benefit of national R&D activities and the development of new value creation chains in strategic target markets. Federal Government objectives are the collaborative exchange of knowledge and the use of complementary skills and resources to improve the competitiveness of the German economy in future technologies such as nanotechnology.
Joint activities also increase consumer confidence in nanorisk research (in an international context mainly designated as nanosafety research) and in legal framework conditions, accelerate the transfer of technology and thereby enhance the implementation of nanotechnology in products and applications.

The objectives of international measures in nanotechnology are:

- **Initiation of scientific and technological cooperation**
  Early evaluation of the scientific and economic performance of target regions to establish new and strengthen existing international research collaborations.
- **Use of the innovation potential and better market penetration**
  Implementation of industrial research and development projects with a high technological-scientific risk, which are cross-technology and application-related and enable direct access to foreign markets.
- **Enhancement of the interests of the specialist nanotechnology scene in Germany**
  Cooperation with the EU through the activities of the National Contact Point Materials and the National Contact Point Nanotechnology; assertion of German interests in the thematic orientation of individual support measures through participation in the programme committee.

- **European harmonised legal framework conditions**
  Active participation of German representatives in the technical, regulatory and political bodies at EU level (e.g. REACH, Food and Cosmetic Directive, the medicinal product and medical sector).
- **Standardisation**
  German participation in international standardisation activities with ISO, CEN and CENELEC.
- **Promotion of internationally comparable requirements for occupational safety**
  Participation in the development of an evidence-based guideline for the safe use of nanomaterials in the workplace by the WHO and international dissemination of the English version of the guide "Nano to go", which was prepared by the BAuA on the basis of the recommendations of the Committee for Hazardous Substances (AGS).
- **Active participation in OECD working groups**
  Participation in the Working Party on Manufactured Nanomaterials (WPMN), OECD Working Party on Resource Productivity and Waste (WPRPW), OECD Working Group of the National Coordinators of the Test Guidelines Programme (WNT) and the Working Party on Biotechnology, Nanotechnology and Converging Technologies (WPBNCT); influencing the focus and joint development of harmonised standards for testing and evaluation.
- **Participation at trade fairs and conferences**
  Presentation of nanotechnology developments from Germany at international trade fairs and specialist events for materials research. This participation serves to support SMEs in foreign markets and to initiate collaborations.

International activities are often the starting point for cooperation and for attracting the next generation of talent.

9.1 Supporting German Involvement in EU Funding Programmes

The European Framework Program for Research and Innovation (Horizon 2020):

In "Horizon 2020" nanotechnology together with advanced materials, biotechnology and production techniques form the so-called key technologies (key enabling technologies, KETs) within the single objective "Fundamental and Industrial Technologies". In this context, in 2015 the technology platform "Nanofutures" presented a comprehensive "Implementation Roadmap" for nanobased technologies, services and products for the period 2015–2022.[46] Activities related to nanotechnology can also be found in other areas of the Horizon 2020 programme, such as under the European Research Council, the Marie-Sklodowska-Curie mobility measures, the SME instrument, or the programme area Future and Emerging Technologies (FET).

Programme planning in Horizon 2020 takes place on the basis of proposals from the European Commission, in close cooperation with the EU Member States. The BMBF represents the Federal Government in the Horizon 2020 programme committee configuration "Nanotechnologies, Advanced Materials, Biotechnology, and Advanced Manufacturing and Processing (NMBP)", with the objective of introducing the priority issues from the point of view of German experts and industry into the work programmes and support measures of Horizon 2020. Issues such as nanosafety research receive special attention as they enjoy a high priority at both national and EU level.

In addition to German funding instruments, European research funding represents a second major pillar of R&D funding for German applicants. In the previous 7th EU Research Framework Programme (7th FRP; term 2007–2013) about 3.5 billion euros were invested in nanotechnology research by all Commission areas concerned. Approximately 21% of this funding flowed to Germany. German applicants therefore took a leading position in the competition for European funding. They received funds for nanotechnology amounting to 740 million euros.

