Report

FachDialog 4

The potentials of research to strengthen the business location

January 2012

Ökopol GmbH
Institut für Ökologie und Politik
Nernstweg 32-34
D-22765 Hamburg

Authors: Antonia Reihlen, Dirk Jepsen

Imprint

ÖKOPOL GmbH
Institut für Ökologie und Politik

Nernstweg 32–34
D – 22765 Hamburg
✆ 0049-40-39 100 2 0
fax:0049-40-39 100 2 33

www.oekopol.de
info@oekopol.de

Content

Figures

1 Background

Nanotechnology research should contribute to meeting societal challenges, such as climate change or resource scarcity. This should ensure that the application of the technology is sustainable. It is expected that the targeted design of nanomaterials (generation of desired and avoidance of undesired properties) and the production of new, nano-enhanced materials and products initiates innovations, which could open new ecological, economic and social perspectives.

The term nanotechnologies may refer to many different applications and the 'nano-component' of products or processes may be designed in various ways. Nanotechnologies could address the production of structures at the nano-scale, such as electronics, or the research and development of new materials with novel functions. It could also refer to research on hazardous properties of nanomaterials, their emission behaviour or methods for their characterization. This report focuses on the use of nanomaterials as such or as components of materials which are integrated into end-products.

Current research on nanotechnologies can be divided into three main areas:

- Innovation research:
  In product and process oriented research, specific applications of nanomaterials are identified and assessed. Research frequently includes all actors in the supply chain from the manufacture of the nanomaterials or nanostructures to their use in end-products.
- Safety research:
  Safety research in a narrow sense mainly relates to the identification of the hazardous properties of nanomaterials, their potential emissions from processes and products and their distribution in human bodies and the environment. Also social and economic risks may be looked at in the context of sustainability in general.
- Regulatory research
  Federal agencies' research, whether conducted in-house or by external contractors, aims at increased protection of human health and the environment through the regulation of nanomaterials. The research activities include the assessments of nanomaterials' toxicities and the development of procedures, methods and devices for the measurement or modelling of exposures, for sampling or for the identification of the occurrence of nanomaterials in the environment or in specific products.

In this report different questions related to the interlinks of the above mentioned three 'research types', the public perception of research activities and results as well as regarding the development of the 'research agenda' are described. The

content of the report is based on the discussions at the FachDialog 4 of the German Ministry of the Environment (BMU) to a large extent. The topic of this FachDialog was 'Potentials of Research for Securing the Business Location'. It took place in October 2012 in Berlin.

2 Regulation of nanomaterials

2.1 Interaction between research and regulation

In the ideal case, research and regulation of nanomaterials should influence one another. Research is oriented towards the regulation requirements and the demands posed for its implementation and enforcement. Regulators set their priorities and define the need to take precautionary measures based on information on the potential application areas of as well as the risks from the use of nanomaterials and nanotechnologies.

Research aimed at innovating and developing new products should anticipate future (safety) demands towards these products. Hence, it should already be assessed during the development process, if risks to humans or the environment could occur. The anticipation of the future regulatory requirements is important in order to direct research and decision making and select the appropriate pathways for product or process development.

Regulatory research aims at improving the protection of human health and the environment by closing knowledge gaps and supporting the development and implementation of regulation of nanomaterials. This includes the development of missing methods or measurement procedures and techniques. Furthermore, information indicating priority materials, uses or subjects of protection, which could be addressed by future regulation or which should be enforced with high priority are also of interest.

Research on risks may support regulatory priority setting and could form the basis to identify the need to take regulatory action (and which uses pose high risks and which don't). Risk research could also be performed in the context of assessment and authorization procedures to demonstrate the safety of specific products.

2.2 State of the regulatory discussion (November 2012)

The nano-definition constituted in the 'Commission Recommendation[1] on a Definition of Nanomaterials' is intended for the integration into existing or new legislation. It should be adapted according to the needs of these specific regulatory areas, if necessary. However, standardized measurement methods to implement the definition do not exist. This may cause difficulties in the practical application of the definition and lead to uncertainty on whether or not nanomaterials and / or products containing these fall under the definition and consequently are covered by (future) regulation.

In the 'Second Regulatory Review on Nanomaterials[2]' the EU Commission states that nanomaterials are generally not different from 'traditional chemicals' with regard to their potential of having or not having hazardous properties. However, the nanoform and the bulkform of the same substance may have different toxicological properties. Therefore, the potential risks from specific uses of nanomaterials have to be individually determined in risk assessments. The following challenges for the assessment of the safe use of nanomaterials, which could be overcome by respective research activities, are listed in the Commission's review: validation of methods, procedures and devices for the characterization and analysis of nanomaterials and the development of methods for exposure assessment.

In its review, the EU Commission does not regard it necessary to change essential parts of existing legislation in order to improve the protection of the environment, workers or consumers from nanomaterials. This view may be modified in the area of workers' protection, depending on the outcome of an on-going study. The Commission announced with regard to potential changes in the REACH – regulation that these may be proposed as part of the REACH – review[3]. Here, reference is made to a study[4] by the Joint Research Centre (JRC) on the evaluation of registration dossiers covering nanomaterials.

