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Strategic Research Agenda for Safe Advanced Materials

Joint Perspective of the German Higher Federal Authorities on safe use and chemical safety throughout the entire material life cycle



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List of Abbreviations

| Abbreviation | Explanation |
|------------------------|---|
| AdMa | Advanced Materials |
| AdvancedNano IN | AdvancedNano GO FAIR Implementation Network |
| AI | Artificial Intelligence |
| BAM | German Federal Institute for Materials Research and Testing |
| BAuA | German Federal Institute for Occupational Safety and Health |
| BfR | German Federal Institute for Risk Assessment |
| BIPM | Bureau International des Poids et Mesures |
| BMAS | German Federal Ministry of Labour and Social Affairs |
| BMFTR | German Federal Ministry of Research, Technology and Space |
| BMLEH | Federal Ministry of Agriculture, Food and Regional Identity |
| BMUKN | German Federal Ministry for the Environment, Climate Action, Nature Conservation and Nuclear Safety |
| BMWE | German Federal Ministry for Economic Affairs and Energy |
| CIPM | Committee for Weights and Measures |
| Early4AdMa | Early Awareness and Action System for Advanced Materials |
| EC | European Commission |
| ECHA | European Chemicals Agency |
| ECVAM | European Centre for the Validation of Alternative Methods |
| EFSA | European Food Safety Authority |
| EMN | European Metrology Networks |
| EURAMET | European Association of National Metrology Institutes (EURAMET e.V.) programme |
| FAIR | Findability, Accessibility, Interoperability and Reusability |
| FORUM-MD | Forum on Metrology and Digitalization |
| GD | Guidance Documents |
| GLP | Good Laboratory Practice |
| IAM4EU | Innovative Advanced Materials for Europe |
| IAM-I | Innovative Advanced Materials Initiative |
| ISO | International Organization for Standardization |
| JRC | Joint Research Centre |
| NAM | New Approach Method |
| NSC | Network for Safety and Sustainability of Chemicals and Materials |

| Abbreviation | Explanation |
|---------------------|--|
| OECD | Organisation for Economic Cooperation and Development |
| PARC | Partnership for the Assessment of Risks from Chemicals |
| PTB | Physikalisch-Technische Bundesanstalt |
| QI-Digital | Initiative on Digital Quality Infrastructure |
| REACH | Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals |
| SSbD | Safe and Sustainable by Design |
| TG | Test Guidelines |
| UBA | German Environment Agency |
| VAMAS | Versailles Project on Advanced Materials and Standard |
| WNT | Working Party of the National Coordinators of the Test Guidelines Programme |
| WPMN | Working Party on Manufactured Nanomaterials |

Executive Summary

Advanced materials comprise most diverse groups of materials with new and improved functionalities, variations of structures and increasing complexity. They hold the potential to support addressing global and societal challenges in, e.g. health care, energy transition and substituting substances of concern or critical raw materials. The assessment of safety and sustainability over the whole life cycle is of central relevance to enable full exploitation of societal and economic benefits of advanced materials. The aim is to avoid or mitigate potential adverse impacts related to the production, use and end of life of advanced materials. From a authority perspective, it is essential to become regulatory prepared for these new materials. Therefore, the German higher federal authorities responsible for human and environmental safety, and metrology – the Federal Institute for Materials Research and Testing (BAM), the German Federal Institute for Risk Assessment (BfR), the Federal Institute for Occupational Safety and Health (BAuA), the German Environment Agency (UBA) and the National Metrology Institute (Physikalisch-Technische Bundesanstalt, PTB) - are accompanying the rapid pace of innovation of advanced materials with a long term research strategy focusing on research needs from a regulatory perspective. The current strategy includes the early identification of emerging safety issues related to advanced materials early on within the plethora of materials that are currently in development or on the market. Closing knowledge gaps on chemical safety and to provide appropriate testing and assessment strategies for advanced materials is the next step towards Regulatory Preparedness. The strategy highlights the research objectives to develop and validate test methods. Such methods allow the collection of appropriate and reliable safety data, considering the specific properties of advanced materials and acknowledging the challenges connected to investigating complex systems. In addition to research needed to develop, validate and standardise test methods for regulatory settings, the need for methods that allow balanced decisions already in the early phase of innovation to be used in the Safe and Sustainable by Design framework are pointed out. Finally, the strategy addresses research and development enablers related to research on advanced materials, including FAIR data approaches, digitisation, education and networking as well as the technical equipment and personnel capacities at the higher federal authorities to conduct relevant research. The research strategy intends to better connect safety research with innovation research under consideration of regulatory obligations and the aim for an appropriate risk assessment. The presented research objectives should be implemented via projects and other research-related activities. The higher federal authorities will contribute to the realisation of the necessary research. In addition, commitments from national and European funding bodies and the scientific community (from both academia and industry) are needed to scientifically address open questions and regulatory challenges of advanced materials in an effective and coordinated way.

Kurzfassung

Neuartige Materialien umfassen verschiedenste Gruppen von Materialien mit neuen und verbesserten Funktionalitäten, unterschiedlichen Strukturen und zunehmender Komplexität. Sie haben das Potenzial, bei der Bewältigung globaler und gesellschaftlicher Herausforderungen beispielsweise im Gesundheitswesen zu helfen, beispielsweise bei der Energiewende und beim Ersatz bedenklicher Stoffe oder kritischer Rohstoffe. Um die gesellschaftlichen und wirtschaftlichen Vorteile neuartiger Materialien voll auszuschöpfen, ist es jedoch von zentraler Bedeutung ihre Sicherheit und Nachhaltigkeit über den gesamten Lebenszyklus hinweg zu beurteilen. Das Ziel ist es, potenzielle negative Auswirkungen bei der Herstellung, Verwendung und Entsorgung neuartiger Materialien rechtzeitig zu vermeiden oder zu mindern. Aus behördlicher Sicht ist es unerlässlich auf neuartige Materialien regulatorisch vorbereitet zu sein. Daher begleiten die für die Sicherheit von Mensch und Umwelt und für Metrologie zuständigen deutschen Bundesoberbehörden – die Bundesanstalt für Materialforschung und -prüfung (BAM), die Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA), das Bundesinstitut für Risikobewertung (BfR), das Umweltbundesamt (UBA) und die Physikalisch-Technische Bundesanstalt (PTB) – die rasante Innovation von neuartigen Materialien mit einer langfristigen Forschungsstrategie, die sich auf den Forschungsbedarf aus regulatorischer Sicht konzentriert. Die aktuelle Strategie umfasst die frühzeitige Identifizierung neu auftretender Sicherheitsfragen im Kontext neuartiger Materialien, die sich derzeit in der Entwicklung oder auf dem Markt befinden. Das Schließen von Wissenslücken im Bereich Chemikaliensicherheit und die Bereitstellung geeigneter Prüf- und Bewertungsstrategien für neuartige Materialien ist der nächste Schritt auf dem Weg, um die regulatorische Risikobewertung für neuartige Materialien sachgerecht auszugestalten. Die Strategie hebt zudem Forschungsziele für die Entwicklung und Validierung von Prüfmethoden hervor. Diese Methoden ermöglichen die Erhebung sachgerechter und zuverlässiger Sicherheitsdaten unter Berücksichtigung der spezifischen Eigenschaften neuartiger Materialien und der Herausforderungen, die mit der Untersuchung komplexer Systeme verbunden sind. Neben den Forschungsarbeiten, die zur Entwicklung, Validierung und Standardisierung von Prüfmethoden für den regulatorischen Bereich erforderlich sind, wird beschrieben, welcher Bedarf an Methoden besteht, um bereits in frühen Phasen eines Innovationsprozesses ausgewogene Entscheidungen im Rahmen des „Safe and Sustainable by Design“ Konzeptes treffen zu können. Abschließend befasst sich die Strategie mit erforderlichen Maßnahmen in Querschnittsbereichen zur Sicherheitsforschung zu neuartigen Materialien, einschließlich FAIR-Datenkonzepten, Digitalisierung, Ausbildung und Vernetzung sowie die technische Ausstattung und Personalkapazitäten der Bundesoberbehörden für die Durchführung notwendiger Forschung. Unter Berücksichtigung der regulatorischen Anforderungen und dem Ziel einer sachgerechten Risikobewertung beabsichtigt die Forschungsstrategie, Sicherheitsforschung besser mit Innovationsforschung zu verknüpfen. Die vorgestellten Forschungsziele sollen durch Projekte und andere forschungsnahe Aktivitäten umgesetzt werden. Die Bundesoberbehörden tragen zur Durchführung der erforderlichen Forschungsarbeiten bei. Darüber hinaus sind Beiträge seitens nationaler und europäischer Förderinstitutionen und der Wissenschaft (sowohl akademisch und industriell) erforderlich, um offene Fragen und regulatorische Herausforderungen im Zusammenhang mit neuartigen Materialien auf wissenschaftlicher Basis wirksam und koordiniert anzugehen.

1 Introduction

Advanced materials (AdMa) hold significant potential for enabling technical solutions that support a green and sustainable transformation, particularly in areas such as the energy transition, climate and resource protection, healthcare and digitisation. Their utilisation can help, for example, to deploy energy more efficiently, to save resources, and to reduce or even replace the use of problematic or less sustainable chemicals. The German governance views material research as playing a central role in the transformation of German industry and Germany's technological and economic resilience (BMW & BMUKN, 2026). The European Commission (EC) has recently prioritised AdMa in its strategic agenda (European Commission, 2024, 2025b), underlining their importance in advancing a more sustainable and resilient European economy. Furthermore, the EC believes that AdMa can strengthen Europe's global competitiveness and reduce dependence on critical raw materials typically sourced from outside the European Union (EU).

Advanced Materials (AdMa)

The term "advanced materials" can be interpreted broadly. A universally or legally accepted definition of AdMa does not yet exist.

The Organisation for Economic Co-operation and Development (**OECD**) **describes** that (OECD, 2022a): "..., **Advanced materials** are understood as materials that are rationally designed to have new or enhanced properties, and/or targeted or enhanced structural features, with the objective of achieving specific or improved functional performance.

This includes both new emerging manufactured materials, and materials that are manufactured from traditional materials. This also includes materials from innovative manufacturing processes that enable the creation of targeted structures from starting materials, such as bottom-up approaches. It is acknowledged that what are currently considered as AdMa will change with time. ..."