NANoREG as a successful example of research for regulatory purposes

The BMUB as "political adviser" has succeeded in attracting significant participation by German Industry and federal authorities in the EU "NANoREG" call. This call under the 7th FRP was the first not to focus on innovation research, but rather on regulation research.[47] A specific part of this project is a worldwide-unique, long-term study on the health effects from inhalation of biopersistent particles in the low dose range. The results of the long-term study are expected by the end of 2017 and have implications for the derivation of the limit and guide values in occupational health and safety and environmental protection.

ERA-Net and PPP

Alongside the EU Member States, there are also a variety of opportunities for partners from other countries to become involved in the activities of Horizon 2020. In addition to targeted calls for research and innovation projects there are joint initiatives for international cooperation, such as the European networks (ERA-Net) or the European Cooperation in Science and Technology (COST) initiative. The BMBF participates in a series of ERA-Nets in the field of nanotechnology.

Applications in nanomedicine generally target the controlled interaction of medical products with cells in the nanometre range. Since 2009 the BMBF has been involved within networks of the European Research Area (ERA) in the European funding measure "ERA-Net EuroNanoMed". ERA-Net funds collaborative projects from companies, research institutes and clinics that have set themselves the objective of exploring innovative nanotechnological solutions in the areas of drug transport, diagnosis or regenerative medicine. Together with the European network partners, funding institutions from Norway, Israel and Switzerland have participated in the tenders.

M-ERA.NET (ERA-NET on Material Science and Engineering) is a joint initiative of 41 partners from 28 European and non-EU countries and regions (including Israel, Norway, Brazil, Taiwan, South Africa, Russia and Turkey). It covers a wide variety of topics from fundamental materials sciences, research and development of innovative material concepts to the manufacturing processes. Nanotechnological R&D approaches form part of suggested solutions addressed in the funded projects.

ERA-NET SIINN ("Safe Implementation of Innovative Nanoscience and Nanotechnology") is a joint initiative of 19 partners from 14 countries and 3 regions. Israel, Switzerland and the United States are other countries to have become involved in ERA-NET SIINN tenders. ERA-Net SIINN targets secure implementation of nanotechnological results in industrial applications. National and regional resources are hereby pooled in order to develop findings on nanosafety research in cross-border collaboration. SIINN aims to pool research activities into possible human and ecotoxicological risks from nanomaterials.

Moreover, nanotechnology is a key topic of country-specific ERA-Nets with German participation, such as ERA.Net Plus with Russia.

A nanotechnology relationship can also be found in the four public-private partnerships (PPP) established by the EU Factories of the Future (FoF), Energy-efficient Buildings (EeB), European Green Cars (GC) and Sustainable and Low-Carbon Technologies in Energy-Intensive Process Industries (SPIRE).

9.2 Strengthening International Collaboration

In implementing Action Plan Nanotechnology 2020, checks are to be made on measures that can be incorporated which specifically target international collaboration.

The United States and Asia are leading regions of the world in the field of nanotechnology. Some countries

Internationally available know-how provides potential both for nanotechnology innovations and for the opening up of new markets.

have established targeted programmes and initiatives and made a high level of funding available in order to further strengthen their technology leadership in nanotechnology. Israel, China, India, Japan and Korea are particular target countries with which Germany has for many years engaged in intensive collaboration over various scientific and technological areas.

German participation in the OECD WPMN

The BMUB heads the German delegation of the WPMN, which since 2006 has pursued the goal of reviewing and if necessary adjusting internationally coordinated and mutually recognised methods and strategies, in order to record and master the potential health and environmental risks of nanomaterials. The results will be made available to the public and are intended to assist the countries involved to adopt measures to ensure the safe handling of nanomaterials.[48]

One central WPMN objective is currently the review of existing test methods with regard to their applicability for nanomaterials and the development of proposals for the adaptation of these test methods. A test programme was conducted for this purpose, the results of which have now been published[49] and are to be scrutinised with respect to the suitability of the methods used. Initial projects dealing with adaptation and development of OECD test guidelines and guidance have already started and are running in close collaboration with the OECD Test Guideline Programme (WNT). The transition of recognised OECD test methods will focus in particular on the test method regulation of existing regulations for the safety of chemicals such as REACH and thus provide the basis for comparable and reproducible results. Further WPMN objectives are international exchange and cooperation in the risk research and regulatory aspects of nanomaterials. Current OECD WPMN topics include inter alia the development of a basis for exposure assessment and for grouping and analogy concepts for nanomaterials.