In the second phase of the NanoDialog, Working Group 3 of the NanoCommission[5] discussed the regulatory situation of nanomaterials. For most regulatory areas it was concluded that existing legislation is a good basis to ensure safe use of nanomaterials. However, some stakeholders demanded

---

[1] COMMISSION RECOMMENDATION of 18 October 2011 on a definition of nanomaterials (2011/696/EC)

[2] European Commission: Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee; COM(2012) 572 final; Brussels 3.10.2012

[3] At the time of writing the report the communication by the EU Commission was not yet published.

[4] European Commission; Joint Research Center: NANO SUPPORT Project: Scientific technical support on assessment of nanomaterials in REACH registration dossiers and adequacy of available information; Final Report on analysis and assessment (Task I, step 3&4&5) and options for adapting REACH (Task II, step 1), March 2012. (http://ec.europa.eu/environment/chemicals/nanotech/pdf/jrc_report.pdf)

[5] C.f. Report of the working group http://www.bmu.de/files/english/pdf/application/pdf/nano_abschlussbericht3_en_bf.pdf

to complement and add further regulatory provisions. There was a consensus that modifications to the REACH – regulation, its annexes and the related ECHA guidance documents are necessary, in particular to introduce a nano-definition, to add specific data requirements for substances at the nanoscale and respective methods, to provide for the inclusion of nano-specific information in the safety data sheet as well as to adapt registration deadlines and tonnage thresholds for nanomaterials.

3 Discussions on research in the NanoDialog since 2006

The NanoCommission recommended in its first and second dialogue phase to enhance activities on safety research and to strengthen the stakeholder dialogue on the sustainable use of nanotechnologies. This should increase understanding and acceptance of the risks and opportunities of nanotechnologies. These recommendations emphasise the importance of working on both aspects at the same time – the closure of knowledge gaps and the transparent communication and management of the technology.

The NanoCommission defined priorities for safety research in the first dialogue phase (2006 – 2008). It recommended strengthening co-operation between research institutions and increasing funding for safety research. Furthermore, research results and knowledge on risk management measures currently applied in companies should be made accessible to the general public in a structured form.

The recommendations of the first dialogue phase were renewed and underlined by the NanoCommission in its second dialogue phase (2009 – 2011). In addition, instruments to assess (the use of) nanomaterials and nanoproducts were (further) developed to support enterprises and other stakeholders in the decision making of the use of nanotechnologies.

Different aspects of nanotechnology research were discussed in all of the four FachDialog conferences in the third dialogue phase (2011 – 2012).

The topic of the first FachDialog was ‘Risk Management in the Nano World’. One of the conclusions was that gaining knowledge on risks and opportunities of nanomaterials remains the core goal of nanotechnology research. However, until sufficient information is available, the decision support instruments for the companies’ development activities as well as for other stakeholders are useful to guide the direction of nanotechnology uses.

The topic of the second FachDialog was ‘Traceability of Nanomaterials’. One of its conclusions was that, apart from the creation of market transparency, nano databases could deliver a lot of useful information for researchers. For example, they could provide information on use amounts of nanomaterials in specific

applications and thereby contribute to the identification and assessment of risks by national or European authorities. Vice versa, research activities and their results could contribute to the design of nano databases and support setting respective priorities for content and data collection.

In FachDialog 3 the topic was 'Sustainability of Nanotechnologies'. It was confirmed that the sustainability assessment of nanomaterials requires a differentiated evaluation of the respective use contexts. Both potential opportunities and risks are determined and only assessable in relation to a specific use: the concrete benefits can only be determined in relation to a specific use (of a nanomaterial) and the potential risks depend on, apart from the hazards of a nanomaterial, the potential releases along the lifecycle. Safety information from research on nanomaterials should therefore be made available to all stakeholders so they can be taken into account in their work on the respective different uses and applications of nanomaterials.

4 Nanotechnology research in Germany

In Germany, research on nanotechnology is normally funded with finances from the national level (Bund), from the federal states (Bundesländer), from industry and from foundations. The financially supported institutions are universities, academies, regulatory research institutions (federal agencies), institutionalized research institutes, other research organizations as well as enterprises.

According to the report 'nano-DE[6]' by the German Ministry for Education and Research (BMBF), approximately 600 research institutions are financed with public funding in the area of nanotechnology. For 80% of these institutions, national funding constitutes a large share of their overall budget (> 25%).

The German research institutions rank German research at a 'top position equal to the USA'. They evaluate the location factors in Germany, e.g. the possibility to co-operate and participate in networks as well as the available infrastructure and access to funding as 'above average'. Many research institutions develop patents and some have created spin-off companies.