In the context of this research strategy, we follow this description with a focus on AdMa that fall under chemicals legislation and have a nanometre size range (i.e. 1-100 nm) (European Commission, 2022b) and beyond, generally up to potentially a few micrometres. Thus, we focus mainly on AdMas such as particulate materials including fibres or platelets. Materials from advanced manufacturing are not in focus of this strategy. A definition by the International Organization for Standardization (ISO) is currently under development (ISO, 2026).

In its communication *Advanced Materials for Industrial Leadership*, the EC outlines strategic initiatives to promote AdMa development and integration across industrial sectors. Accordingly, innovation of AdMa play a major role in four priority areas (mobility, electronics, energy, construction), identified by the EC and integrated in the strategic research and innovation agenda of the Innovative Advanced Materials for Europe (IAM4EU) partnership (IAM-I, 2025a). AdMa also have potential applications in agriculture, in agri-food industry, for pharmaceuticals and for healthcare. While the communication highlights the transformative potential of AdMa, it falls short in its attention to issues such as human and environmental safety and sustainability. In addition, the EC announced a legal initiative for an Advanced Materials Act to be introduced by end of 2026 (European Commission, 2025f). It will aim to establish a strategic framework for AdMa that is crucial for industrial leadership, strategic autonomy and competitiveness in the EU. However, to ensure that AdMa foster the success of other current initiatives of the EC such as the Chemicals Strategy for Sustainability (European Commission, 2020a), the Zero Pollution Action Plan (European Commission, 2021a), the Critical Raw Materials Act (Ierides et al., 2025;

European Commission, 2026c), the Strategic Energy Technology Plan (European Commission, 2023a; Kuzov et al., 2025), the Battery booster strategy (European Commission, 2026b), and the Clean Industry Deal (European Commission, 2025a), it is essential to identify and address potential impacts on human health and the environment across their entire life cycle as well as associated conflict of goals (UBA, 2023a). A critical step in doing so is, amongst others, addressing regulatory uncertainties, e.g. with regards to suitability of requested and provided data due to the lack of clear guidelines or standards, and with regards to knowledge gaps. To address these regulatory uncertainties, a proactive strategy of Regulatory Preparedness was introduced by OECD with the aim to support safe and responsible innovation (OECD, 2020a). This approach involves raising awareness among regulators and fostering activities to ensure that regulations can keep pace with technological advancements, preventing unintended consequences. Given the EC's strong push for innovation in materials, advancing Regulatory Preparedness is now more urgent than ever to prevent a growing gap between innovation and regulation that could hinder progress. Therefore, it is called for a broader concept of innovation that besides economic and technological progress also considers societal and ecological implications. Such a concept allows to integrate precautionary thinking and existing standards of protection into innovation, starting from the early development, and thus will facilitate the transition to sustainability.

Regulatory Preparedness

OECD Working Description on Regulatory Preparedness (OECD, 2020a): *“Regulatory Preparedness refers to the capacity of regulators, including policymakers, to anticipate the regulatory challenges posed by emerging technologies such as nanotechnology, particularly human and environmental safety challenges. This requires that regulators become aware of and understand innovations sufficiently early to take appropriate action, and that appropriate regulatory tools are modified or developed as needed. Regulatory Preparedness helps to ensure that innovative materials and products undergo suitable (and, if appropriate, adapted) safety assessment before entering the market.”*

Discussions on AdMa with respect to chemical safety often overlap with those about nanomaterials, especially when AdMa meet the EC recommendation for a definition of nanomaterials (European Commission, 2011, 2022b). As with earlier experiences involving nanomaterials (European Commission, 2012; Schwirn et al., 2014; Bleeker et al., 2023; BAuA, 2025b), there are concerns about the adequacy of current legal frameworks in addressing these kinds of materials, meaning substances that are not easily soluble, fall within small size ranges, and have special properties. Regulatory challenges become even more complex with AdMa because of their higher structural and functional complexity, and diversity. Because of these ambiguities, early identification and addressing of regulatory and safety concerns is essential to keep pace with innovation to ensure protection of human health and the environment. Addressing proactively the scientific questions and legal challenges related to safety will furthermore strengthen the EC strategy on AdMa for industrial leadership and the future AdMa Act, and enhance their chances of success. It will facilitate safe innovation, by including Safe and Sustainable by Design (SSbD) approaches and increase legal clarity and certainty for innovators in all sectors (e.g. the priority areas mobility, electronics, energy and construction), reducing the risk of regulatory hurdles or delay of market entry. Ensuring that AdMa are not only technologically effective but also safe for human health and the environment is vital for their long-term adoption and public trust. Safety research plays a pivotal role in ensuring safe and sustainable material innovation. A multi-stakeholder effort is needed to enable that materials innovation foster technological advancements needed to tackle global challenges while at the same time to guarantee a safe and sustainable material life cycle. From a regulatory perspective,

both preparatory and regulatory relevant research is needed. Preparatory research identifies potential risks to human health and the environment at an early stage of innovation. Moreover, it generates appropriate data to enable at least preliminary governance on the basis of the precautionary principle. Regulatory relevant research provides for example appropriate strategies and methods for assessing safety and sustainability implications of AdMa. Thereby, it significantly supports risk assessment in the frames of legislation for chemical safety, for product safety and for occupational safety.

The higher federal authorities responsible for the safety of humans and the environment and for metrology in Germany - the Federal Institute for Materials Research and Testing (BAM), the Federal Institute for Occupational Safety and Health (BAuA), the German Federal Institute for Risk Assessment (BfR), the German Environment Agency (UBA), and the National Metrology Institute (Physikalisch-Technische Bundesanstalt, PTB) - are accompanying the rapid development of AdMa with a joint long-term research strategy. From the perspective of the higher federal authorities, this research strategy describes the presently identified research needed to become regulatory prepared for the rapidly growing area of material innovation. The research needs identified are to be realised within projects and other research-related activities. The higher federal authorities contribute to the realisation, either in their own laboratories in support of public research projects or via tendering and extramural research funding. Just as important, the higher federal authorities substantiate knowledge gain and Regulatory Preparedness for AdMa by academic reviewing and identifying the state of scientific knowledge, e.g. as part of their official duties in regulatory processes. In addition to these efforts, the commitments of national and European funding bodies and the scientific community are necessary to scientifically address open questions and regulatory challenges of AdMa. Such commitments are especially relevant as (1) regulatory relevant research is usually lacking behind the high speed of material innovation, and (2) in considering that material innovations are funded with the promise to provide safer and more sustainable solutions.

In 2007 and in a review in 2013, the joint research strategy of the aforementioned higher federal authorities initially focussed on the health and environmental risks of nanomaterials (Orthen et al., 2007; Burgdorf et al., 2013). Its update in 2016 then broadened the perspective to include further material innovations and focussed on the safe and environmentally friendly design of AdMa (Packroff et al., 2016). In 2021, BAuA, BfR and UBA published joint considerations on risk governance of AdMa (Schwirn et al., 2021), including first considerations regarding safety research on AdMa. The now presented research strategy builds on the results of the previous joint strategies and concretises the current knowledge gaps and research needs.

2 Identify relevant advanced materials, signals of concern and knowledge gaps

Horizon scanning is a strategic approach that helps organisations and decision makers to identify future trends, challenges and opportunities for technology, the society, the environment and the economy. The results of horizon scanning help to recognise areas that deserve a deeper look e.g. by early awareness approaches regarding potential implications. In such a follow up process signals for potential issues such as signals of concern or knowledge gaps may be identified. The results of such an approach provide organisations or decision-makers with valuable insights that support making strategic decisions, develop long-term plans, but also proactively anticipate future developments. Hence, for AdMa, horizon scanning and early awareness approaches allow regulators and policy makers to exploit opportunities of these materials in relevant technologies, and to decide on relevant next steps to identify and minimise potential risks. As innovation is a continuing process, horizon scanning and early awareness are continuous efforts as well.

2.1 Horizon scanning on material innovation

State of the Art

Fostering the development and application of AdMa is a crucial element of Europe's ambition to become more sustainable, competitive, and resilient. However, for regulators there often is a lack of knowledge about which AdMa are under development, their respective specialities, which of them will have the potential to enter the market and if so, in what kind of applications. While regulators may identify signals of potential concern for emerging new materials during their daily work duties, also strategic approaches are employed. Different aims for scanning the field of AdMa are conceivable to gain an overview on: (1) AdMa under development and in application in general, (2) relevant areas of application of selected (subtypes of) AdMa, and their potential implications for human health and environmental safety as well as challenges for sustainability or (3) AdMa relevant for (potential or future) utilisation in a specific area of application (e.g. the strategic research and innovation areas prioritised by the EC) and which concerns this application might imply for human health and the environment. To gain a better insight, the higher federal authorities started first activities to scan the field on AdMa.

In 2019, a series of so-called thematic conferences on AdMa was initiated by UBA which aimed to kick off an international stakeholder exchange on AdMa with subjects such as what kind of materials they include, in which areas or applications they may be or become relevant, and what kind of challenges they may entail with regard to chemical safety and sustainability (Reihlen et al., 2022). The thematic conferences laid the ground for the commitment of the OECD Working Party on Manufactured Nanomaterials (WPMN) to AdMa (see chapter 2.2). Furthermore, UBA has commissioned the drafting of several systematic overviews of AdMa. This includes an overview on possible AdMa in general (Giese et al., 2020), an overview on nanocarriers as specific sub-group of AdMa and their applications (Gressler et al., 2024), and the (potential) application of AdMa in technologies for energy transition (Knigge & Radnik, 2025).

Research Needs

Systematic overviews of AdMa in areas of interest, their functionalities, (potential) applications, and (future) market share will be supportive in keeping up-to-date on current and new AdMa of relevance. This is especially relevant for those AdMa that are not yet under the consideration of the higher federal authorities. Considering EC's research and innovation priorities highlighted in its communication on AdMa, a systematic overview on AdMa in development and on markets for these applications areas is pivotal in first place. These priority areas include energy, mobility,

construction and electronics, potentially complemented by a strategic area concerning health. Examples of technologies of interest for horizon scanning could include light weight construction and battery materials. In addition, the EC's digital strategy (European Commission, 2022e) and strategy on Artificial Intelligence (AI) (European Commission, 2018) may reveal further areas of relevant applications of AdMa to be explored via horizon scanning activities. Depending on the integration of AdMa into products, from a life cycle perspective, horizon scanning is also needed to disclose potential implications of AdMa in production and recycling processes. As an example with regards to occupational exposure, horizon scanning concerning AdMa such as graphene-related materials or nano- and micro-sized advanced polymeric particles will help to highlight the relevance of potential release during production or processing.

