NanoDialogue
of the German Government

Opportunities and Risks of Advanced Materials

Summary of the Discussions at the Expert Dialogue on Advanced Materials

August 2019

Institut für Ökologie und Politik GmbH

Authors: Antonia Reihlen, Till Zimmermann & Dirk Jepsen

Imprint:

ÖKOPOL GmbH
Institut für Ökologie und Politik

Nernstweg 32–34
D – 22765 Hamburg

www.oekopol.de
info@oekopol.de

Tel.: ++ 49-40-39 100 2 0
Fax: ++ 49-40-39 100 2 33

Content

1 Introduction

The term ‘advanced materials’ covers materials with properties and functionalities that differ from ‘prior existing’ materials. It does not include limitations regarding the size, physical form or properties and describes a heterogeneous group of materials. Nanomaterials are generally regarded as sub-group of advanced materials.

Advanced materials are used in a large number of applications and products and frequently fulfil (particularly) high performance requirements. Some unite totally new functions or different functionalities within one material. Others may enable the production of qualitatively new products or processes. The development of advanced materials aims at, among others, saving critical resources, increasing the performance of electronic components and devices, improving health treatment or reducing adverse environmental impacts of products and processes.

The German Ministry of the Environment, Nature Protection and Nuclear Safety (BMU) is (also) responsible for the regulation of advanced materials. Therefore, it dedicated the ExpertDialogue on May 22 and 23, 2019 to the topic. The dialogue aimed at providing information and supporting an initial exchange of opinions on the state of regulation and research on advanced materials.

At the ExpertDialogue, stakeholders presented their views of the topic. Information about advanced materials addressed in the report ‘Support for 3rd regulatory review on nanomaterials’[1] dealing with advanced materials was presented. Five federal agencies[2] explained their perspectives on advanced materials, complemented by a presentation of the future umbrella strategy on materials by the Ministry of Education and Research (BMBF). Five application areas of advanced materials were introduced. At the end, ideas were collected on how a stakeholder process to discuss regulatory needs on advanced materials could be designed which takes into account safety, societal needs and expectations as well as opportunities and development potentials of advanced materials.

This report summarises the ExpertDialogue’s presentations (Chapter 2) and discussions (Chapter 3). The presentations are available (in German) on the Internet[3].

[1] Ricardo Energy and Environment: Support for 3rd regulatory review on nanomaterials. Final report, Brussels, 2016

[2] Federal Environment Agency (UBA), Federal Institute of Occupational Health and Safety (BAuA), Federal Agency for Risk Assessment (BfR), Physical-Technical Federal Agency (PTB) as well as the Federal Agency for Material Research and Evaluation (BAM)

[3] https://www.oekopol.de/themen/chemikalienpolitik/nanodialog/nanofachdialoge-2016-2017/fachdialog-chancen-und-risiken-von-advanced-materials/

2 Summaries of the Presentations

2.1 Introduction: Categorisation of Advanced Materials

Mr. Hansen (Danish Technical University (DTU)) explained that no formal definition but descriptions of the term ‘advanced materials’ exist. These descriptions are mainly based on the ‘novelty’ of properties or the materials’ state of development.

He also stated that several categorisation systems with different classification criteria[4] and numbers of categories exist. Composite materials would play a central role in all these systems but he indicated a need to scrutinize the reasons of this core position. Nanomaterials would be one among many categories in these systems. What these systems have in common is that advanced materials are characterised as products with a high added value, which are superior to conventional materials because of their novel, unique functionalities and improved properties.

Mr. Hansen also said that during his research for the 3rd regulatory review on nanomaterials[5] he wasn’t able to identify and compile much information on the advanced materials’ uses as well as the used and release amounts or on trends in research, development and markets. He saw a regulatory need only for a few categories of advanced materials. Among these are materials that are not or not clearly covered by the REACH substance definition.