The BMUB is also participating in OECD WPRPW, which includes some projects dealing with waste that contains nanomaterials.

ISO TC229 and CEN TC352

In the area of standardisation, the ISO deals with the preparation of norms and standards at international level and the CEN at European level. The Federal Government is involved in these international bodies through the active commitment of German experts to the respective standardisation committees. This introduces national interests into the standardisation of nanotechnological solutions. Topics in these standardisation committees are increasingly related to metrology for a wide range of applications, be it in the determination of particle size, registration of toxicological effects, material specification of chemicals, instruments for risk assessment or the development and adaptation of test methods.

EURAMET

EURAMET coordinates, implements and supports the European metrology research programme EMPIR, which lasts from 2014 to 2023 and has a funding volume of EUR 600 million. Various issues of nanometrology have also been addressed in the previously tendered research topics.

10 Conclusion and Outlook

Achievements can be recorded in the context of inter-departmental collaboration to date; there are however also recognisable deficits and needs, which provide important impulses for the future activities of the federal ministries. A number of new formats are planned that will run in parallel with maintaining the continuity of proven priorities and measures. There is also a need to ensure that Action Plan Nanotechnology 2020 provides sufficient flexibility to also be able to react quickly to new developments.

Conclusion

The inter-departmental collaboration under Action Plan Nanotechnology over a period of 10 years has proven to be effective from the point of view of the federal ministries involved (BMBF, BMAS, BMEL, BMG, BMUB, BMVg and BMWi). Collaboration has succeeded in creating synergies, pooled various ministerial activities and prevented double funding. For this reason, the Federal Government has decided to continue Action Plan Nanotechnology for the next 5 years in the form of this present Action Plan Nanotechnology 2020.

Action Plan Nanotechnology 2020 is geared towards the priorities of the Federal Government's new High-Tech Strategy (HTS), which has as its objective the solution of societal challenges by promoting research. It will play its part in the fulfilment of the Federal Government's strategic objectives with a view to the use of key technologies to increase the international competitiveness of the German economy and for the benefit of society.

The positive balance of state support will be confirmed by successful development of nanotechnology in Germany. Besides the internationally well-positioned nanotechnology research, there has also been success in networking the nanotechnology bodies (for example through the establishment of networks of competence) and in strengthening the commercial use of this key technology in many sectors. This positive trend in the industrial sector was positively accompanied by the federal structure through targeted support measures for SMEs or start-up financing and by application-oriented, collaborative research. Although there is still further optimisation potential at national and EU level as regards the timely implementation of scientific findings from research into application or in the form of marketable products.

Risk research into nanomaterials was established and continuously expanded as an independent BMBF funding priority in the 2010 Action Plan. This was in order to ensure the responsible use of nanotechnology and to investigate possible risks when dealing with nanomaterials. Equally, the federal departmental research institutes pooled and intensified their activities relating to risk research into nanomaterials in a joint research strategy. In particular they develop political and administrative decision-making tools. Public project funding and departmental research complement each other in this area. The objective of risk research into nanomaterials is to gather findings concerning the possible impact of nanomaterials on man and the environment. The results of a number of research projects have shown that nanomaterials are not per se linked with a risk for people and the environment due to their nanoscale properties. This is in reality influenced more by structure, chemical composition and other factors and is therefore dependent on the respective material and its application. Other advanced materials can also exhibit similar risk profiles.

The results generated from risk research will be introduced into regulations in all relevant areas, such as occupational, consumer and environmental law. Differentiated evaluation standards and packages of measures for the protection of employees working with nanomaterials have been derived and anchored into the technical rules for hazardous substances, for example. In the foreground of this was protection against exposure to respirable, biopersistent dust and fibres at the workplace.

Through its consistent state support Germany is now an international leader in the field of risk research into nanomaterials. Alongside national anchoring, since the 7th EU Framework Research Programme the Federal Government has also successfully campaigned for thorough consideration of the topic of nanosafety in the funding of European research and with Horizon 2020 is also extended to other advanced materials.

The Federal Government is strengthening Germany's role in the national and international regulatory and standardisation bodies relevant to nanotechnology with the objective of advancing the protection of humans and the environment and of making a contribution to the creation of innovation-friendly framework conditions. The work already commenced on analytical verifiability of existing legal regulations concerning nanomaterials is to be continued, since standardised instrumental and analytical methods for exposure assessment and routine control are still largely lacking.