In addition, review of current research funding programmes on material innovation as well as new patents will improve the understanding of upcoming material trends. Insights on AdMa in innovation and application can also be gained by involvement of the higher federal authorities in research projects on material innovation, surveys, and by stakeholder exchange via dedicated thematic conferences or workshops.

Expected Impact

Horizon scanning of AdMa, their functionalities and areas of application allows the higher federal authorities to gain an overview of the status quo and identify trends early on. Outcomes of horizon scanning of AdMa help to identify AdMa and areas of application that deserve a closer look from an authority perspective by e.g. early awareness approaches regarding regulatory challenges, challenges for risk assessment and knowledge gaps. Furthermore, results will entail decisions on resources to invest in emerging topics, and generally expand knowledge and contacts in that area.

2.2 Early awareness-raising

State of the Art

To identify potential issues on safety and implications on regulation related to AdMa and to clarify what relevant information is missing, systematic investigations are important. First signals for potential issues of AdMa, but also the identification of knowledge gaps may arise from stakeholder exchange, horizon scanning activities or research and innovation projects. As a tool to systematically anticipate signals of concern and knowledge gaps related to safety, sustainability, and regulatory issues of AdMa, the Early4AdMa approach was developed by the OECD WPMN (OECD, 2023b). This tool aims to enhance Regulatory Preparedness by helping policymakers and regulators to contemplate issues of material innovations at an early stage. Based on the identified issues, follow-up actions can be deduced. Early4AdMa has already been employed by the OECD WPMN in the course of expert workshops for a number of AdMa, i.e., nanocarriers (OECD, 2024a), Mxenes (OECD, 2025a; Ouhajji et al., 2025), graphene-related materials (OECD, 2026), as well as fibre-aerogel-mats for façade insulation by the EU-funded project HARMLESS (OECD, 2023a).

Recently, as part of the EU-funded project HARMLESS, the HARMLESS Early Warning System for AdMa has been developed, focussing primarily on the needs of regulators and risk assessors (Prinz et al., 2025). The HARMLESS Early Warning System is an easy and functional stand-alone tool that facilitates the screening phase of AdMa. It is organised in two tiers, each underpinned by a specific methodology and facilitated by a dedicated online tool. It was presented to the OECD WPMN with the aim to provide input for the revision of the screening assessment tier of the Early4AdMa.

Research Needs

For AdMa that could be of relevance from a regulatory point of view, potential signals of concern and existing knowledge gaps need to be identified and successively addressed. AdMa of regulatory relevance are those that affect the area of responsibility of the higher federal authorities (i.e., materials that can impact occupational, consumer or environmental safety). Identification of signals of concern and knowledge gaps should also include those AdMa that are under development for or in use in the strategic research and innovation areas prioritised by the EC.

Similar to horizon scanning, for the identification of signals of potential concern and knowledge gaps, participation of authorities in research projects, surveys, stakeholder exchange and conferences related to material innovation are a way forward to identify regulatory research needs. The Early4AdMa approach as well as the HARMLESS Early Warning System can be applied to identify signals of concern and existing knowledge gaps for relevant AdMa. At the same time, these tools need to be further developed and updated based on experiences gathered.

Expected Impact

Identification of signals of concern and knowledge gaps via early awareness approaches on AdMa support authorities in proactively reacting to innovation trends and being better prepared for respective regulatory challenges presumably connected to the innovation. It allows the authorities to strategically plan and decide on the next steps. Those may include commissioning of and participation in research projects addressing questions related to safety testing and assessment. In addition to research, this may include activities on the development of harmonised test methods, closer assessment of identified signals, updates of regulatory guidance and frameworks or other measures. Early awareness together with horizon scanning are first steps towards Regularly Preparedness. The latter will support safe innovation and a legislation that adequately covers AdMa by providing legal clarity and certainty to industry, and leads to a better protection of the society and environment.

The OECD Working Party on Manufactured Nanomaterials

Since 2006, the OECD Working Party on Manufactured Nanomaterials (**WPMN**) (OECD, 2025c) is **engaged with the development of internationally coordinated methods, strategies and guidance to identify and manage potential risk of nanomaterials**. In 2021, the OECD WPMN extended its focus to include **AdMa**. Experts of the OECD WPMN work together in dedicated Steering Groups. The Steering Group on Testing and Assessment focuses on the development of methods and guidance on hazard assessment of nanomaterials while the Steering Group on Exposure focuses on such methods and guidance for exposure measurement and mitigation. A further Steering Group takes action to facilitate safe(r) and (more) sustainable innovation approaches. The main task of the Steering Group on AdMa is the identification of signals of concerns and knowledge gaps related to safety, sustainability, and regulatory issues of selected AdMa and to derive recommendations to address these findings. Led by the German Federal Ministry for the Environment, Climate Action, Nature Conservation, and Nuclear Safety (BMUKN), experts from BAM, BAuA, BfR and UBA are deeply engaged in OECD WPMN.

3 Perform safety research for Regulatory Preparedness

Safety Research for Regulatory Preparedness encompasses on the one hand preparatory research to unravel “known unknowns” as well as to substantiate signals of concern by closing knowledge and methodological gaps relevant for regulatory risk assessment. On the other hand, it includes regulatory relevant research to provide reliable and robust test methods that are applicable in multiple sectors and legislation as well as to deduce testing and assessment strategies for adequate risk assessment considering emerging chemicals and materials, hazards, and methodological developments. The aim of regulatory relevant safety research is to keep regulatory risk assessment fit for purpose and at the same time to modernise it.

3.1 Close knowledge gaps on safety of advanced materials

State of the Art

Underlying considerations and approaches for risk assessment were established mainly for organic substances and substances with a sufficiently high degree of solubility. These were developed under the assumption that hazard and risk of a substance are determined by its intrinsic chemical nature only. Such an assumption is inadequate for an assessment of materials (solid substances with limited solubility). To overcome these weaknesses in the assessment for nanomaterials, the risk assessment approaches have been amended (e.g. new/ amended test methods and test strategies, guidance for sample preparation or analytics). It is conceivable that similar approaches are relevant for AdMa in and close to the nanoscale. However, it remains unclear whether or to what extent the nano-specific amendments will be sufficient or adequate to resolve challenges in risk assessment of the heterogeneous groups of AdMa and their complexity. BAuA, BfR and UBA already addressed this topic in 2021 in a joint publication (Schwirn et al., 2021). Most AdMa that are under consideration of the higher federal authorities are regarded as substances, some as mixtures. Other AdMa are discussed to be somewhere between a substance and an article, which raises questions on how to treat AdMa under legislation.

Amongst others, knowledge gaps on selected AdMa were identified during the OECD WPMN expert workshop on Nanocarrier (OECD, 2024a), MXenes (OECD, 2025a; Ouhajji et al., 2025) and graphene-related materials (OECD, 2026). The EU-funded project HARMLESS performed cases studies on oxide-perovskites for automotive catalysts, imogolites for agricultural solutions, aerogel mats for facade insulation and colloidal silica for paint formulations (Adam et al., 2025).

Research Needs

Based on the experiences gained so far and lessons learned from nanomaterials, a set of questions related to safety research from a regulatory point of view can be deduced that should be answered by preparatory research to support a better risk assessment of AdMa (Schwirn et al., 2025). First of all, there are some general questions:

- ▶ How to characterise AdMa properly?
- ▶ Do they exhibit a (eco)toxicological potential?
- ▶ How do they behave in the environment and the human body?

In addition, there are more specific questions to be answered to enable an appropriate regulatory risk assessment.

- ▶ Are there special mechanisms that drive toxicity beyond chemical composition and which properties are responsible for it?

- ▶ Which characteristics determine fate, toxicokinetics, hazard and risk, and which variation in characteristics modulates these?
- ▶ What is the impact of morphology and other structural or design features?
- ▶ Which information on physicochemical characterisation is needed for the identification and the description of types and forms of AdMa?
- ▶ Which characteristics and degree of modification are relevant to distinguish between different types and forms of AdMa?
- ▶ How to improve the comparability of results from different characterisation methods within their measurement uncertainties?

Because AdMa often are quite complex, the question from the safety point of view arises whether an AdMa in its entirety is more than its building blocks or composition, i.e., will a certain AdMa feature a different hazard profile than its individual building blocks? Can the release of building blocks or (a)biotic transformation increase or modify hazard or risk? Building blocks might also include specific additives to, e.g. support functionality or stability during product shelf life. Moreover, which safety objective (i.e., consumer, worker, environment) is affected by AdMa, via which route and to what extent?

In relation to these previous points, it needs to be examined to what extent methods and strategies mainly developed to assess soluble chemicals but also nanomaterials are sufficient or adequate to address the heterogeneous group of AdMa and their complexity. The current uncertainty whether hazard and exposure information based on existing methods and strategies is adequate for AdMa severely hampers reliable risk assessment. Even if existing methods can in principle be applied to nanomaterials, there is still an uncertainty whether these methods are appropriate to cover potential hazards which could be associated with low solubility and resulting slower kinetics that are typical for many materials. This uncertainty is further increased by the challenges to determine effects, release, and exposure of the various AdMa during their life cycle. The challenges in investigating AdMa include lack of standard measurement routines (including appropriate reference materials), interference of the material with the measurement techniques, sensitivity to sample preparation, or high background concentration of the same chemical element (e.g. for carbon-based AdMa).

Expected Impact

Answers to the above-mentioned questions will support a better understanding of hazard and risk that could arise from AdMa and facilitate the development for adequate testing and assessment strategies (see next section). It is assumed that there won't be one overarching strategy for all AdMa but various strategies suitable for respective types of AdMa as well as their applications. Such research will also help to identify the development and amendment needs for methods to adequately test AdMa regarding their physicochemical properties, hazards and exposure (chapter 4). Finally, the findings will provide the basis to update regulatory guidance and to decide on adaptation needs for regulatory relevant information requirements to provide legal clarity and certainty.

3.2 Develop testing and assessment strategies

State of the Art

AdMa challenge safety testing and assessment in various ways. There are multiple reasons why currently available test methods, developed for substances with a sufficient high degree of solubility, are only partially suitable to predict the effects of AdMa and test their safety. In

addition to their chemical identity, AdMa are characterised by further physicochemical properties, e.g., their morphological or mechanical properties. These physicochemical properties need to be taken into account in safety testing by (i) characterising all relevant physicochemical properties and (ii) considering the influence of these properties on the toxicokinetic as well as on the environmental fate and behaviour. Since AdMa of the same chemical identity can differ in their physicochemical properties, testing individual forms of AdMa is of particular relevance. Other factors such as multi-component composition or analytic challenges (e.g., for carbon-based materials) add further complexity (Wohlleben et al., 2024).