2.2 Perspectives of the Authorities on Advanced Materials

2.2.1 The Umbrella Strategy on Materials and Safety Research of the BMBF

Ms Gerhard-Abozary explained that the BMBF is currently preparing an umbrella strategy on materials. The strategy should enforce the BMBF’s new strategic orientation in material research funding and would complement the ongoing material research programme ‘From Material to Innovation’. It would aim to highlight the societal and economic importance of materials, as it is already noted in the coalition agreement of the Government. The overall (or umbrella) material strategy will be based on the main topics of the ‘Hightech-Strategy 2025’ and the new topics ‘Digitalisation’ and ‘Biologisation’ will be anchored in the strategy as new technologies in material sciences. Funding on nanomaterial safety research will continue and be extended to advanced materials. This should ensure their

[4] Differentiations are made, e.g. according to type of end product and processes for which AMs are developed, novel or unique properties or according to material composition.

[5] Ricardo Energy and Environment: Support for 3rd regulatory review on nanomaterials. Final report, Brussels, 2016

sustainability and the protection of humans and the environment. The strategy's aim to closely relate innovation funding to regulation should prevent innovation barriers as well as intensify the societal benefits of material innovations.

2.2.2 Challenges from the Perspective of Chemical Safety

According to Ms Völker (German Environment Agency (UBA)), the UBA mainly approaches advanced materials from a regulatory perspective. Ms Völker described how the regulatory adaptions implemented for nanomaterials would clarify the legal situation and improve data availability. The possibility to transfer experiences collected on nanomaterials to advanced materials was mentioned as one of the open questions for UBA. In addition and from UBA's perspective, it would be necessary to assess if the REACH substance definition and the chemical risk assessment tools could (all) be applied to advanced materials and whether safe use could thus be assessed and ensured. She expected difficulties, among others, because the identity and properties of some advanced materials cannot be derived only based on the chemical properties.

To answer these basic questions, a research and dialogue project[6] commissioned by UBA will identify relevant advanced materials and applications. The current state of knowledge will be compiled for those materials and applications identified as relevant and their importance for (risk assessment in chemicals) legislation be evaluated. In the context of his project, which will last until 2021, stakeholder conferences are scheduled to support the reflection of (interim) results.

2.2.3 Dangerous Chemicals at Work and Advanced Materials

Mr. Packroff (Federal Agency for Occupational Health and Safety (BAuA)) presented BAuA's priorities regarding advanced materials. He stated these as justified by the lack of new 'nanotoxic effects' and the sufficiently developed regulation of substance-specific toxicity of chemicals. Therefore, BAuA would focus on two groups of particles, which are particularly relevant for occupational health: granular biopersistent dusts (GBD) and respirable fibres[7].

The particularity of these substance groups is, according to Mr. Packroff that risks can occur only after inhalation. However, information would be missing on exposure, while hazard potentials are frequently better known. In his view, it is not sufficient to state that a substance is inert but that in risk assessments the morphology should

[6] "Thematic conferences on advanced materials: Assessment of needs to act on chemical safety", FKZ 3719 66 402 0. Contractors: Ökopol; ISR BOKU Wien

[7] GBD accumulate in the lungs and may cause inflammations (dust problem). Respirable fibres can cause cancer (asbestos problem), here, the fibres' diameters determine the effect. It is assumed that thin fibres can coil up in the lungs and behave like particles when taken up by phagocytes but can nevertheless damage the lungs.

also be considered. From a health perspective, fibre fractions would be more critical than granular dusts. Since some advanced materials include fibres, Mr. Packroff advised evaluating if and how information could be made available to support employers in deriving and implementing sufficient prevention measures in the workplace.

Mr. Packroff reported that BAuA coincidently found out that pitch-based carbon fibres may break down into asbestos-like fibres. He stated that REACH lacks options to specifically address fibres. Therefore, BAuA is currently working on proposals to adapt the REACH annexes and occupational health legislation so that respirable fibres and GBD can be adequately considered. This would also include the respective assessment, measurement and interpretation strategies.

2.2.4 Safe Consumer Products

Ms Haase (Federal Institute for Risk Assessment (BfR)) showed some examples of advanced materials applications, which may cause risks to consumers:

- Filaments that are used in private 3D printing are covered by the general product liability rules but the produced goods are not assessed. It is therefore possible that hazardous materials migrate into products that come in contact with food.
- Due to the lack of specific legislation on textiles, exposures and risks from sensors in clothing cannot be identified and controlled.
- The BfR regards materials that interact with biological systems, such as implants and so-called wearables[8] as critical.

Ms Haase also mentioned that active and intelligent materials used in food contact materials are designed to release and absorb specific substances. This is covered by specific legislation. Therefore, possible risks should be identified and controlled.