Progress has been made under Action Plan Nanotechnology in the evaluation of health and environmental risks and in the derivation of differentiated options for safe development and handling of commercially relevant nanomaterials. Although there is still a need for action in relation to the disposal of waste, but also in relation to nanomaterials that are only in development or at the initial marketing phase.

Internationally agreed methods and strategies are required in order to achieve comparable results for the risk assessment and risk management of nanomaterials. These must be developed. Germany is committed to continuing with the development and adaptation of the OECD test guidelines in order to create the prerequisite for comparability of international research results.

Transparent dialogue with the public about the opportunities and risks of nanotechnology has improved knowledge of nanotechnology within the general population and contributed to the openness of citizens towards nanotechnology. Various Federal Government initiatives such as the NanoDialogue, the "nanoTruck" and the Internet-based information portal DaNa have played their part in this context. The populace will only accept nanotechnology that is safe to use and environmentally-compatible.

BMBF promotion of young talent has contributed to the establishment of excellent interdisciplinary research groups in the field of nanotechnology at German universities. Further training and education opportunities and the establishment of interdisciplinary courses at German universities also supported the availability of well-trained, skilled workers for our industry. Industry, associations and federal states have also contributed to this success with complementary funding activities.

The international networking of nanotechnology research has been successfully expanded in recent years. The Federal Government supports the participation of German project partners from industry and research by means of international announcements (for example through bilateral tenders) or through the consultancy services of the national contact points within EU programmes. International industrial collaborations support the development of new markets and sources of expertise outside Germany.

Outlook

The Federal Government will continue to conduct its inter-ministerial cooperation in the field of nanotechnology for the period 2016 to 2020 under the present Action Plan Nanotechnology 2020.

The BMBF will integrate its nanotechnology activities – including nanosafety – into the "From Material to Innovation" material research programme. Other specialist programmes will also have relationships to nanotechnology. Announcements under the materials research programme will address applications relating to the priority future tasks defined in the Federal Government's new High-Tech Strategy: Digital Economy and Society, Sustainable Economy and Energy, Innovative Working Environment, Healthy Living, Intelligent Mobility and Civil Security. The objectives of promotion will be to use various research and innovation funding instruments to map the entire innovation chain, to improve the transfer of scientific know-how into application and to position innovative nanoproducts quickly, safely and successfully on the market. This will require that projects involving advanced materials also actively include non-technological aspects, such as regulatory and safety matters.

The Federal Government will also grant high priority to the funding of SMEs under Action Plan Nanotechnology 2020. Alongside traditional collaborative research, there will also in future be a series of funding programmes open to all types of technology. Of particular importance here are the BMBF SME-innovative and the BMWi ZIM programmes, which take into account the specific needs of SMEs and set no concrete deadlines for project outlines. Entrepreneurs will be supported in the establishment of their own company by the BMWi EXIST programme. The Federal Government will also support activities for location-based marketing (e.g. through trade fair participation), international networking and promotion of the innovative power of SMEs.

The BMBF will continue to consistently pursue its activities with respect to risk research into nanomaterials in Action Plan Nanotechnology 2020. Here the effects of nanomaterials both on human health and the environment will be investigated. The results of ongoing projects into nanorisk research will continue to be made available to the interested public. An accompanying status quo assessment will provide the BMBF with further impetus for the future direction of national and international risk research into nanomaterials. There will continue to be a need in future to weigh up those research issues that are to be pursued in a national approach and those that require a European or international context. The required integration of national and international research policy will be further intensified by Action Plan Nanotechnology 2020.

The joint risk research strategy of BAuA, BfR, UBA, BAM and PTB will be continued in the context of the Action Plan under the title “Nanomaterials and other advanced materials: Application safety and environmental compatibility”. In addition to the further development of instruments for the early identification of risks, the promotion of safe material design and the scientific basis for any necessary adjustments of legislation will be in the foreground of the activities of the participating federal authorities.