All these considerations take place against a backdrop of required development of new assessment approaches that aim to better consider the complexity of AdMa, to assess their safety more accurately, and to comprehensively integrate regulatory requirements and life cycle aspects while phasing out the need for animal testing.

To contribute to the answer on how AdMa can be adequately tested and assessed, the higher federal authorities started various research activities. For example, UBA commissioned a research project to deduce methodological needs for appropriately testing fate and behaviour of nanocarriers, as well as a research project to understand the ecotoxicological impact of fibre- and platelet-like materials on aqueous organisms and how this could be investigated adequately in current test systems. The BfR is working in collaboration with BAuA on, among other things, the development of an animal-free NAM (New Approach Methodologies)-based testing strategy for the safety assessment of fibres for human health. There is no harmonised definition for NAMs but a broad understanding what kind of methods NAMs comprise. In general, NAM based testing strategies aim to replace, reduce or refine traditional animal-based testing strategies. NAMs comprise a variety of *in chemo*, *in vitro* and *in silico*/computational methods which may be used alone or in combination with other methods to provide information for hazard and risk assessment (ECHA, 2023). NAMs are also developed and used for physical-chemical characterisation and exposure analysis. NAMs are in line with several overarching policy changes as described in the EU roadmap to phase out animal tests (European Commission, 2026d) or the EU's Chemicals Strategy for Sustainability. The implementation of NAMs would mean a transition from conventional, resource-intensive methods to more predictive, data-driven frameworks. In the European Food Safety Authority (EFSA) research project NAMs4NANO (NSC, 2023), NAMs are explored for their usefulness for risk assessment of nanomaterials as well as AdMa. A NAMs working definition has been proposed by NAMs4NANO, which is consistent with the proposed definitions of the US Environmental Protection Agency (EPA) (US EPA, 2018), the US Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) (ICCVAM, 2018) and OECD (Usmani et al., 2024). Furthermore, NAMs4NANO suggested a NAMs qualification system in the food and feed sector (Haase et al., 2024), which is based on an expert opinion on the adequacy of a method for a well-defined use in a specific context.

Research needs

The complexity and dimensions of the emerging material universe of AdMa evolves to a rapidly expanding domain, in which traditional regulatory risk assessment frameworks often fall short in covering multi-dimensional risks (i.e., due to chemical nature, but potentially also due to morphology, stereochemistry, physical properties etc.) across the material lifecycle. Amongst others, projects like the EU-funded MACRAMÉ (European Commission, 2022c) or HARMLESS (European Commission, 2021b) and the application of OECD's Early4AdMa to several AdMa have highlighted the need for pragmatic testing and assessment strategies to ensure safety. Based on the findings to date, needs for innovative testing strategies, including tiered approaches and NAMs have been identified for the following topics:

- ▶ physicochemical characterisation methods for the various AdMa
- ▶ assessment of critical fibres (e.g. rigidity) and the release testing of critical fibres from products and processes
- ▶ determination of the release of AdMa and thus their availability in the environment or unintended uptake into the human body with subsequent systemic availability
- ▶ determination of exposure towards AdMa at workplaces and the corresponding absorption, distribution, metabolism and excretion (ADME) in or by the human body
- ▶ risk assessment for human health, among others, specific focus on long-term toxicity, reproductive toxicity, endocrine disruption, genotoxicity, mutagenicity, and carcinogenicity

In addition, the need for approaches to tackle the following topics with regards to assessing the impact to human health and the environment has been identified, including tiered approaches and NAMs:

- ▶ support of grouping and read across for AdMa (starting point from the EU funded projects DIAGONAL, HARMLESS and SUNSHINE (Wohleben et al., 2025))
- ▶ support for decision making on sameness and similarity of AdMa
- ▶ Quantitative Structure Activity Relationship (QSAR) approaches including consideration of relevant physicochemical properties (e.g. morphology, structure/hierarchy, surface properties, crystallinity, partly solubility)
- ▶ appropriate testing and assessment of hydrophobic AdMa
- ▶ appropriate testing and assessment of polymeric AdMa
- ▶ appropriate testing and assessment of multicomponent AdMa
- ▶ appropriate testing and assessment of AdMa which are considered as mixtures rather than substances
- ▶ appropriate testing and assessment of AdMa whose components might be considered as active ingredient, formulation or co-formulant (e.g. in the area of pesticides or pharmaceuticals)
- ▶ development of NAM-based testing strategies: Priority should be given to investigate NAMs that address the following endpoints: cytotoxicity, genotoxicity, inflammation, reactivity/oxidative stress and barrier penetration. However, the need to address systemic and chronic toxicity would be a (very) long-term goal.
- ▶ translation of data from lab-based, non-animal experiments (*in vitro*) using NAMs into predicted effects on living organisms by using *in vivo* approaches (IVIVE)
- ▶ development of safe strategies for separation of AdMa in recycling processes

Apart from this, NAM-based strategies have the potential to modernise AdMa risk assessment into a more integrated and evidence-based direction, potentially fostering innovation while enhancing safety. The overall aims are to enhance risk assessment by providing faster results, improving the relevance of human health endpoints (e.g. via human-derived cells), and facilitating regulatory acceptance through OECD Test Guidelines enabling adherence to the Mutual Acceptance of Data principles (See chapter 4). However, testing and assessment

strategies containing individual NAM-based methods must first be proven for their suitability for AdMa. Furthermore, general challenges in application of NAM based testing and assessment strategies like data integration and uncertainty quantification have to be overcome, and solutions for benchmarking against legacy data need to be found.

Expected Impact

The provision of adequate strategies and approaches to test and assess various AdMa considering their specificities but also emerging methodological developments will reduce the testing amount that is expected to be associated with the complexity and diversity of AdMa. Furthermore, provision of such strategies and approaches can contribute to modernise regulatory risk assessment including the reduction of animal testing. Based on these testing and assessment strategies, the need for test method developments (chapter 4) can be deduced. Last but not least, the outcome of these activities can provide a basis for the uptake of regulatory guidance that are needed to appropriately address and assess AdMa within legislation. This will improve clarity for industry regarding the implementation of regulatory requirements.

4 Develop and validate standards and harmonised test methods

The standardisation of test methods on international level takes place in two bodies primarily. Of particular importance for regulation is the standardisation and harmonisation work within the OECD. OECD Test Guidelines (TGs) are internationally accepted harmonised standards for the safety testing of chemicals, supporting the implementation and enforcement of chemical legislation. OECD TGs and Guidance Documents (GDs) guarantee that the safety assessment of chemicals and materials over the whole life cycle is based on valid data. OECD TGs fall under the Mutual Acceptance of Data agreement that ensures that test results generated in accordance with OECD TGs and the OECD Principles of Good Laboratory Practice are accepted for fulfilling regulatory obligations in all OECD Member Countries and adherent countries.

In addition, international standardisation work is taking place within the framework of the ISO. The development of ISO standards is mostly industry driven and ISO standards are more technical and diverse than OECD TGs. Beside ISO standards, ISO develops technical specifications and technical reports. Calibration and testing laboratories working according to ISO standards should generally work in accordance with ISO 17025 (ISO, 2017).

The Malta Initiative and the initiative towards an EU Test Method and Validation Strategy

In the Malta Initiative (Malta Initiative, 2026), a voluntary network without an official mandate, representatives of European countries, several Directorates-General of the EC, the European Chemicals Agency (ECHA), academia, NGOs, and industry work together on a **voluntary and self-organised** basis. They work together to **find possibilities for developing and amending the measurement and test methods required to enforce chemicals legislation**. In a first step, the Malta Initiative focuses on projects in which OECD TGs are amended or developed needed to make REACH enforceable for nanomaterials. The Malta Initiative has broadened its focus also on AdMa. Other legislative areas, such as European regulations on biocides, cosmetics and plastic food packaging also refer to some extent to the OECD TGs. Thus, also these regulations benefit from the activities.

In order to achieve a long-term strategy, the Netherlands and Germany have proposed to establish an **EU Test Method and Validation Strategy** ensuring coordination and prioritisation, as well as funding for test method development and validation (Min lenW et al., 2025). As such, the strategy should be driven by the overall aim to improve the risk assessment of chemicals and to improve the insight into hazardous properties of chemicals and materials. In general, results of the strategy will provide harmonised test methods which are essential for the enforcement of chemicals legislation.

State of the Art

There have been some advances in the development of OECD TGs and GDs for (simple) nanomaterials in the last 10 years, focussing mainly on (nearly) spherical, metal(-oxide) nanoparticles. The OECD WPMN and WNT (Working Party of the National Coordinators of the Test Guidelines Programme) have developed various TGs, GDs and guidance for the testing of nanomaterials, e.g. in the fields of sample preparation and dosimetry, the physicochemical characterisation of test materials (in test matrices), or for ecotoxicological and environmental fate testing. In many of these activities, the higher federal authorities have been heavily involved such as in OECD TG 125 (OECD, 2022b), OECD TG 318 (OECD, 2017), OECD GD 318 (OECD, 2020b), and the Guidance on Sample Preparation and Dosimetry for Manufactured

Nanomaterials (OECD, 2025b). Quite some of the developments in this field might certainly be transferrable to AdMa. However, the higher complexity of AdMa need to be considered to enable reliable testing. In the course of setting up the Malta Initiative priority list (Malta Initiative, 2024) of outstanding adaptation needs for nanomaterials, first needs for some AdMa were also identified (Bleeker et al., 2023). Furthermore, considerations on the adaptation needs for nanocarrier (OECD, 2024a), MXenes (OECD, 2025a; Ouhajji et al., 2025), and graphene-related materials (OECD, 2026) were made during expert workshops of the OECD WPMN. Based on these results, it is foreseeable that for some (types of) AdMa the development of specific GDs to support application of existing TGs or even new TGs and standards is needed to cover specific features that currently challenge adequate testing. These might include, but are not limited to, harmonised methods to cover specific toxicity mechanisms (e.g. fibre toxicity) or to consider fate and behaviour of specific AdMa (e.g. of nanocarrier) adequately. However, based on the complexity and diversity of AdMa and the limited experience with the testing of them, the specific needs for new TGs are currently hard to deduce conclusively.