According to Ms Haase, specific challenges stem from the structures of advanced materials as this could stipulate sequential effects[9] that would not be assessable with existing risk assessment tools.

[8] "Miniature computer", designed to be worn on the body but which may also be implanted in the future

[9] She addressed effects that could be relevant for advanced materials consisting of several layers. An example is a nanoparticle consisting of a core and two coatings. Only the surface (the outer coating) could interact with biological systems. If, for example, it is taken up into the body, the outer coating could be degraded and the inner coating would start interacting and potentially causing adverse effects. If this layer were also degraded, the core of the particle could exhibit the next, potentially adverse effect. Whether or not sequential effects do occur, how relevant this is in reality and how it could be predicted are issues for further research.

In this context, the BfR together with several partner institutions will conduct a research project to assess the safety of different ‘innovative materials’[10]. The project is funded by the BMBF and is called InnoMatLife. Which findings, approaches and methods can be transferred from nanomaterials to advanced materials will also be assessed.

2.2.5 Challenges for Materials Assessment

Mr. Rühle (Federal Agency for Material Research and Assessment (BAM)) explained that the BAM produces reference materials and designs measurement methods as well as provides data on advanced materials. As the functionality of advanced materials results from their structure, measurement methods should consider their morphology. However, he questioned whether this will always be possible. The dependence of properties on the advanced materials’ structures would also limit the applicability of grouping approaches. He also stressed that the functionality of advanced materials frequently seems to exceed those of the individual components.

He confirmed that advanced materials have a broad spectrum of applications, which poses safety challenges for chemicals and technologies. Using different examples, he showed which aspects of the materials could be relevant for their functionality and how to measure them. Mr. Rühle highlighted the need to consider the safety of advanced materials (in their uses) already in the design process.

2.2.6 Advanced Materials and Metrology

Mr. Richter (Physical-Technical Agency (PTB)) explained that reliable and defined measurement methods to characterise materials are the foundation for their use and safety assessment. In order to describe the effects of nanomaterials or advanced materials, those chemical-physical properties responsible for the effect would have to be described first. Then, a measurement method would have to be found for this particular property. Mr. Richter explained the measurement principles of some methods and showed what the design of analytical methods could look like in practice. He also demonstrated how different particle properties influence the measurement results.

[10] Three classes of advanced materials are subject to InnoMat.Life: polydisperse materials in industrial uses (e.g. metal/polymer powders for 3D printing), materials with specific and potentially critical morphologies and hybrid materials, e.g. with mixed organic/inorganic structures.
(https://www.bfr.bund.de/de/presseinformation/2019/13/innomat_life__mehr_sicherheit_fuer_neuartige_materialien-240513.html).

2.3 Examples of Application Areas

2.3.1 Challenges of Additive Production

Mr. Mühlhaupt (Freiburgian Centre for Material Science (FMF)) gave a broad overview of processes in the field of additive production. He described that the advantages of 3D printing compared to conventional production technologies are that no mould-making is needed, that production can be decentralised and that several materials can be used simultaneously. Disadvantages he named included the need for support structures, the considerably long duration of production as well as quality deficits. Mr. Mühlhaupt mentioned different R&D activities to optimise the various processes.

Mr. Mühlhaupt also introduced the large spectrum of materials used, including organic, inorganic and biological materials. These could be applied as powders, liquids or filaments. The processes would be based upon different principles, which would have to be adapted to the specific requirements of an application area. This would be one incentive for the current developments in 4D printing. Here, time is the fourth dimension and products that carry out movements are developed, which could be used for orthoses, for example.

2.3.2 High Performance Polymers in Light Weight Construction Applications

Mr. Dreyer (Fraunhofer IAP and TH Wildau) explained that high performance polymers used for light weight construction are used in the aeronautics and automotive industries but also in the production of wind power installations. Currently, the majority of used materials are composites, which consist of fibres that are stabilised by a resin matrix.

Mr. Dryer stated that light weight construction could save energy as the loads are reduced and construction could be more load-balanced. Among the disadvantages he named the low recyclability of composites: The resin matrices could only be chemically deconstructed and reused as raw material for new resins. A recovery and reuse of the fibres would not be possible and their disposal causes problems. This would trigger design requirements for efficient chemical decomposition of the fibres.