The German government's research funding on nanotechnology is founded on the 'Action Plan Nanotechnology 2015', which is integrated into the 'Hightech-Strategy' of the German government. The 'Hightech-Strategy' structures research planning according to defined goals and for different research areas. Under this 'Action Plan Nanotechnology 2015', the ministries and other funding institutions support several research and development projects related to research on precaution, safety and dialogue processes, measures to inform the

[6] Bundesministerium für Bildung und Forschung: „nano.DE-Report 2011 Status quo der Nanotechnologie in Deutschland, 2011.

general public as well as national and international co-ordination and networking activities.

Trends in nanotechnology research point to increasingly larger co-operations or networks, which include different institutions, such as universities, companies and research institutes as well as small and medium sized enterprises. The most important reason for the enlargement of research co-operations is the complexity of issues to be solved related to (innovative) nanotechnology applications. This complexity is a result of the manifold possible uses and the related interdisciplinary, scientific and technological details of nanomaterials. Another factor triggering the increased number and type of partners in of research co-operations is the understanding that the entire supply chain should be involved in innovation research. It is realised that this would ensure that innovative materials can be and are actually processed into products and that this is cost efficient. Both aspects are a precondition for a successful market introduction and commercialization of nanomaterials and nanoproducts.

Changes in funding policies aim to and actually direct the research community towards the creation of larger networks: the BMBF supports such research co-operations with its new funding instrument, the so called 'innovation alliances' and also at the EU level, respective funding policies were developed.

4.1 Research funding by the Ministry of Education and Research (BMBF)

The Ministry for Education and Research (BMBF) is the largest public national funding institution in the area of nanotechnology research. It has funded nanotechnology-related projects for 20 years. The research topics changed over time and shifted from fundamental research for the identification of basic physical-chemical principles of nanomaterials to application-oriented projects supporting innovation in important industry sectors with high market relevance.

So called 'accompanying measures' are not only implemented in the scope of funded projects, but also as self-standing activities to identify and consider risks and opportunities as well as possible impacts of the application of nanotechnologies. Furthermore, communication of research results to the general public is financed as part of the 'accompanying measures'.

In 2011 the BMBF supported around 1,700 projects related to nanotechnologies. Approximately 57% of BMBF's respective budget was awarded to research institutes (funding quota normally 100%) and 43% were provided to industry (funding quota normally up to 50%). The newest BMBF funding instrument - the 'innovation alliance' - is intended to support partnerships of politics, science and economy generating information to improve either production technologies or products with strategic relevance for future markets. Innovation alliances should cover the entire supply chain and hence ensure that innovations are actually commercialized in the long term.

In 2011, BMBF funded nano safety research by supporting the programmes NanoCare and NanoNature. Furthermore, several 'accompanying measures' and other projects[7] were financed. Subjects of these 'accompanying measures' were among others: research on the impacts of nanotechnologies on human health, the environment and workers protection, participation in European and international activities on safety research on nanomaterials, transparent presentation of research results, dialogue activities in different contexts involving different stakeholders as well as activities for knowledge transfer.

4.2 Research funding by other ministries and institutions

The Ministry of Economy is the second largest, public funding institution and supports a variety of projects related to nanotechnologies. Examples of research topics are nano-enhanced coatings, membranes, sensors or (new) materials. Whereas the BMBF funds projects prior to marketing, the Ministry of Economy may also support pilot applications. Hence, projects funded by the Ministry of Economy are in principle closer to products and applications actually marketed.

In the frame of the 'Environmental Research Plan' for example, the Ministry of the Environment supports different projects on the environmental behaviour, the (eco)toxicology and toxicokinetics of nanomaterials as well as the further development of testing methods for specific nanomaterials.

The total budget of other ministries funding nanotechnology projects in Germany is normally between 0.5 and 1.2 million Euros, which constitutes only a small percentage of the total public research funding.

Institutions which are funded based on their institutional status rather than on specific projects receive approximately the same amount of funding as is provided in total by the ministries.

Institutes, initiatives, networks and projects on nanotechnologies exist at the level of the federal states (Bundesländer) and are funded respectively. Furthermore, the federal states provide financial resources to the institutional funding budget.

The industry invests parts of its budgets in their own research activities either in form of 'co-financing' in publicly funded projects or in the context of safety research, which is necessary for the commercialization of products, e.g. under REACH or for notification or authorization processes (e.g. food additives, cosmetics). Furthermore, additional scientific research may be conducted according to the individual needs, preferences and priorities of companies.

[7] Further information are available at www.nanopartikel.info

5 Nanotechnology research in the EU

In the 'European Strategy on Nanotechnologies'[8] high importance is attributed to the research and development of new materials and products. Responsible technology development is to be ensured by considering ethical principles, societal impacts and scientific assessments of potential risks regarding safety, health and the environment. If necessary, adequate regulatory controls should be followed or initiated.

Research projects on technological innovations were and will be funded in the area of nanotechnologies as part of the research framework programmes. Through the co-operation of public and private organisations in different Member States on interdisciplinary research issues, a European research area should be created and maintained that should contribute to sustainable development.