Many new standards on nanomaterials have also been published within the ISO framework in recent years. In addition to the specific standardisation committees for different individual measurement techniques, the Technical Committee 229 was established specifically for nanotechnology. The most important activities during the last ten years have been the revision of the nomenclature standards (ISO, 2023), and many standards on measurement methods, including various overview standards such as on measurement techniques and measurands for characterising nano-objects (ISO, 2016b, 2021). Currently, many standards are under development that primarily address AdMa.

The development and validation of standardised and harmonised methods for AdMa have been supported by various initiatives with the involvement of the higher federal authorities. This has been achieved through the departmental research funding of the BMUKN, by participation in third-party funded projects like NanoHarmony (European Commission, 2020b), in projects of the Versailles Project on Advanced Materials and Standard (VAMAS) (VAMAS, 2026) or through Bureau International des Poids et Mesures (BIPM)-related (BIPM, 2026a) or EURAMET metrology activities. Recent examples are interlaboratory comparisons to measure dissolution of nanomaterials with regards to their environmental fate and on dissolution in biological media, on the measurement of dustiness, on measuring surface chemistry, on measuring nanoparticle populations with imaging methods including protocols on sample preparation, measurement and data analysis (and reporting), and on the composition, as well as structural and dimensional analysis of graphene-related materials.

Research Needs

OECD TGs and GDs need to be continuously scanned, critically reviewed, and, if needed, adapted regarding their applicability for AdMa to ensure that the test results are adequate, relevant and reliable to support the identification of potential risks. Such activities would include also validation of methods to demonstrate the robustness and reliability of the method which are needed for approval by OECD Member Countries.

Based on the findings to date, for the following endpoints and aspects, TG development and amendment as well as guidance needs have been identified:

- ▶ determination of the potential of critical fibre release (fibre splinter test)
- ▶ measurement of the rigidity of fibres
- ▶ sample preparation and dosimetry including measurement of stable dispersions for testing of (hydrophobic) materials in liquid test media

- ▶ aerosol generation from particulate materials for *in vitro* and *in vivo* testing
- ▶ detection, identification, quantification and characterisation of AdMa in environmental and biological complex media, e.g. for carbon-based materials
- ▶ determination of relevant physicochemical parameters for the testing of 2D materials
- ▶ automated detection and quantification methods for AdMa
- ▶ tools for modelling of exposure towards AdMa
- ▶ release testing of AdMa

Additional need for the development of new OECD TGs and GDs is foreseeable due to the increasing effort to develop NAMs (see chapter 3.2). Such development of harmonised NAMs together with high throughput methods are promising to facilitate the extensive testing effort of the multitude of materials and, if validated as OECD TG or approved as OECD GD, ensure needed accuracy of data collected. The toxicological assessment of AdMa for human health relies on trustworthy NAMs that reduce or replace animal testing, and which are endorsed by OECD, ECHA, EFSA as well as European Centre for the Validation of Alternative Methods (ECVAM). Currently, NAM based test methods are under development and validation such as the *in vitro* micronucleus test for engineered nanomaterials (OECD WNT Project 4.174) (OECD, 2025d). However, taking into account the toxicological endpoints that are important for the assessment of human health besides genotoxicity, there is still a very high need for research and development to adapt the corresponding methodologies for AdMa. Compared to human health assessment, the development of agreed NAMs like *in vitro* assays, -omics (e.g. genomics, proteomics or metabolomics) analysis and computational models for ecotoxicity and environmental exposure assessment is lacking behind, hindering the application in a regulatory setting or to support the application in Safe and Sustainable by Design approaches (see chapter 5). An important example for an already adopted OECD TG to employ for environmental hazard assessment is the OECD TG No. 249 using a fish gill cell line for the determination of acute aquatic toxicity testing (OECD, 2021). The protocol employed in this OECD TG was already used to test various nanomaterials (Hildebrand et al., 2009; Yue et al., 2015; Hernández-Moreno et al., 2022). A potential alternative method for fish bioaccumulation testing is the bioconcentration test using *Hyalella acteca* (OECD TG 321) (OECD, 2024b) for which an extension of the existing OECD TG to also test nanomaterials has been currently proposed by Germany. More of such targeted initiatives are needed to facilitate the development of regulatory accepted NAMs for AdMa for environmental assessment.

In the domain of ISO, the need for projects has been identified for the characterisation of AdMa (e.g. impurities, coating, surface chemistry, liposomes), the characterisation of AdMa in media, for reference materials for test assays, and for projects focusing on specific aspects of carbon nanotubes and graphene. Furthermore, interlaboratory comparison within EURAMET activities show that measurements to determine the number concentration of nanomaterials need further improvement to reduce uncertainties.

The adaptation and development of standardised and harmonised methods including validation and completion of the defined processes in OECD and ISO until adoption require intensive effort in terms of time as well as human and financial resources. Often the process towards standardisation and harmonisation exceeds the funding period of research projects. Therefore, institutional networks are important to coordinate the development and adjustment efforts among the different public bodies as well as national and international cooperation partners. Setting priorities and advocating for targeted and long-term funding is a key task as well as the establishment of knowledge transfer and the exchange with key stakeholders. The higher federal

authorities play a central role towards the coordination, setting of priorities and collaboration in these institutional networks, and at the same time also benefit from the commitment in these networks.

Expected Impact

The timely provision of up to date standardised and harmonised methods and other guidance documents provide the basis for reliable data for an appropriate hazard and risk assessment, including for AdMa. The availability of validated and harmonised test methods is key to obtain comparable and reliable information on their properties and risks for regulatory purposes. OECD TG are essential for the enforcement of legislation to protect workers, consumers and the environment. As such, OECD TGs provide legal certainty for industry but also for regulators, and reduce their efforts within assessment processes. Without timely provision of reliable, standardised, and harmonised methods for safety assessment, regulatory gaps may persist, leaving industry stakeholders and regulators in a state of uncertainty. At the same time, data on chemicals and materials gained by OECD TGs enhance the trust of consumer and by that support market establishment and growth.

The importance of method validation

A **crucial step** in setting up an OECD TG and also ISO standards is the **validation** of the described methods. Validation is defined as the **systematic verification whether selected methods are suitable, precise, and robust for the intended purpose**. This ensures the quality of the data under reproducible conditions. Validation activities include intra- or inter-laboratory comparisons, with the aim of making the selected methods and their accompanying protocols comparable and harmonised across individual laboratories and regions. Thereby, it is an essential step to transfer methods from the research domain to the regulatory sphere. The higher federal authorities are deeply involved in the development and validation of appropriate methods for AdMa in different ways, including leading individual projects of the OECD TG programme. One further example for validation work of the higher federal authorities is the involvement in framework programmes such as VAMAS. BAM and PTB are reference institutes for the measurement of specific units and thus, involved in the work of the BIPM which defines the basic parameters for international standardisation within the work of, e.g. the OECD WNT programme and the ISO Technical Committees. A further indispensable component for reliable methods comparability and validity of data are suitable (certified) **reference materials**. In the domain of reference materials, new approaches must be considered like multi-method reference materials and reference materials with more complex structures, in particular with regard to applications in the energy sector and assessing effects on human health and environment.

5 Develop methods for Safe and Sustainable by Design

Safe and Sustainable by Design (SSbD) is a voluntary pre-market approach that should help innovators to assess the safety and sustainability of a chemical, material or product starting from (early) innovation stages and to include the outcome for potential re-design considerations.

State of the Art

To facilitate SSbD assessment, the Joint Research Centre (JRC) developed an SSbD Framework (European Commission: JRC et al., 2022) and an accompanying methodological guidance (European Commission: JRC et al., 2024). The SSbD Framework was updated by JRC in 2025 (European Commission: JRC et al., 2025). In December 2022 and again in March 2026, following the JRC publications, the EC issued a recommendation to foster the implementation of the proposed EC SSbD Framework into innovation (European Commission, 2022a, 2026a). In addition, the EC has funded a number of research projects to further advance and operationalise SSbD in numerous case studies (Fantke, 2025), including ongoing effort in one task of the EU Horizon Europe Partnership for the Assessment of Risks from Chemicals (PARC) to operationalise SSbD and develop a SSbD toolbox (EU PARC, 2024). In PARC, UBA together with the PARC partner RIVM (Dutch National Institute for Public Health and the Environment) leads an activity to establish an online portal for the exchange of knowledge on SSbD (EU PARC, 2025b). Through the portal, users can find important announcements on SSbD, access tools that support the implementation of SSbD principles and explore links to educational materials aimed at building knowledge and expertise. Additionally, the portal offers a direct connection to a public user community group on SSbD at PARCopedia (EU PARC, 2025a), the knowledge management and community platform for chemical risk assessment professionals created by PARC. At the same time, a growing research community on SSbD has been established in Europe, e.g., the Network for Safety and Sustainability of Chemicals and Materials (NSC) (NSC, 2026). The EC SSbD Framework builds on assessment criteria and requirements laid down in legal frameworks dealing with safety and diverse sustainability aspects. Developing safe AdMa and taking into considerations their entire lifecycle contributes not only to the safety of consumer and the environment but also of workers along the value chain of AdMa. Therefore, while applying the EC SSbD Framework, the applicant becomes also aware of challenges to fulfil regulatory requirements or obstacles a chemical, material or product might face once ready to be placed on the market (Schwirn et al., 2025). To investigate the recycling and release of membranes from used batteries, BAM is involved in the recently launched EU project “PFAS-Free Membranes for Energy Storage and Conversion Systems (PFESS)” (SAF€RA ERA-NET, 2025a). Another example is the EU-funded PHAMA project (“PHotocatalytic decomposition of PFAS and their detection utilizing sustainable Advanced Materials”) (SAF€RA ERA-NET, 2025b) which includes the goal of optimising and implementing a sustainable ZnO NPs production process including recycling to minimise environmental impact (e.g. CO₂ footprint) and occupational risks.