In thermal recycling the matrix would smoulder and the fibre remains could clog the electro filters of incineration plants. The shrinking of carbon fibres during thermal recycling might cause an increased severity of hazards of the materials.

Compared to conventional materials, a further disadvantage would be the fact that composite materials are more brittle and therefore less tolerant against impact damage. This would require more intense quality monitoring and potentially a precautionary repair of products, in particular in safety relevant applications, such as airplane construction.

2.3.3 Opportunities and Challenges of Using Organic Materials in Electronics

Mr. Meerholz (University of Cologne Köln, COPT) reported about the application of organic semi-conductors in electronics.

He named advantages of organic semi-conductors, such as the lower content of inorganic compounds (lower toxicity, lower use of (critical) resources) and the possibility to produce flexible and (large) plane modules (e.g. in photovoltaics or the generation of light). Organic semi-conductors usually account only for a very small share of the overall mass of the devices in which they are used. Therefore, their environmental benefits can normally not be seen, as they are overcompensated by the environmental burdens of the other materials contained.

Organic semi-conductors are generally slower and less powerful than inorganic semi-conductors. Therefore, according to Mr. Meerholz they cannot replace the 'classic' semi-conductors. Organic semi-conductors could, however be used in addition or in a complementary form. Apart from the generation of light and energy, important uses are, according to Mr. Meerholz, the integration of electronic functions into packaging, clothing, bags and medicinal products and applications.

2.3.4 Use of Intelligent Materials for a Digitalised and Wireless Measurement of Freshness in Food Packaging

Mr. Yakushenko (is it fresh GmbH) introduced how organic electronic components could be used in packaging to measure and communicate freshness of food. The aim of the introduced system is to reduce the share of food stuff that decays during transport and storage. This could be achieved by replacing the fixed expiration date by a flexible freshness monitoring system, the data of which could be used in the transport chain and by the food retail.

Mr. Yakushenko explained that the electronic sensor (chip) would provide different freshness parameters to a reading device. The chip is a printed, flexible layer, which is more economic than inorganic systems[11], due to the low material amounts and complexities. No batteries would be needed. The chip could also be used as unambiguous identity of a packaging, which could then be linked to other information from the production and supply chain.

[11] The sensor chip also includes a small share of inorganic semi-conductors but mainly consists of organic layers.

Food packaging is covered by food legislation, which is contradictory in this specific use case, according to Mr. Yakushenko: the chip may not come into direct contact with food. However, if it were separated from the food by a membrane, the migration limits would not be exceeded, even if all components of the chip migrated to the food. It would also be unclear, if the used thin film electronics are covered by the Directive on Waste Electrical and Electronic Equipment and how it should be disposed. While the common collection with other electronic devices appears neither practically possible nor meaningful, there are no barriers to the collection and recycling together with other packaging wastes.

2.3.5 Innovation by Functionalisation – Potentials and Risks of Nano-Functionalised Fibres

Mr. Brüll (Institute for Textile Technologies of the RWTH Aachen) introduced two approaches to functionalising textiles: additivation of fibres during the production process and the generation of nano structures though structuring fibres or textiles.

Examples of additivation are: invisible marking with fluorescent pigments, generation of electrical conductivity via metal or soot particles as well as achieving biological effects of agricultural textiles by integrating biocides or odorants. The additives are directly bound to the fibres during the spinning process. Therefore, only little migration of particles is observed. During use, damage or weathering could cause uncontrolled releases of these particles. This could only be hindered by a high polymeric adhesion of the particles.

According to Mr. Brüll, nanostructures are produced by using specific spinning technologies. Examples are fleece fabrics from endless filaments for filter-making, hollow fibres for dialyses or so-called snowflake fibres for acoustic absorption.

With regard to microplastics, two approaches are being researched: the filtration of waste waters to separate microplastics and the use of degradable polymers. The latter requires solving the conflicting goals of recyclability and biodegradation: Degrading products could reduce environmental burdens but cannot be recycled and therefore have to be newly produced.

3 Discussions on Advanced Materials

The following chapters summarise the content of the discussions at the ExpertDialogue topic-wise.