The future European research programme 'Horizon 2020'[9] is supposed to strengthen European competitiveness and contribute to achieving the goal of a knowledge and technology-based economy (smart growth) formulated in the EU strategy 'Europe 2020'. Nanotechnology research is funded under the program area 'key enabling technologies'[10] (KETs), for which the proposed strategic approach is, among others to combine different technologies. Research funding by the EU pursues as one essential goal to close the gap between research and marketing of innovations.

The EU Commission funds and supports safety, health and environmental research on nanomaterials and nanotechnologies as an important part of its framework programmes. From 2007 to 2011 approximately 110 million Euros were dedicated to projects assessing risks under the 7th research framework programme.

When the 7th research framework programme was started it was acknowledged that there was a need to co-ordinate and co-operate between researchers. Therefore, activities like the NanoImpactNet[11] were initiated and financed. In addition, long-term co-ordination on safety research was provided for by the creation of the so called 'NanoSafety Cluster'[12] which enables research teams to co-operate and facilitates the knowledge transfer between projects. The 'vision document' which is being created by researchers of the NanoSafety Cluster is supposed to define the goals of safety research for the future.

[8] http://cordis.europa.eu/documents/documentlibrary/66637841DE6.pdf

[9] http://ec.europa.eu/research/horizon2020/index_en.cfm?pg=home&video=none

[10] Key technologies are among others: Photonics, micro- and nano-electronics, nanotechnologies, advanced materials, biotechnologies and advanced production and processing techniques.

[11] http://www.nanoimpactnet.eu/

[12] http://www.nanosafetycluster.eu/

6 The role of research for nanotechnology acceptance

In the following paragraphs, different aspects of the role of research for the acceptance of nanotechnologies are discussed. The potentials of nanotechnologies to support sustainable development, the development of sustainable (new) products as well as how these potentials are perceived in the general public is summarized in Section 6.1. The following sub-chapters summarise some challenges discussed at the FachDialog 4 of which it was assumed that overcoming these could improve acceptance, visibility and trust in (safety) research in Germany.

6.1 Nanotechnology research as economic factor

In the report 'nano.DE' 2011 it is estimated that approximately 1,800 organisations work on nanotechnologies in Germany. Of these, 40% are small and medium sized enterprises, 13% large enterprises, 24% universities and 9% 'other' institutions.

According to the report, the most important sectors of nanotechnology applications are the chemical industry, engineering (including measurement technologies), the service sector and the areas of medical devices and pharmaceuticals.

In 2010 approximately 61,000 workers were employed in the nanotechnology sector in Germany with increasing trends for the following years. The enterprises' turnovers in the area of nanotechnologies is estimated at ca. 13 billion Euro in 2010, also with an increasing trend.

The companies' research budgets in the area of nanotechnologies are estimated at 1.3 billion Euros for the same year (research quota of 10% of the turnover). According to the statements from the enterprises, research spending will increase in the future as well.

According to the 'nano.DE-report', Germany is a leading business location for nanotechnology enterprises with a high number of scientific publications, patents and is the market leader for some important nanotechnology products.

An expert survey conducted for a study on nanotechnologies in Germany[13] reveals that good market opportunities are projected for some nanomaterials in particular carbon nanotubes and nano-silver. However, the surveyed experts doubt that large-scale manufacturing of nanoproducts will start in the near future.

[13] Grimm et.al: „Nanotechnologie: Innovationsmotor für den Standort Deutschland"; 2011

The authors of the study confirm that research activities and the application of nanomaterials may result in product innovations, may open new markets and may strengthen the demand on national markets. In addition, a demand for qualified workers may be created. However, the construction of new manufacturing plants and the introduction of higher safety standards and related risk management measures at workplaces or for the environment may also be necessary.

The study concludes that the competitive position of the 'business location Germany' is good for the nanoproducts analysed in the study. Competitiveness is seen, among others as a result of the involvement of all relevant actors in the technology development. The study also confirms that co-operation of all relevant actors in the development of (innovative) nanoproducts in (new) application areas is important for successful marketing and technology acceptance.

The authors of the study 'Nanotechnologies: innovation motor for the business location Germany' and the 'nano.DE report' constitute that the views on nanotechnologies of the general public in Germany are generally positive. However, this perception is expected to be prone to change, in particular in relation to consumer products and applications.

6.2 Understanding of the terms 'risk research' and 'safety research'

There is no generally applicable, unified definition of the terms 'risk research' and 'safety research' regarding nanotechnologies / nanomaterials.[14] It appears that both terms are used synonymously. The use of these terms is normally not explained and this can create misunderstandings to which research questions or activities are addressed.

In general, the use of the terms 'safety' and 'risk' in the context of chemical substances seems to have changed due to the discussion on the REACH regulation. According to the 'old chemicals legislation' authorities carried out a risk assessment for existing substances in order to demonstrate whether or not there were risks to human health or the environment from the use of a substance. These risk assessments provided the justification for EU wide risk management measures, such as restrictions. The task of risk assessment was shifted by the REACH-regulation from authorities to registrants in the form of the 'chemical safety assessment'. This 'renaming' mirrors the shift of the burden of proof for the safe use of substances. Under REACH, registrants have to

[14] This chapter specifically relates to the German use of the terms "Risikoforschung' and "Sicherheitsforschung'. Whether or not the use of the terms and the interpretations introduced here also apply to the debate in English-speaking countries or at EU level is not assessed and analyzed here but merely a translation of the discussion in the FachDialog is provided.

demonstrate the safe use of substances, i.e. show that risks are adequately controlled.