Research needs

To be able to assess chemicals, materials, and their products regarding SSbD, predictive assessment tools are necessary. This need comprises methods that, on one hand, address the criteria and requirements as laid down in the corresponding EC SSbD Framework. And on other hand, these methods must deliver predictive results for the different stages of innovation. The aforementioned research and development needs to adequately assess the hazard and risk of AdMa also support SSbD assessment of these materials and their applications. Generally, research to understand potential hazard and risk of AdMa also provides basic information for safe innovation. The development of screening and high throughput methods, NAMs, Adverse

Outcome Pathways, and modelling tools to estimate hazards and exposure can facilitate SSbD assessment during early stages of innovation while the development of OECD TGs and GDs as well as Integrated Approaches for Testing and Assessment can substantiate SSbD assessment in the stage of market entry preparation. However, these methods will be only suitable to assess AdMa with respect to safety criteria of SSbD. There is a further need for methods and tools to determine the sustainability of AdMa. This comprises two questions: (1) whether existing methods to assess sustainability such as Life Cycle Assessment require adaptations to be able to adequately assess AdMa; (2) similar to safety assessment, whether screening methods to assess sustainability at early stages of innovation would be available and practicable. Generally, while acknowledging the uncertainty that comes in particular with assessing early innovation stages, it is essential that methods applied in SSbD will be predictive enough to anticipate subsequent risk assessment outcomes in the regulatory arena to avoid failure. A big advantage promises the use of numerical pre-screening methods with advanced simulation tools, where feasible combined with automated experimentation in a closed feedback loop of a self-driving lab. This would allow the readily integration of safety and sustainability aspects into the (pre-)screening process when developing new AdMa (or AdMa lead candidates), e.g., by excluding critical raw materials from the search space of AdMa alternatives.

Expected Impact

The involvement in the aforementioned method development for regulatory purposes also supports the provision of predictive methods in the context of a voluntary pre-market SSbD assessment. Therewith, it assists innovators of AdMa in their innovation process towards safer and more sustainable AdMa, protecting workers, consumers and the environment. At the same time, SSbD supports innovators to recognise and meet requirements towards regulatory acceptance. Conversely, chemicals and materials developed with SSbD in mind might lower the need for regulatory action by agencies upon market entry.

6 Research and Development Enablers

The research for safe AdMa and Regulatory Preparedness is a common effort that requires the allocation of sufficient funding and capacities, a multistakeholder cooperation and communication. Further important research and development enablers include, amongst others, the integration of FAIR data, advanced computational methods to support risk assessment of AdMa, training and education, and appropriate technical equipment facilities in in-house laboratories. In addition to the higher federal authorities, other stakeholders also benefit from developments and activities related to these cross-cutting issues as they provide opportunities for stakeholders to partake in underlying processes and benefit from the results achieved.

6.1 Resources and funding for safety research

Different sources are available to cover resources and funding for safety research and the development of regulatory tools for the safety of AdMas. The higher federal authorities can either invest in the safety research by using their own resources or by awarding projects to external parties. For the latter case, e.g. the BMUKN supports environmental safety research on AdMa through individual projects via the departmental research programme (i.e. “Ressortforschungsplan”). The higher federal authorities describe their research work that is in the focus of the upcoming years in their internal work and research programmes. These programmes are oriented on scientific and political developments.

Another pillar for safety research is third party funded projects on national or EU level. To cover the different levels of research and development needed, projects on different issues are required: Safety research needs to be an integral part of research and development to ensure safety considerations in the innovation process and also serve as a tool for horizon scanning and Regulatory Preparedness. Additionally specific projects on safety research and method development and validation are needed. On a national level, for example the German Federal Ministry of Research, Technology and Space (BMFTR) funds research on material innovation in their material research programme Mat2Twin (BMFTR, 2026c). On the EU level, research and innovation projects on AdMa are funded via the Horizon Europe research programme (European Commission, 2025d), including its partnership IM4EU (IAM-I, 2025a) and by EURAMET (EURAMET, 2025a). Despite various funding programmes that support the innovation of AdMa, there is currently a lack of funding for safety and regulatory relevant research for AdMa.

Funding programmes on material innovation and metrology

On the **national as well as European level**, different **funding programmes** exist to support research activities related to AdMa. These programmes mainly **focus on the innovation aspects**. In Germany, the importance of AdMa has recently been addressed in the HighTech Agenda (BMFTR, 2026b) and the Mat2Twin programme (BMFTR, 2026d). Topics related to materials such as production of batteries, microelectronics, critical raw materials and recycling of materials were identified to be of strategic importance for Germany (BMFTR, 2026a, 2026c).

Within the ongoing Horizon Europe research programme (FP9, 2021-2027), annual calls address different aspects related to AdMa, see e.g. the work programmes for 2025 of cluster 4 (Industry) (European Commission, 2025d) or cluster 5 (Climate, Energy and Mobility) (European Commission, 2025e). Moreover, in 2025 the new “Innovative Advanced Materials for Europe (IAM4EU) Partnership” (IAM-I, 2025a) was launched as European Partnership under Horizon Europe, dedicated to advancing the design, development, and uptake of innovative advanced materials (IAM) to support Europe’s twin green and digital transitions and the Clean Industrial Deal. The Innovative Advanced Materials Initiative (IAM-I) (IAM-I, 2025b) will operate the partnership. In July 2025, the EC announced its plans for the 2028–2034 Multiannual Financial Framework, which

contains a budget of €409 billion for the European Competitiveness Fund (European Commission, 2025c) and proposes a €175 billion Framework Program 10 (FP10), the successor to Horizon Europe. These proposals by the EC still are to be agreed with the EU member states and the European Parliament.

EURAMET, the association of European Metrology Institutes, operates metrology research programmes since several years, which have been co-financed by the EC. The currently running metrology research programme is the European Partnership on Metrology (EPM) (EURAMET, 2025a). In addition to the metrology research programme, EURAMET also has established so-called European Metrology Networks (EMN) (EURAMET, 2025d). Currently, twelve different EMNs focus their activities on topics of strategic importance for Europe. One of these EMNs is the EMN for Advanced Manufacturing (EURAMET, 2025e) which aims to maintain a regular stakeholder dialogue including open consultations (EURAMET, 2025g) to identify metrology research gaps for the further development of advanced manufacturing technologies in Europe. AdMa are one of three pillars of the EMN for Advanced Manufacturing to structure its work along a generic manufacturing chain, including design and recycling aspect of products, components and materials.

6.2 Cooperation and Networking

Communication between stakeholders offers the opportunity to build a mutual understanding, to identify challenges from respective perspectives, and to agree on jointly taken next steps accordingly. Stakeholder exchange and cooperation with, e.g. academia and industry can support the higher federal authorities in their understanding about AdMa and applications in innovation as well as their specialities and functionalities. For multistakeholder cooperation and exchange, conferences and workshops, joint research projects and common initiatives as well as networks (e.g. the NSC) are important tools.

Exchange and networks between authorities are of fundamental importance to anticipate new topics of relevance in the areas of the authorities' responsibilities, especially in case of topics that affect different safety objectives (i.e., consumer, worker, environment), include regulatory challenges, or entail conflicts of goals. To foster exchange on perspectives and to mutually benefit from each other's expertise and perspective, different formats were established, not necessarily limited to new topics or AdMa. Since 2024, BAuA invites agencies to exchange on topics related to safety and sustainability for human, environment, occupational safety, and chemical safety at the interface of neighbouring legal areas (Sicher und nachhaltig für Mensch und Umwelt, Arbeitsschutz und Chemikaliensicherheit and der Schnittstelle benachbarter Rechtsbereiche – SNACS). In 2020, several German higher federal authorities (including the authorities authoring this strategy) established an inter-authority working group under the lead of BfR to foster cooperation and exchange on regulatory challenges and needs for AdMa between authorities. The working group aims to allow for an early anticipation of potential impacts of AdMa on safety and sustainability in a joint manner. Thereby, the group discusses possible regulatory action needs under consideration of the different perspectives and responsibilities of the involved authorities. Within this informal network, amongst others, progress on research performed or commissioned by the involved agencies is presented and future research needs are identified. At European level, cooperation between EU member state authorities is sought to coordinate and to join efforts to promote better regulation and risk assessment of AdMa, including research efforts.

The development and adaptation of OECD test methods demands combined European efforts. The Malta Initiative or the initiative for an European Testing and Validation Strategy are important to agree on demands and make priority methods available. Within these initiatives,

contributions from the EC, Member States, industry, academia and other stakeholders are essential to share efforts to provide standardised and harmonised test methods (see also chapter 4).

6.3 Training and Education

In addition to communication and networking, training and education enable to raise awareness about safety issues and increase knowledge, skills and competency on legal obligations and regulatory risk assessment relevant for AdMa amongst stakeholders. Training and education are needed for different stakeholders (e.g. large industry, small and medium enterprises, contract research organisations, testing laboratories, students and PhD candidates, regulators and decision makers) and should contain customised content of different formats (e.g. lectures, educational material, webinars, knowledge platforms) and levels of expertise. The higher federal authorities are heavily involved in activities related to communication, training, and education, e.g. by UBA's thematic conferences on AdMa or the EU-funded projects NanoHarmony (European Commission, 2020b; Heunisch et al., 2022; Pohl et al., 2025) and MACRAMÉ (European Commission, 2022c; Friedrichs et al., 2025). With regard to SSbD, together with partners in the EU partnership PARC, UBA set up a web-based knowledge sharing portal on SSbD (EU PARC, 2025b). The BAM Academy (BAM, 2025a), in collaboration with the European Advanced Materials Academy, will provide training courses and workshops on several topics related to AdMa. Furthermore, regular webinars addressing the actual developments and perspectives at VAMAS in combination with regional needs and benefits are organised by BAM Academy. The higher federal authorities, furthermore, support knowledge transfer on legal obligations and regulatory risk assessment with the AdMa innovation community.

6.4 Integration of FAIR data

Progressing safety research, SSbD approaches, and provisions in various legislation require access to high-quality data for appropriate analysis, modelling, assessment, as well as reporting. The principles of Findability, Accessibility, Interoperability and Reusability (FAIR) (Wilkinson et al., 2016) provide the foundation for achieving this goal. However, clear rules for their sustainable implementation, and for active promotion of data reuse are still lacking. Ground-breaking steps are needed in areas such as metadata, ontologies¹, and persistent identifiers, along with guidance to support implementation and achieve machine-readability. For instance, BAuA is working towards implementing a database of the chemical and morphological characteristics of toxicologically relevant fibrous aerosols. Detailed knowledge of the physicochemical characteristics of fibrous materials is being collected. In order to facilitate the knowledge transfer, the obtained data will be made available in the database and thereby information on advanced fibrous materials can be used in various contexts.

Further strengthening of the implementation of FAIR data principles is necessary. To illustrate, the AdvancedNano GO FAIR Implementation Network (AdvancedNano IN) (GO-FAIR, 2025) aims to maximise data-driven safe and sustainable application of nanoscale materials and AdMa with the aim to facilitate 'FAIRification' of nanosafety data. Amongst others, AdvancedNano IN addresses quality assessment approaches for evaluating the reliability, relevance, and completeness of data that can be incorporated into community-agreed standards (Dumit et al., 2025) and emphasises the need for harmonisation and adaptation of nanomaterial-specific requirements to AdMa (Cassee et al., 2024). The AdvancedNano IN contributes to the

¹ An ontology is a way of showing the properties of a subject area and how they are related, by defining a set of terms and relational expressions that represent the entities in that subject area.

automatisation to reduce manual labour in making (meta)data FAIR, support trusted data reuse, and enable the safer, more sustainable innovation of AdMa. Awareness and prioritisation of these challenges are essential for building robust data infrastructures that embed FAIR workflows to ensure the safety of AdMa.