3.1 Definition of Advanced Materials

At the ExpertDialogue, several participants emphasized that the regulatory discussion about advanced materials needs one or possibly several definitions, which are unambiguous, understandable and can be scrutinized. However, several participants doubted that it is possible and sensible to develop one single, common definition for regulatory purposes because of the high number of materials and their combinations.

The stakeholders at the ExpertDialogue discussed that many of the proposed 'definitions' of advanced materials contain 'relative' elements. Advanced materials would be described by delineation from other, (also) non-defined groups of materials, which are named 'existing', 'older', 'less capable', etc. It would therefore be unclear, when to call a property or functionality 'novel', 'innovative' or 'different than before'. In addition, it would be problematic that 'old/new' or 'innovativeness' changes over time.

In the discussion, some participants proposed an exemplary, self-standing definition:

- Advanced materials are materials with properties that cannot be explained based on the chemical composition, only.
- Advanced materials are materials with specific functionalities, which are more than the sum of the individual components.

3.2 Categorisation of Advanced Materials

The participants of the ExpertDialogue regarded it necessary to differentiate advanced materials into groups: due to the high material diversity, the assessment of each individual variant in the context of regulatory requirements would practically be impossible. It could be assessed, to what extent the experiences from nanosafety research and the developed grouping approaches can also be transferred to the more complex advanced materials. A reduction of complexity and diversity was desired, among others to:

- Support experience exchange on advanced materials, by unambiguously clarifying and specifying the object of communication;
- Structure and prioritise data collection and processing on advanced materials;
- Organise funding of projects on innovation and safety research;
- Support the development of regulatory definitions of (sub-groups of) advanced materials;
- More systematically assess the adequacy of existing regulation.

However, it was also critically questioned if it is at all possible to develop a system to clearly differentiate advanced materials because an unambiguous allocation of a material to (only) one category was found (partly) to be impossible. In addition, some participants feared that very complex categories could be formed if all combinations of materials and technologies are considered.

3.3 Aspects for the Relevance Assessment of Advanced Materials

The participants of the ExpertDialogue agreed that monitoring technical developments and regulatory needs of advanced materials, the prioritisation of 'relevant' materials would be necessary. The evaluation of relevance could, for example; integrate the following aspects:

- Production and use amounts;
- Toxicity;
- Size (however, no arbitrary threshold should limit relevance);
- Particle properties that could damage human health and/or the environment; contents of 'critical fibres' or GBD, respectively their release potential;
- Combinations of materials:
    - For which little information is available;
    - That contain biological materials;
    - That could exhibit mixture or sequential effects, or which can (probably) not be assessed using existing risk assessment tools.
- Possibility of translocation of materials in the body;
- Uses with high environmental or consumer exposures;
- Low recycling potential;
- Use of rare/critical resources (resource protection).

It was not discussed which criteria would indicate a particularly high or low relevance and what weight they should have in the context of a prioritisation.

As the evaluation of relevance was discussed primarily with a view to risk prevention and regulation, the criteria do not address opportunities of advanced materials. However, it was frequently mentioned that, apart from risk prevention, the focus should be set on supporting and enhancing the benefits from the use of advanced materials.

3.4 Risk Potentials of Advanced Materials

Some risk potentials of advanced materials were discussed in-depth at the Expert Dialogue, while other areas, such as resource scarcity and criticality, circular economy and ethics were named, but not elaborated further.

The stakeholders agreed that the chemical composition is only one of the factors that determine the (eco) toxic effects, and hence the possible risks from advanced materials. Even if the types of hazardous properties are known, some participants feared that the conventional risk assessment tools would not suffice as further factors would influence the effects, such as the simultaneous presence of materials (and their combinations) and their material structure (sequential effects).

With a view to the particle properties of some advanced materials, stakeholders repeatedly referred to the regulatory adaptations for nanomaterials, which concerned both the requirements on data generation as well as the risk assessment instruments. It was not discussed in detail but formulated as a research need, to assess if new properties that are hazardous to human health or the environment could occur for other (groups of) advanced materials and if these would trigger a need for further regulatory adaptations.

The participants agreed that respirable fibres and GBD may cause risks (c.f. Chapter 2.2.3). These groups would be relevant as some advanced materials contained such particle forms or could decompose into them. For the risk assessment it was emphasized, however, that the grouping is not unambiguous and that, in addition (classical) toxic properties could exist.