The use of nanotechnologies in medicine (nanomedicine) will open up innovative possibilities to combat disease at the molecular level and allow new approaches in the fields of diagnostics, therapy and monitoring, whereby medicinal products and thus patient safety must not be neglected. The Federal Institute for Drugs and Medical Devices (BfArM) and the Paul Ehrlich Institute (PEI) will apply and, where required, improve and extend their existing expertise in the area of nanomedicine and continue their dialogue with all relevant stakeholders.

Transparent presentation and communication of findings from risk research into nanomaterials is a prerequisite for the open-mindedness of our citizens towards nanotechnology. It also facilitates acceptance and confidence in nanoproducts on the part of consumers. The BMBF “DaNa – data and knowledge on nanomaterials” project will therefore also be continued in the context of this present Action Plan. This Internet-based information portal will supplement other technology conversations with citizens and societal participants in order to engage in a discourse with the general public about the opportunities and potential risks of nanotechnology. From 2017 the “nanoTruck” that has toured to date in the service of nanotechnology will once again set out on its journey through Germany with an extended range of topics under the motto “InnoTruck”.

In the adaptation of regulations for the protection of man and the environment, a coherent approach oriented towards the precautionary principle and identified risks will be essential for supporting the competitiveness of German companies. The particular focus here will be on the necessary adaptation of the REACH European chemicals regulation. The Federal Government confirms its commitment to continue in a constructive process to ensure that the European Commission supplements REACH with the findings from risk research into nanomaterials and closes any existing gaps in the protection of human health and the environment.

The Federal Government will motivate start-ups and research facilities, even at an early stage of innovation, to consider approaches for development of safe to use and environmentally compatible materials. Already existing networks in nanotechnology and materials science will be used for the exchange of information and be linked with expertise in risk research and regulation. Government action is to keep pace with innovation. Companies will make an important contribution to their future competitiveness and sustainable development by means of safe material design.

The Federal Government will in future also continue its active efforts within the relevant European committees and bodies to meet the needs and interests of experts involved in nanotechnology in Germany in the design of the work programmes of the EU Framework Programme for Research and Innovation (Horizon 2020) and in the follow-up programme to Horizon 2020. The National Contact Points for materials and nanotechnology will advise and support German applicants in the preparation of funding applications and use events and newsletters to provide information about current topics of EU research funding.

International collaborations will enable the use of know-how available outside Germany for the benefit of national R&D activities and the development of new value creation chains in strategic target markets. In the middle of 2016, the BMBF will launch an SME-oriented innovation programme between Germany and Israel covering “Applied research and technology transfer in the field of nanotechnology” in order to increase value creation in the two countries. The aim of the programme will be the networking of research, technology and the economy (SMEs and start-ups) of both countries to create new business and exploitation models. Activities will be funded that deal with the development of new recycling technologies, solutions and consortia, technology transfer, method development and exploitation models with SME focus and accompanying research.

To meet the growing demand for highly-qualified young scientists for industry and research and in the field of nanotechnology, Action Plan Nanotechnology 2020 provides measures for training and further education of qualified, skilled workers. The BMBF NanoMatFuture funding programme for young scientists and researchers will support particularly talented researchers from Germany and abroad in building up their own research group at a German university. Experience from the previous promotion show that independent junior research groups can serve as nuclei for new interdisciplinary areas of research at universities and thus contribute to the formation of centres of excellence at these universities. The Federal Government will also promote the qualification of young risk research scientists via its departmental research.

Annexes

Further Information

BAuA
www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/Nanotechnologie/Nanotechnologie.html

BfArM
www.bfarm.de/DE/Arzneimittel/zul/zulassungsverfahren/zVerf/nano.html

BfR
www.bfr.bund.de/de/a-z_index/nanotechnologie-7585.html

BMBF
www.bmbf.de/de/neue-werkstoffe-und-materialien-536.html

BMUB
www.bmub.bund.de/themen/gesundheit-chemikalien/nanotechnologie
www.bmub.bund.de/themen/gesundheit-chemikalien/nanotechnologie/oecd-wpmn/

BMWi
www.bmwi.de/DE/Themen/Technologie/Schluesseltechnologien/nanotechnologie.html

COM
ec.europa.eu/programmes/horizon2020/en/h2020-section/nanotechnologies
www.nanofutures.eu/
www.nanoreg.eu; www.nanoreg2.eu