6.5 Digitisation for safe advanced materials

To accelerate innovation, ensure sustainability, and uphold safety standards, a comprehensive, end-to-end digitalisation of materials research is essential—spanning from synthesis and characterisation to simulation, modelling, and data-driven design. To unlock the full potential of digital research for AdMa, structured, interoperable, and semantically annotated data must become the norm. This includes data from synthesis, processing, and characterisation by techniques such as spectroscopy, microscopy, and surface analysis. These datasets form the backbone of reproducible and traceable research and are critical for enabling AI-ready infrastructures across laboratories.

Machine-readable data not only supports the documentation of experimental workflows but also fuels predictive modelling and machine learning algorithms. These algorithms rely on high-quality, standardised datasets to identify patterns, optimise synthesis parameters, and predict material properties with high accuracy. By enabling cross-laboratory data sharing and integration, harmonised datasets foster collaborative innovation, reduce duplication of effort, and significantly shorten the time from development to application. Ultimately, they are the foundation for a new paradigm of accelerated, data-centric materials science.

Advanced computational methods are an important raising task for industry, but also for the higher federal authorities. Alongside the adherence to FAIR data principles, the reliability and traceability of data is of importance. An ongoing initiative coordinated by the International Committee for Weights and Measures (CIPM) and its Task Group on the International System of Units (SI) Digital Framework (BIPM, 2025), is to develop and establish a world-wide uniform and secure data exchange format based on the International System of Units. These digitalisation activities of the CIPM are carried on within its Forum on Metrology and Digitalization (FORUM-MD) (BIPM, 2026b), led by PTB. The SI Digital Framework provides the basis for the new Digital Calibration Certificate (PTB, 2026) which is an important part of the digital quality infrastructure (QI), currently under development by PTB, BAM, the German Accreditation Body (DAkkS), the German Institute for Standardisation (DIN) and the German Commission for Electrical, Electronic & Information Technologies (DKE) within the initiative QI-Digital (QI Digital, 2026), supported by BMW. The initiative QI-Digital seeks to develop solutions for a modern, digital QI that allows for smarter and automated quality assurance: quality-related documentation is increasingly being transformed into structured, machine-readable formats. This shift is a prerequisite for digital quality management and a cornerstone of next-generation automated and self-driving laboratories. For example:

- ▶ The Digital Calibration Certificate provides an extensible markup language (XML)-based format that consolidates all calibration data in a harmonised structure, compliant with ISO/IEC 17025 (ISO, 2017) and the system on good laboratory practices (GLP).
- ▶ The Digital Reference Material Document (BAM, 2026) digitally encompasses reference material certificates in accordance with ISO 17034 (ISO, 2016a). It includes administrative metadata, data of certified and uncertified properties with uncertainties, and safety and traceability information - all within a unified XML format.

Advanced computational methods can support the innovation of AdMa from the perspective of risk assessment in various ways. For predicting hazard and exposure, computational methods

can be used to support first indications. An example for an advanced computational model that promises support for regulatory risk assessment of AdMa are artificial neural networks to analyse results of physicochemical characterisation. BAM, PTB and BAuA are developing software solutions for automated image acquisition and analysis using artificial neural networks, for example for the analysis of scanning electron micrographs.

In particular during the development phase of AdMa, computational methods are essential for prediction because sufficient amount of material is not yet produced to run experiments. For developing or optimising AdMa that are safe and sustainable, advanced computational tools can be combined with automation in self-driving labs and Materials Acceleration Platforms. By means of self-driving labs and Materials Acceleration Platforms, numerical pre-screening approaches and predictions of synthesizability can be used to identify the most promising candidate materials that fulfil certain design criteria under defined constraints (e.g., avoiding the use of critical raw materials or potentially hazardous or unsustainable reactants or reagents). Use of machine learning or AI-guided online learning approaches helps to efficiently navigate the high-dimensional search space. Thus, candidate materials can then be automatically synthesised, tested and improved in a closed feedback loop, potentially leading to new (pareto-)optimal materials.

To successfully use advanced computational methods for regulatory risk assessment of AdMa, criteria need to be developed and implemented that define when a method is acceptable to be used for this purpose. In addition, such methods need to be validated and guidance for their use has to be provided. While standardisation of data exchange of chemicals and other disciplines is already addressed in the framework of the German research data infrastructure (NFDI) (NFDI, 2026), nanomaterials and AdMa come with additional parameters to be digitally exchanged. There is a strong need for the development of standards for ontologies, database structures as well as for detailed and structured reporting of data for AdMa. Semantic standards are essential for linking experiments, simulations and safety assessments, as well as for powering AI-driven materials design, autonomous laboratories and Materials Acceleration Platforms. Digital FAIR data, combined with harmonised ontologies and digital quality certificates, enable seamless digital workflows across the entire materials lifecycle.

There are several additional challenges driven by the fast development of AI-methods. AI-methods based on open-source code can be adopted and further developed by higher federal authorities to become a standard in the evaluation of AdMa including the collection of reference data for the validation of AI-methods. For all methods and especially for the AI-based methods, the reproducibility and reliability of the results from the different digital approaches have to be validated. Such validation is needed for the development of standards like for analysis of images, for automated graphs, and for big data.

6.6 Technical equipment and personnel capacities at the higher federal authorities

In order to gain a better understanding about hazard and exposure of AdMa, to develop and validate test methods for standardisation and harmonisation, and to develop appropriate test and assessment strategies, the higher federal authorities must be able to rely on and maintain high quality laboratories including state-of-the-art measurement techniques. For the appropriate physicochemical characterisation of AdMa, techniques like high-resolution electron microscopes, energy-dispersive X-ray spectroscopy as well as Raman spectroscopy are mandatory. Sample preparation needs to take place in wet-laboratories. To support the development and validation of safety testing methodologies, e.g., contamination-free and sterile working areas with cellular assays including all relevant characterisation methods (e.g.,

fluorescence spectroscopy), technical and IT equipment for -omics analyses as well as further technical set ups and laboratory animal husbandry are crucial. To keep the infrastructure up to date, equipment for advanced computational methods including large computational storage facilities, access to work stations, and possibilities to collaborate at the data and equipment level with national and international institutions become increasingly important. For the conduction of research and development enabling meaningful risk assessment of AdMa, well-trained staff is essential. This is important not only to fulfil the quality requirements of research projects and to progress according to the foreseen project plan. It is also fundamental to preserve the institutional memory, and ensure continuous knowledge transfer and knowledge gain in the higher federal authorities to protect human health and the environment.

7 Summary

AdMa have the potential to play a central role in the transformation towards a more sustainable society. They may provide technical solutions for urgent global needs such as for health care, energy transition or circular economy. Therefore, the EC has placed AdMa high on its strategic agenda for achieving a more sustainable, competitive and resilient Europe and promotes different actions to accelerate the innovation of AdMa in various technical fields. However, these innovations are accompanied with knowledge gaps on potential implications of these materials for safety (and sustainability) and challenges with regards to perform an appropriate regulatory risk assessment based on appropriate methods and testing strategies. This leads to a situation in which safety assessment is clearly lacking behind the speed of material innovation. Measures such as horizon scanning, early awareness raising as well as closing knowledge and methodological gaps need to be undertaken to become regulatory prepared for these materials and by that, reduce uncertainties connected to their application. The higher federal authorities contribute to realise these measures. This includes ongoing and finalised projects that are listed in table 1. The commitments of national and European funding bodies and the scientific community (including both academia and industry) are still necessary in order to scientifically address open questions and regulatory challenges of AdMa. While remarkable funding is provided for innovation research related to AdMa, the provision of explicit funding for safety research by these initiatives is currently negligible. Proactively addressing knowledge gaps on safety and sustainability and regulatory relevant questions facilitates safe innovation and increase legal clarity and certainty for innovators, reducing the risk of regulatory hurdles or delay of market entry. Thus, solving the regulatory relevant challenges is a pre-requisite in achieving the aims of the EC's strategy to employ AdMa as key enabler for a more sustainable, competitive, and resilient Europe.

Table 1: Ongoing and finalised projects of the higher federal authorities to address knowledge gaps and research needs on AdMa (in alphabetic order).

| Project | Horizon scanning | Early awareness raising | Closing knowledge gaps | Testing & assessment strategies | Test methods | SSbD | Cross cutting issues |
|---|------------------|-------------------------|------------------------|---------------------------------|--------------|------|----------------------|
| BAM | | | | | | | |
| ACCORDs (European Commission, 2023b) | | | | x | x | | |
| AdMa in technologies of renewable energies (Knigge & Radnik, 2025) | x | | | | | | |
| ConcenSus (EURAMET, 2025b) | | | x | | x | | |
| Graphene Flagship (Graphene Flagship, 2014) | x | x | | | x | x | |
| IMPACTIVE (European Commission, 2022d) | | | | | | x | x |

| Project | Horizon scanning | Early awareness raising | Closing knowledge gaps | Testing & assessment strategies | Test methods | SSbD | Cross cutting issues |
|---|------------------|-------------------------|------------------------|---------------------------------|--------------|------|----------------------|
| METRINO (METRINO, 2023)(METRINO, 2023) | | | | x | x | | |
| PFESS (SAF€RA ERA-NET, 2025a) | | | | x | x | x | |
| PHAMA (SAF€RA ERA-NET, 2025b) | | | x | | | x | x |
| PolyRisk (European Commission, 2021c) | | x | x | | x | | |
| SMURFnano (BAM, 2024) | | | x | x | x | | |
| TransNanoAF (BAM, 2025b) | | | x | | | | |
| BAuA | | | | | | | |
| Determination of exposure to hazardous substance during activities in the recycling of lithium-based batteries from electric cars (BAuA, 2025a) | | x | x | | x | | |
| FAMOSH (Fibres and Advanced Materials for Occupational Safety and Health) Database (BAuA, 2022) | | | x | | | | x |
| Harmless (European Commission, 2021b) | | x | x | | x | | |
| InnoMatLife (DaNa, 2019) | | x | x | x | | | |
| MACRAMÉ (European Commission, 2022c) | | x | x | x | x | x | x |
| NanoHarmony (European Commission, 2020b) | | | x | x | x | | x |
| OECD WNT Project 1.8: TG on Dustiness Determination of Manufactured Nanomaterials (OECD, 2025d) | | | | | x | | |