In analogy, the term 'safety research' would implicate activities related to demonstrating the absence of risks from a specific use of a nanomaterial. Risk research could be seen as more generally addressing the identification of hazardous properties and risks related to the use of a nanomaterial as well as the development and improvement of related methods and procedures.

The Ministry of Education and Research (BMBF) has established the following understanding of the term 'safety research': safety research aims at ensuring civil safety including protection from terrorist attacks or natural catastrophes of any kind[15][16]. In contrast, the term 'risk research' in relation to nanotechnologies is used to address the identification of hazardous properties, emissions and exposures as well as potential risks for human health and the environment. Hence, BMBF uses the term according to the traditional understanding of a chemical risk. This understanding is shared by the other ministries and the federal agencies[17]; however no clear distinction between the uses of the two terms is evident.

Also in the NanoCommission's reports the terms 'risk research' and 'safety research' are used synonymously.

In the FachDialog 4 it was clarified that the industry addresses activities aimed at demonstrating product safety with the term 'safety research', i.e. the identification of substance properties and exposures. 'Risk assessment' is seen as an instrument to demonstrate the safe use of nanoproducts. The enterprises' 'safety research' may serve meeting demands of specified regulatory procedures (authorisation or notification) or is conducted in the context of ensuring product safety.

Some actors consider more aspects than the identification of hazards and exposures from nanomaterials 'in general' when using the term 'safety research'. In accordance with the concept of sustainability, they also include ethical, legal and / or societal impacts of the use of nanotechnologies.

In this report the term 'safety research' is used in the sense of the research on hazardous properties of nanomaterials, potential emissions, exposures and risks (traditional understanding of chemical risks).

6.3 Role of safety research for innovation

[15] "[…] What can research do, to alleviate the consequences of catastrophes? How can the safety of citizens from terroristic attacks be improved? Such questions are in the focus of safety research in the context of the high-tech-strategy of the German Government." http://www.bmbf.de/de/6293.php; translation Ökopol

[16] The term is however not used consistently: In the nano action plan the term safety research is used with a meaning of risk research in a wider context, which may also include accompanying measures of research.

[17] According to this understanding, safety research also includes procedures and devices for the reduction of emissions and exposures.

In order to realise the opportunities of nanotechnologies in a sustainable way, it is important to ensure that the technology as such is accepted in general and that there is a high level of trust in the safety of the manufactured products in particular. Safety research essentially contributes to both aspects by closing knowledge gaps on potential risks and by demonstrating product safety.

In addition, with regards to the insurability of nanotechnology risks the concrete and the general safety research are important because they strengthen the innovation capacity of companies. In the evaluation of the insurability of companies, the research activities which are undertaken to ensure product safety and which basic risk management policy predominates are assessed. In addition, the general availability of information on a nanomaterial's properties, its potential applications and the related exposures are important because based on this information acceptance of technologies and the likelihood of liability claims can be anticipated. Increased risks from the perspective of insurance companies arise from regulatory uncertainties, such as the unclear nano-definition by the EU. Lack of public acceptance of a technology may be a risk indicator as well, because this may also lead to an increased number of liability claims. An increase in insurability of nanotechnology risks for companies is achieved by a transparent dialogue with all stakeholders, openness on the on-going research activities and their results as well as their interpretation.

There are several critical discussions on safety research on nanotechnologies which are presented in the following. They are based on the discussions from the FachDialog 4. The critical debates partly resemble past or parallel discourses on other new technologies. In that sense they are not specific for nanotechnologies; hence the discussions can be regarded as exemplary or 'among others' as being lead in the field of nanotechnologies.

6.3.1 Quality of research

Compared to other technologies, the trustworthiness of nano-research is discussed fairly intensively. The most important issues under discussion are the:

- quality of studies and the scientific criteria of validity and evidence;
- lack or the insufficient adaptation of standardized methods;
- practice not to publish 'negative' research results;
- objectivity of researchers.

In the first NanoCommission it was already observed that many studies are not useable or not comparable because the nanomaterials are not sufficiently characterized or the studies are not conducted according to standardized methods. This finding was recently confirmed by the report of the Joint Research Centre on the registration of nanomaterials.

If data of insufficient quality is published, credibility in research is lost. Furthermore, it becomes more laborious to describe the state of knowledge, because information that conforms to scientific standards and information that doesn't must be distinguished. In addition, animal protection groups criticise that

animals are used in studies and tests which are not even useful with regard to scientific or technical progress.

Results of scientific research are more prone to criticism because standardised methods are missing or not well adapted to nanomaterials. Therefore, the information quality in general is questioned. Respective standardization work is on-going at the OECD level in different working groups. However, in particular the validation of non-test methods for nanomaterials is not yet very advanced,.