DaNa
www.nanopartikel.info

DGUV nano portal
nano.dguv.de

EMA
www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000345.jsp&

Federal Government
www.hightech-strategie.de

Individual state activities
www.nanoinitiative-bayern.de
www.nanoportal-bw.de
www.hessen-nanotech.de
www.nmwp.nrw.de
www.nina-sh.de
www.nanomikro.com
www.nanobionet.de

nanoTruck
www.nanotruck.de

NKS
www.nks-nano.de

OECD WPMN
www.oecd.org/science/nanosafety/

Research map
www.nano-map.de

Teaching unit
www.lehrer-online.de/dasa-nano-ue.php

Training opportunities
www.nano-bildungslandschaften.de

UBA
www.umweltbundesamt.de/themen/wirtschaft-konsum/innovative-produktionsverfahren/nanotechnologie

List of Acronyms

AGS Ausschuss für Gefahrstoffe – Committee on Hazardous Substances

AiF Arbeitsgemeinschaft industrieller Forschungsvereinigungen – German Federation of Industrial Research Associations

BAM Bundesanstalt für Materialforschung und -prüfung – Federal Institute for Materials Research and Testing

BAuA Bundesanstalt für Arbeitsschutz und Arbeitsmedizin – Federal Institute for Occupational Safety and Health

BfArM Bundesinstitut für Arzneimittel und Medizinprodukte – Federal Institute for Drugs and Medical Devices

BfR Bundesinstitut für Risikobewertung – Federal Institute for Risk Assessment

BMAS Bundesministerium für Arbeit und Soziales – Federal Ministry of Labour and Social Affairs

BMBF Bundesministerium für Bildung und Forschung – Federal Ministry of Education and Research

BMEL Bundesministerium für Ernährung und Landwirtschaft – Federal Ministry of Food and Agriculture

BMG Bundesministerium für Gesundheit – Federal Ministry of Health

BMUB Bundesministerium für Umwelt, Naturschutz, Bau und Reaktorsicherheit – Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety

BMVg Bundesministerium für Verteidigung – Federal Ministry for Defence

BMVI Bundesministerium für Verkehr und digitale Infrastruktur – Federal Ministry for Transport and Digital Infrastructure

BMWi Bundesministerium für Wirtschaft und Energie – Federal Ministry for Economic Affairs and Energy

BVL Bundesamt für Verbraucherschutz und Lebensmittelsicherheit – Federal Office for Consumer Protection and Food Safety

CEN European Committee for Standardisation

CENELEC European Committee for Electrotechnical Standardisation

CLP Classification, Labelling and Packaging of Substances and Mixtures

COST European Cooperation in Science and Technology

DaNa Data and knowledge on nanomaterials

DFG Deutsche Forschungsgemeinschaft – German Research Foundation

DGUV Deutsche Gesetzliche Unfallversicherung – German Statutory Accident Insurance

DIN Deutsches Institut für Normung – German Institute for Standardisation

DKE Deutsche Kommission Elektrotechnik Elektronik Informationstechnik – German Association for Electrical, Electronic & Information Technologies

ECHA European Chemicals Agency

EMA European Medicines Agency

EMPIR European Metrology Programme for Innovation and Research

ERA European Research Area

ETSI	European Telecommunications Standards Institute
EURAMET	European Association of National Metrology Institutes
FET	Future and Emerging Technologies
FhG	Fraunhofer Gesellschaft – Fraunhofer Society
FRP	Forschungsrahmenprogramm – Research Framework Programme
FuE	Forschung und Entwicklung – R&D Research and development
GBP	Granuläre biobeständige Stäube – Granular biopersistent particles
GefStoffV	Gefahrstoffverordnung – Ordinance on Hazardous Substances
GHS	Globally Harmonised System
HGF	Helmholtz-Gemeinschaft Deutscher Forschungszentren – Helmholtz Association of German Research Centres
HTGF	High-Tech Gründerfonds
HTS	High-Tech Strategy
IEC	International Electrotechnical Commission
IGF	Industrielle Gemeinschaftsforschung – Industrial collective research
ISO	International Organization for Standardisation
IT	Information technology
KMU	Kleine und mittlere Unternehmen – SME Small and medium-sized enterprises
KOM	EU-Kommission – COM EU Commission
MPG	Max-Planck-Gesellschaft – Max Planck Society
MRI	Max Rubner Institute
NKS	National Contact Point
NMBP	Nanotechnologies, Advanced Materials, Biotechnology, and Advanced Manufacturing and Processing
OECD	Organisation for Economic Co-operation and Development
PEI	Paul Ehrlich Institute
PPP	Public-Private Partnership
PTB	Physikalisch-Technische Bundesanstalt – National Metrology Institute
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
TC	Technical Committee
UBA	Umweltbundesamt – German Federal Environment Agency
VDI	Verein Deutscher Ingenieure – Association of German Engineers
WGL	Leibniz-Gemeinschaft – Leibniz Association
WHO	World Health Organization
WNT	Working Party of the National Coordinators of the Test Guidelines Programme
WPBNCT	Working Party on Biotechnology, Nanotechnology and Converging Technologies
WPMN	Working Party on Manufactured Nanomaterials
WPRPW	Working Party on Resource Productivity and Waste