Advanced materials containing biological materials or uses inside the human body (implants) as well as applications with high consumer exposures were named as relevant due to potential risks.

From the consumer protection perspective, attention was drawn to technologies that are developed for particular applications but later ‘spill over’ to further uses. This might result in the original technology and material assessment not covering all possible use scenarios and risks. For example, innovations from the medicinal area would already be partly used in cosmetic applications, for which they have not been risk assessed (e.g. nano carrier systems). Another example given was additive production technologies, which enter private homes as 3D printers.

3.5 Waste Treatment

Opportunities and risks from advanced materials for the circular economy were frequently mentioned. Stakeholders identified only few possibilities to circulate composites. The named reasons were in particular the firmness of the bonds of material combinations, which hinder mechanical separation and hence mechanical recycling. While it appeared theoretically possible to chemically recycle the main component of a composite material, the likelihood that this would be economically beneficial for all or at least several of the combined materials was regarded as very low. It was not discussed if chemical recycling is (ecologically) beneficial in general.

Some actors mentioned that products or product parts containing advanced materials would have to be detected and separately collected, in order to introduce them to specific recycling or to extract them from the material cycles, if they contaminated the recyclate or disrupted waste processing. Neither identification systems nor separate collection and treatments would be available. The additivation of textiles with fluorescent pigments (c. f. Chapter 2.3.5) or use of chips, e.g. in packaging (c. f. Chapter 2.3.4) could provide helpful functionalities for the circular economy, if used as markers for a later identification of products in waste streams.

3.6 Societal Needs and Technology Development

In some discussions it was questioned if and how technological innovations from advanced materials are necessary for the society and sensible for the environment. With a view to the very fast developments and the high number of application areas it would be challenging to monitor and evaluate this. Ethics commissions or 'codes of conduct' were two possibilities to regard the ethical and societal aspects.

Some participants doubted that advanced materials could (significantly) contribute to resource protection and solving environmental problems, even if they were particularly designed to do so. This would be caused mainly by the fact that potential environmental benefits are overcompensated by environmental burdens of the missing recyclability or the (assumed) high resource needs for their production.

The participants agreed that companies and scientists in academic institutions should consider risks and unwanted effects of advanced materials early in the (product) development. This included, according to the discussion, in particular:

- (Eco-)toxic aspects, including the considerations on if and how materials change during their life cycle;
- Uses, exposures and risks along the lifecycle;
- Resource efficiency;
- Criticality of raw materials;
- Adequacy for the circular economy;
- Ethical aspects in the application area;
- Regulatory requirements for future uses.

Some participants stated that investors in Germany rather invest in digital start-ups than in material start-ups. Even though an early clarification and design of an adequate, regulatory frame would minimize investment risks from a content perspective, in practice, an early assessment of possible legal requirements would not only limit 'search and play' with possible solutions but would also discourage investors. Investors would not have the resources to engage in regulatory assessments and would be rather guided by the 'spotlight' observations on the societal acceptance of products. A regulatory discussion focussing only on risks would discourage science and companies active in research and innovation.

Overall, societal needs and concerns known from the discussions on chemical safety and nanomaterials should guide companies and academia in product development. It would therefore be important that societal perspectives and aims of innovations are stated specifically and transparently and are discussed, e.g. in participatory processes (open innovation).

3.7 Regulation

Regarding possible regulation(s) a 'top-down' and a 'bottom-up' approach, which is triggered by evidence-based risk hypotheses, were discussed.

At the ExpertDialogue the top-down approach was understood as follows: Advanced materials are described using one or more definitions.[12] For the defined materials, requirements are set regarding the generation of information, safety assessment and the identification of potential risk management measures. This corresponds to the regulatory approach of REACH.

In contrast, regulation based on risk hypotheses (bottom-up) was understood as dynamic process. First, it would be identified for which (combinations of) advanced materials and application areas indications of possible risks exist. In a second step, these cases would be further analysed. If risks were identified, appropriate and potentially specific requirements would have to be defined, including an assessment if further regulatory adaptations are necessary.

The majority of stakeholders preferred the second, risk hypotheses-based approach, as they found the high number and heterogeneity of advanced materials and application areas otherwise not manageable. However, it was remarked that the bottom-up approach bears the risk that the responsibility for risk assessment and management of advanced materials could be partly shifted from industries to the authorities.