'Negative' research results, i.e. results demonstrating that a certain theory is refuted or that a specific process does not work, are not normally published. This is due to the fact that success stories are more frequently quoted and (therefore) are ranked higher than publications of 'negative' results. This practice results in the loss of important information for future research. In addition, 'mistakes' may be repeated because the state of knowledge is only partly available. On the other hand, the non-publication of information may foster the impression in the general public that data are 'hidden' in case the results of a project or study are against the interests of the researchers or their contractors.

Parts of the general public regard industry research as directed by interests and it is thereby assumed that the results are not objectively generated or reported. The partial mistrust in industry research, at least in the area of safety research for products, contradicts the regulatory principle of self-responsibility of industry and the REACH-obligation to demonstrate the safe use of nanomaterials prior to marketing.

6.3.2 Communication of research results

In the study 'Nanotechnologies a positive perception of nanotechnologies is stated from consumers' perspective; however the share of consumers evaluating the technology as positive has decreased and the share of 'ambivalent persons' has increased over time. The consumers' concerns on the use of nanoproducts mirror the arguments of the scientific debate on risks.

The authors of the study also observe a decrease of consumer knowledge on the different nanotechnology applications. One reason is assumed to be the lack of understandable information. It is therefore recommended that all actors, including academia, assess and improve their communication strategies.

All participants at the FachDialog agreed that all stakeholders (such as consumers, environmental organizations but also policy makers and regulators) have their own risk perceptions and that these don't necessarily correspond to the risk characterization in the scientific discourse. The Federal Institute for Risk Assessment has published on its website a statement regarding the risk perception[18]:

[18] http://www.bfr.bund.de/de/forschung_zur_risikokommunikation-8078.html; translation: Ökopol

'A variety of factors determines whether or not a risk is perceived. These are among others characteristics of the risk itself, such as the extent of a possible damage, the likelihood of occurrence or the freedom of choice of humans in relation to the risk. However, also personal and societal factors, such as risk-benefit-considerations, knowledge of certain risks and the influence of trust in institutions and organizations play an important role. Last but not least the way how risks are communicated decides on whether or not a risk is perceived. The media have a dominant role in this'.

Research results are communicated outside the scientific community mainly via the public media[19] and via internet platforms (e.g. DANA[20]). At the FachDialog 4 some of the research actors expressed their frustration that the information they deliver is not sufficiently taken note of outside the scientific community. On the other hand, civil society groups felt that it is not sufficient to 'only' make information accessible, but that in addition it would be necessary to actively communicate it.

All actors were also concerned about the lack of instruments and structure to get a better orientation in selecting and evaluating relevant information.

6.4 The role of research in regulation

Regulation of nanomaterials is not yet fully developed due to several reasons. These are among others:

- nanomaterials are not sufficiently characterised for regulatory risk assessments,
- it is not agreed how toxicity and ecotoxicity of nanomaterials should be quantified,
- exposure measurements are not reliable and it is not clear how the exposure levels should be expressed,
- in-situ methods to characterize nanomaterials are missing as well as information on the lifecycle.

The above mentioned methodological deficits make it difficult to understand which findings are 'assured' and whether or not this should trigger regulatory action. Furthermore, regulation is not useful if implementation and control instruments are missing, e.g. in the field of measuring exposures or the characterisation of nanomaterials. The lack of methods hampers the implementation of existing obligations, e.g. the development of authorization applications. There are also uncertainties regarding the general safe handling and use of nanomaterials. This is equally true for authorities and enterprises.

Another aspect regards the transfer of research results into (a basis for) regulatory action. The activities of regulatory research institutions aim at

[19] C.f. for example: René Zimmer, Rolf Hertel, Gaby-Fleur Böl (Hrsg.): Risikowahrnehmung beim Thema Nanotechnologie – Analyse der Medienberichterstattung, Berlin 2008

[20] www.nanopartikel.de

concrete and direct support to regulators and enforcement authorities. The research projects are designed in a way that results are processed and formulated as specific answers to specific regulatory questions.

The results of other researching institutions; however are not translated sufficiently into information that is useful for regulators. The results from innovation research and fundamental research are normally provided in a concentrated report during project or programme evaluation.

This means that overall results are principally available to the different ministries / regulators. However, a contextualization, analysis and assessment of the different results in a wider (regulatory) perspective is missing. Therefore, the information is of limited value to regulators and their activities.

6.5 Priorities for the research agenda

Innovation research on nanotechnologies at national and EU level is mainly oriented toward solving the main societal problems and satisfying the main societal needs (e.g. climate protection, securing food safety, health, mobility). In Germany the governmental 'Hightech-Strategy' serves as a reference frame.

In parallel to the strategically oriented, publicly funded innovation research, the different research institutions promote their own research agendas. Research questions are mainly posed based on scientific interest. They should contribute to further developing scientific knowledge about the basic properties and (effect) mechanisms of substances and materials at the nanoscale. The focus of this research develops through the self-steering mechanisms of scientific discourses and the self-administration of the scientific community.