Footnote Directory

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7. www.nano-map.de
8. nano.dguv.de/home/
9. nano.dguv.de/nanoramen
10. www.euramet.org/index.php?id=research-empir
11. www.euramet.org
12. www.dguv.de
13. www.nano-map.de
14. www.nano-bildungslandschaften.de
15. Final Nano View Report, BfR Science, 2013; www.bfr.bund.de/cm/350/nanoview-einflussfaktoren-auf-die-wahrnehmung-der-nanotechnologien-und-zielgruppenspezifische-risikokommunikationsstrategien.pdf
16. Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (EC 1907/2006); CLP: Regulation on classification, labelling and packaging (EC 1272/2008)
17. Second Regulatory Review on Nanomaterials (COM (2012) 572)
18. In particular Regulation (EC) No. 178/2002 (the so-called base regulation in food law) and the German Food and Feed Code
19. Regulation (EC) No. 1333/2008 of the European Parliament and of the Council on food additives
20. Regulation (EC) No. 258/97 of the European Parliament and of the Council on novel foods and novel food ingredients. It is to be replaced on 1 January 2018 by Regulation (EC) 2015/2283
21. Regulation (EU) No. 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers
22. Regulation (EC) No. 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food
23. Regulation (EU) No. 10/2011 of the Commission on materials and articles intended to come into contact with food
24. EU Regulation No. 528/2012 on making available on the market and use of biocidal products
25. Regulation (EC) No. 1107/2009 of the European Parliament and of the Council on the placing of plant protection products on the market
26. Regulation (EC) No. 1223/2009 of the European Parliament and of the Council on cosmetic productsl
27. Directive 2001/83/EC of the European Parliament and of the Council establishing a Community code relating to medicinal products for human use

28. Directive 2001/82/EC of the European Parliament and of the Council establishing a Community code relating to medicinal products for animal use

29. Council Document 9364/3/16 Rev3 dated 15 June 2016 on medicinal products

30. EC Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work ("Agents Directive")

31. Annex I No. 2 GefStoffV

32. Publication BekGS 527 on manufactured nanomaterials

33. www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/AGS/pdf/A-Staub.pdf

34. Work is carried out on the basis of EU mandate M/461

35. DIN: German Institute for Standardisation, DKE: German Commission for Electrical, Electronic & Information Technologies in DIN and VDE

36. OECD Guidelines for the Testing of Chemicals: www.oecd.org/chemicalsafety/testing/oecdguidelinesforthetestingofchemicals.htm; ECHA

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47. www.nanoreg.eu

48. The WPMN results are available at www.oecd.org/science/nanosafety/

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Innovationsallianz Photovoltaik: S. 16
Laser Zentrum Hannover e.V.: S. 24
NürnbergMesse: S. 18
Physikalisch-Technische Bundesanstalt (PTB): S. 42
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Cover: The world's most perfect, nanometre-precise, monocrystalline silicon spheres are produced at the Physikalisch-Technische Bundesanstalt (PTB). With their help it will be possible in two years to redefine the base unit known as kilogramme, which is currently referenced on the original kilogramme in Paris. To do so, the number of atoms in an almost perfect silicon sphere will be determined, thereby enabling the production of any number of subsequent mass standards based thereon.

Photo: Physikalisch-Technische Bundesanstalt (PTB), National Metrology Institute