It was controversially discussed if regulation should be horizontal (e.g. sectoral or for specific application areas) or if a vertical regulation (chemicals/material specific perspective) would be more meaningful.
In the discussion on possible regulatory instruments the participants preferred to complement or adapt existing legislation over the development of new legislation. A number of participants emphasised that several advanced materials might not be covered by the scope of any or at least some legislation, such as multi components

[12] It was not considered useful to develop a general definition for regulatory purposed due to high efforts and costs. For nanomaterials, the EU Commission proposed a definition, which should be included (and specified) in further legislation, such as the Annexes of REACH.

systems, which would not be covered by the REACH substance definition.
A ‘regulatory preparedness’ would be needed with a view to the fast technological developments.

Some stakeholders stressed the importance of activities that complement legislation, such as an enhanced communication along the supply chains. This would happen e.g. to comply with the information requirements on SVHC in articles. Some IT systems, such as blockchain or other distributed ledger technologies would be under discussion to support this information exchange.

3.8 Safety Research

At the ExpertDialogue, a need for research on methods became obvious, which relates to:

- The identification of advanced materials and/or their fields of application with high risk potentials;
- The assessment of the applicability of tools for risk assessment and risk management and, according to the result, potentially the adaption and/or development of new tools.

Several interventions concerned the need and importance of a stronger integration of safety research in innovation research and product development. This would include considerations on regulatory aspects during product development, in order to prevent products that are incompliant with the safety requirements. In this regard it was proposed that institutions supporting start-ups should provide regulatory know-how in form of lectures, consultancy and informative talks.

4 Conclusions at the ExpertDialogue

At the end of the dialogue, the findings were reflected along a number of questions.

4.1 How can Developments in the Use of Advanced Materials be Monitored?

The number, diversity and heterogeneity of advanced materials and their application areas in combination with the very fast developments aggravate efforts to gain overview and identify potentially critical trends. Participants proposed several options to monitor the developments, of which none received obvious general support. Among these proposals were:

- Evaluation of research programmes;

- Publication of regular and focussed reports about material science (similar as the reports ‘nano.DE’ in nano research) or
- Extension of the monitoring by the EUON[13].

Participatory and dialogue processes could be used not only to monitor but also identify priorities and regulatory principles. Continuous and established communication structures were supported, as existing in the workers protection area. These participatory elements were regarded important elements of the advanced materials’ governance.

4.2 How can Societal Needs be Identified and Prioritised?

Prioritisation of regulation and safety research should be guided by societal needs and concerns. According to the participants, these should be derived from goals and principles of existing regulation. The expectations towards solutions for societal challenges should be considered as risk hypotheses of authorities, environmental and consumer organisations, science platforms and industry organisations. Superordinate policy goals, such as the prevention of risks for health and environment, the increase of recycling and the reduction of resource use would also provide respective orientation.

There were different views on the most efficient approach to form categories of advanced materials and prioritise these regarding potential risks and regulatory needs. Among others, it was proposed to systematically assess risks and opportunities of (categories of) advanced materials (matrix) to analyse fields of application in a structured way or to prioritise using benefits and goals of materials/applications. It was also repeated that advanced materials that could not be assessed with the existing risk assessment tools should be prioritised.

4.3 How could Adequate Regulation be Developed?

Several participants at the ExpertDialogue were of the opinion that participatory activities have their limitations in the discussion on what and how legislation should be developed. It was also pointed out that identified hazards and risks could be managed as restriction under REACH as well as by means of industry self-commitments.

According to the opinions of many stakeholders, the existing legislation should be reviewed and adapted, if necessary (such as the eco-design requirements). The

[13] European Observatory on Nanomaterials. The EUoN is operated by ECHA and is tasked, among others, with the collection and making available of information on nanomaterials for the general public.

development of new legislation should only be considered, if the existing ones are not sufficient.

Some participants doubted that the development of legislation that is based on risk hypotheses is sufficient and possible, as the necessary data are missing. Therefore, a monitoring system should be installed first, that is guided by criteria of concern and ‘low harm’ to identify areas of risk.

In a long-term perspective, several participants believed it possible to develop grouping approaches for regulation based on the experience gained from case-by-case assessments.

Some participants proposed the BMU initiate a wider societal dialogue on the topic, similar to the NanoKommission.