The comprehensive information and experience exchange between the different actors in the research area takes place via respective scientific publications or in the context of expert conferences. Achievements and results as well as remaining knowledge gaps are regularly reported and discussed at these events.

At EU level respective key issues are defined in the research framework program 'horizon 2020'. Consequently, projects are funded which contribute to the solution of these questions (key enabling technologies (KET)). The safety research is funded as integral part of these projects. In preparation of the EU research program 'horizon 2020', results and issues from projects of the Nanosafety Cluster are summarized by a group of researchers in a so called 'vision document'. It derives the goals of EU safety research from the current state of knowledge and the needs for further information, methods, procedure for the identification and avoidance of risks from nanomaterials.

7 Conclusions

Nanotechnology research takes place in a societal context with high expectations regarding the realisation of sustainable and innovative solutions to urgent problems and for the securing of future economic perspectives. At the same time, research should and wants to fill basic knowledge gaps and generate specific, successful products on the market.

The generation and processing of knowledge to support societal processes, such as the definition of unified framework regulations to limit risks or the information of civil society actors, are mainly accompanying activities to the main research.

A variety of research initiatives have achieved significant progress in different areas. However, in the perception of different stakeholders basic questions related to the safety of nanotechnologies are not (yet) unambiguously answered. This is partly due to the fact that the information and knowledge transfer from research to the society as well as the transfer of demands from society to research do not function sufficiently well.

The different societal groups are missing clear answers to their questions. They see few possibilities to influence the research agenda and they partly doubt the credibility of research. One reason for that is seen in the fact that the processes of how research results are generated cannot be followed and understood by the general public. Questions regarding the transparency of research are among others:

- Who defines / how develops a research agenda?
- How is funding for research distributed?
- How quality assured and trustworthy are the research results? What uncertainties exist regarding the results?
- How are results compiled, analysed, put into context and interpreted?
- According to which criteria and philosophies are the research results evaluated by the different actors?

8 Recommendations from FachDialog 4

Based on the conclusions and the discussions of the 4th FachDialog, recommendations to improve the transparency of nanotechnology research were derived. In addition, a process to organise an information transfer in order to develop a commonly agreed research agenda in a dialogue process between researchers and interest groups is outlined.

8.1 Transparency of research

Proposals to improve transparency on the structures and organisation as well as the processes of research mentioned at the 4th FachDialog refer to for example the provision of simple, understandable and attractively designed information on the following topics:

- structure and organisation of research, including a list of institutions involved in research,
- mechanisms of quality assurance in the scientific community (e.g. peer reviews),
- criteria and rules for the publication of scientific studies,
- processes of the scientific self-administration,
- practice of granting project funding (tendering / calls, assessment and selection of projects that should receive funding).

To improve the communication of research results (in particular regarding possible risks / safety of nanotechnologies) it should also be ensured that:

- research on how consumers perceive risks and which methods and information channels are most suitable to convey research results is performed,
- research results are summarized topic-wise, processed and translated to understandable language and published.

8.2 Information transfer and research agenda

Beyond the above mentioned aspects of transparency, the discussion in the FachDialog pointed to that specifically a structured process of collecting questions from stakeholder groups to research and a credible process for the systematic answering of these questions by research is missing. Figure 1 illustrates this state-of-the-art description discussed at the FachDialog

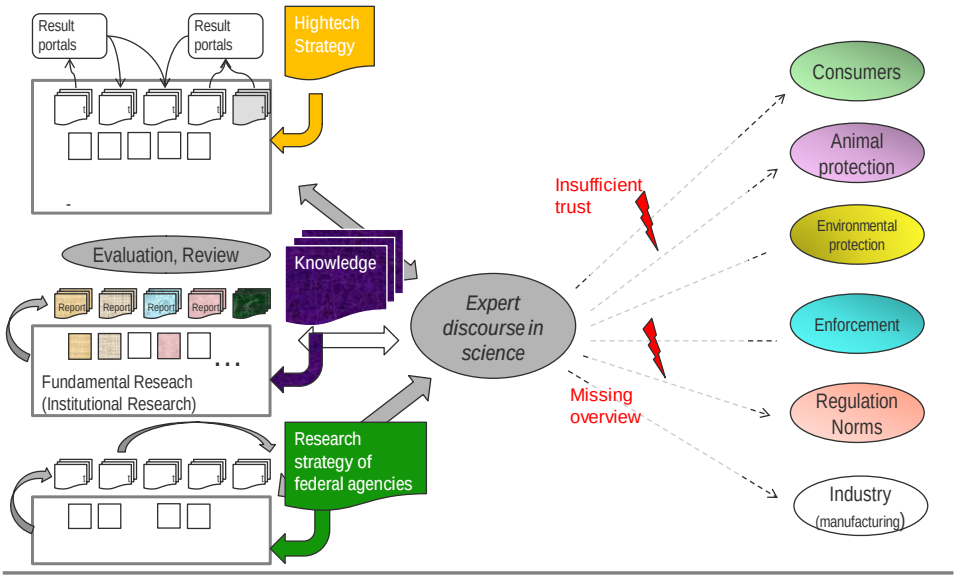

Figure 1: State of play regarding the perception of scientific research results

The researching actors on the left side can be differentiated into[21]:

- Application-oriented innovation research (top left). Their agenda aims at reaching the goals and solving the societal problems defined in the 'Hightech-Strategy'. The results are documented in reports, presented on web portals and discussed at conferences. The state-of-the-art of knowledge is described in applications for research funding.
- Fundamental research. Their agenda depends on the scientific interest and knowledge of the researching institutions. The results and the topic-related state of knowledge are presented among others in project evaluations and topical reviews.
- Regulatory research which is oriented towards the support of the implementation and enforcement of regulation. Their agenda is determined by the regulatory needs and priorities, which are documented in the form of the research strategy of the federal agencies.

On the right side of the figure different stakeholder groups are shown, which (may) have different expectations to research, depending on their own interests. The preconditions of these groups to obtain information, to assess and to interpret it for their needs and purposes are different.

[21] Basic research and applied research are factually not so strictly separable but form a continuum. However, researching institutions show trends to either of the directions and the separation is regarded as useful for illustration purposes.

Industry is listed as one of the stakeholder groups in the figure, because they (may) use the research results for their work and may also formulate their expectations on a research agenda. This is particularly true for industry sectors which don't carry out research themselves, but manufacture and commercialise products based on available, new technologies. The industry is; however also a researching actor (c.f. left side of the figure).

Based on the analysis of the state-of-the-art a first proposal was developed at the FachDialog on how the mutual transfer of research questions and research results between the scientific community and the civil society stakeholder groups could be improved and its credibility be strengthened.

According to this proposal the development of a complementary research agenda would be nourished by the following, closely interlocked processes:

- The societal actors would have to derive their questions which they want to be clarified.
- These questions should be compiled in a discussion process between the different stakeholder groups and condensed so that one consolidated list of questions is established.
- The research community should translate the (at the time actual) state-of-the-art of the scientific discourse and the available research results into concrete answers to the (at the time actual) questions. On the other hand they should actively identify, take up and communicate which research questions are still open and clarify when and how they will be addressed by future research.

It was discussed that it is very important that a translation process takes place on both sides in order to focus and bring questions and answers together and thereby to facilitate the development of a common research agenda. This should increase public perception and acceptance of research results.

The mediation process between research and societal actors is essential for the understanding and acceptance as well as an increased use of research results. This process would extend beyond a mere translation and should be organised by an institution that is trusted by all actors, has manifold competences in natural sciences and in social and political areas and has high communicative capabilities, too.

Figure 2 illustrates this additional process graphically.

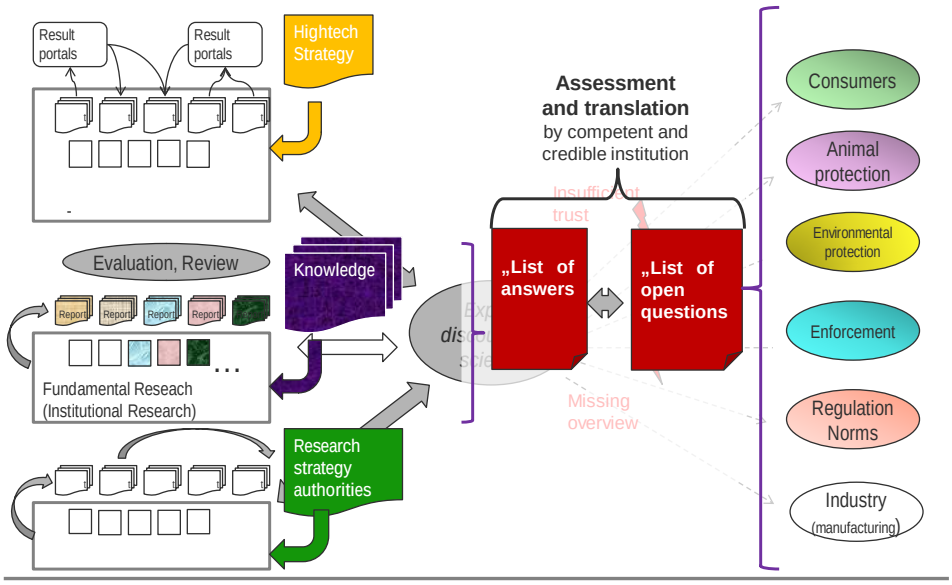

Figure 2: Proposal for a process to develop a common research agenda

According to the understanding of participants in the FachDialog, the federal agencies have the basic competencies and are sufficiently trusted by the general public to carry out this transfer process. As of the current time, this function is exerted only to a limited extent[22]. Some stakeholders believe that also the consumer protection organisations could be entrusted with this task.

[22] Mainly in relation to the „own" regulatory research