| Project | Horizon scanning | Early awareness raising | Closing knowledge gaps | Testing & assessment strategies | Test methods | SSbD | Cross cutting issues |
|--|------------------|-------------------------|------------------------|---------------------------------|--------------|------|----------------------|
| PolyRisk (European Commission, 2021c) | | x | x | | x | | |
| BfR | | | | | | | |
| Harmless (European Commission, 2021b) | | x | | x | | x | |
| InnoMatLife (DaNa, 2019) | | x | x | x | | | |
| NAMs4Nano (NSC, 2023) | | | | x | | | |
| OECD WNT Project 1.05: GD for Determination of solubility and dissolution rate of nanomaterials in water and relevant synthetic biological media (OECD, 2025d) | | | | | x | | |
| OECD WNT Project 1.06: GD for Identification and Quantification of the Surface Chemistry and Coatings for Nano- and Microscale Materials (OECD, 2025d) | | | | | x | | |
| OECD WNT Project 4.146: GD on toxicokinetics to accommodate testing of nanoparticles (OECD, 2025d) | | | | | x | | |
| OECD WNT Project 4.174: Validation of the In Vitro Micronucleus assay for Engineered Nanomaterials (OECD, 2025d) | | | | | x | | |
| PolyRisk (European Commission, 2021c) | | x | x | | x | | |
| PTB | | | | | | | |
| ConcenSus (EURAMET, 2025b) | | | | x | x | | x |

| Project | Horizon scanning | Early awareness raising | Closing knowledge gaps | Testing & assessment strategies | Test methods | SSbD | Cross cutting issues |
|--|------------------|-------------------------|------------------------|---------------------------------|--------------|------|----------------------|
| DINAMO (EURAMET, 2025c) | | | | | x | | x |
| HyMetBat (EURAMET, 2025f) | | | | x | x | | x |
| UBA | | | | | | | |
| AdMa in technologies of renewable energies (Knigge & Radnik, 2025) | x | | | | | | |
| NanoHarmony (European Commission, 2020b) | | | x | x | x | | x |
| OECD WNT Project 3.10: TG on Dissolution Rate of nanomaterials for environmental fate assessment (OECD, 2025d) | | | | | x | | |
| OECD WNT Project 3.16: GD on the abiotic transformation of nanomaterials in the environment (OECD, 2025d) | | | | | x | | |
| Overview on AdMa and thematic conferences (Giese et al., 2020; Reihlen et al., 2022) | x | | | | | | x |
| Overview on Nanocarrier and adaption needs environmental fate testing (UBA, 2022) | x | | | x | x | | |
| PARC: SSbD Knowledge sharing portal (EU PARC, 2025b) | | | | | | x | x |
| Platelet and fibre-like AdMa: Adaption needs ecotoxicological testing (UBA, 2023b) | | | x | x | | | |

Project names in bold indicate those projects in with more than one of the higher federal authorities has been involved.

8 Profiles of the involved higher federal authorities

8.1 Federal Institute for Materials Research and Testing (BAM)

With the mission 'Safety in Technology and Chemistry', we are making a decisive contribution to the development of the German economy. Tasks and responsibilities of BAM comprise:

- ▶ Safety research: BAM conducts research in the fields of energy, infrastructure, environment, materials as well as chemistry and process technology. Current priorities include hydrogen technologies, lithium-ion batteries, offshore wind power, nanotechnology and additive manufacturing.
- ▶ Responsibilities, examination and evaluation: BAM carries out physical and chemical tests on substances, materials and equipment, such as explosives, pyrotechnics or construction products and is responsible for the safe transport of dangerous goods.
- ▶ Reference methods and materials: Development and provision of standards for quality assurance and technical safety
- ▶ Advice: BAM advises the Federal Government, industry and national and international organisations on safety-related issues.
- ▶ Standardisation and regulation: Participation in laws, regulations and standards, e.g. in hazardous materials, explosives and chemicals law
- ▶ Knowledge and technology transfer: Cooperation with universities, research institutions and industry, including internationally

BAM operates its own competence centre called AdvancedMaterials@BAM which deals with the development, characterisation and safe application of advanced materials. Objectives and activities of the competence centre include the topics:

- ▶ Safe synthesis and application: Materials should be manufactured and used reliably and reproducibly.
- ▶ Methods of characterisation: Development of test methods, interlaboratory tests and reference materials
- ▶ AI-based measurement methods: Automated analytics to increase efficiency
- ▶ Knowledge and technology transfer: Workshops, trainings and cooperations with industry and research

8.2 Federal Institute for Occupational Health (BAuA)

The Federal Institute for Occupational Safety and Health (*Bundesanstalt für Arbeitsschutz und Arbeitsmedizin*, BAuA) is a federal departmental research institution dedicated to safety and health at work and human-centred work design. At its three sites in Dortmund, Berlin, and Dresden, nearly 750 staff work at the intersection between science, policy making, and practice. They conduct research and development projects, provide policy advice, perform statutory and official functions, and transfer knowledge into workplace practice. The BAuA is a departmental research institution subordinated of the Federal Ministry of Labour and Social Affairs (BMAS).

As the Federal Office for Chemicals (BfC), the BAuA performs tasks in accordance with the Act on the Protection against Hazardous Substances (Chemicals Act). In doing so, it works to protect

humans, animals, and the environment from chemicals. The BfC is the competent authority for the REACH, CLP (Regulation on classification, labelling and packaging of chemicals and mixtures) and Biocides Regulation. It has sovereign tasks with international activities in the field of regulation and acts as a national and international interface.

Department 4 is responsible for improving the protection of employees against hazardous substances and biological agents. To this end, it describes substance-related risks, assesses them and proposes measures to reduce the risks to an acceptable level for employees. The starting point is the results of research and development, as well as many years of experience in statutory tasks and policy advice.

As part of its research and development activities, the BAuA has extended its focus beyond nanomaterials to AdMa. Measurement and test methods are being further developed, field studies, morphological and toxicological investigations are being carried out in order to generate a reliable basis for assessing possible health risks in the workplace. The focus is currently on investigations into the dusting of substances, the shape, surface and size distribution of released particles as well as their rigidity as indications of a potential hazard. The medium-term goal of these activities is to ensure that protection against respirable dusts and fibres is coherently incorporated into the EU regulations on chemical safety. In addition, the BAuA wants to enable research institutions and start-up companies to recognise risks to humans and the environment as early as possible by establishing governance networks. This is intended to promote the safe design and use of AdMa.

8.3 German Federal Institute for Risk Assessment (BfR)

The German Federal Institute for Risk Assessment (BfR) is a scientific institution within the portfolio of the Federal Ministry of Agriculture, Food and Regional Identity (BMLEH) in Germany. It advises the Federal Government and Federal Laender on questions of food, chemical and product safety. Risk assessment is done on the basis of internationally recognised scientific assessment criteria. In its scientific assessment and research work the Institute is independent.

The BfR conducts its own research on topics that are closely linked to its assessment tasks and cooperates with other institutions, particularly those in the portfolio of the BMLEH, the EU member states, the EFSA-Focal-Point and international partner countries. The BfR performs the role of the "German Centre for the Protection of Laboratory Animals (Bf3R)" and coordinates all associated activities nationwide with the goal of reducing animal experiments to the necessary minimum providing the best possible protection for laboratory animals. The institute employs a quality management system in line with international standards both in the area of practical laboratory work, in its scientific assessment processes and in the field of administration.

In recent years, the focus of material innovation has shifted from spheric particles with an upper limit of 100 nm to more complex materials and morphologies. The BfR has therefore broadened its perspective to include other advanced materials such as fibres and nanocarriers to promote early identification of potential health and sustainability impacts, but also to identify the need for regulatory as well as research action. The BfR does this by closely dovetailing its regulatory priorities with its research priorities. BfR currently chairs the BOB Working Group for Advanced Materials to ensure a broad exchange between higher authorities and ministries.

8.4 Physikalisch-Technische Bundesanstalt (PTB)

The Physikalisch-Technische Bundesanstalt (PTB) is the German National Metrology Institute. Its fundamental task is to realise and maintain the legal units in compliance with the International System of Units. PTB employs about 2200 people, more than 500 with graduate

degrees, to develop new approaches in metrology, and to ensure their dissemination into society and economy.

The PTB applies different measurement methods for characterisation of nanoscale and advanced materials, partly based on commercial instruments and partly on self-developed instrumentation. These are either using local measurement principles (probes), such as atomic force microscope, scanning electron microscope or optical microscopy or integral methods, such as diffraction or small angle x-ray scattering methods. A general requirement for application of measurement methods which are traceable to the SI, is the ability to derive a measurement uncertainty budget according to internationally accepted guidelines, such as the Guide to the Expression of Uncertainty in Measurement. Only by using concept of the Guide to the Expression of Uncertainty in Measurement, a meaningful comparison of different measurement results is possible, which form the basis of decision processes in trade and regulation. The PTB is active in different international metrology activities, often in a leading role and also supports national and international standardisation (DIN/DKE, CEN/CENELEC, ISO/IEC) and guideline developing organisations, such as the VDI (Association of German Engineers). In addition, colleagues from PTB are engaged in organisation of international scientific conferences on nanometrology and AdMa topics, such as the Nanoscale and the ALTECH conference series of the European Materials Research Society.

8.5 German Environment Agency (UBA)

The mission statement of the German Environment Agency (Umweltbundesamt, UBA) is “For our environment”. Founded in 1974, UBA is Germany’s central environmental agency within the purview of the Federal Ministry for the Environment, Climate Action, Nature Conservation and Nuclear Safety (BMUKN). Its main statutory responsibilities are:

- ▶ Scientific support of the Federal Government
- ▶ Enforcement of environmental law (such as e.g. emission trading, authorisation or approval processes of chemicals, biocides, pharmaceuticals and plant protection products)
- ▶ Protection of human health from environmental pollution and health-related environmental monitoring
- ▶ Public information on environmental protection

Identifying tomorrow’s problems today: UBA’s overarching mission is early detection of environmental risks and threats, to assess those and propose viable solutions in a timely manner. UBA experts carry out research, e.g. in the agency’s own laboratories and award research contracts to scientific institutions in Germany and abroad. UBA acts as partner and is Germany’s focal point to numerous international organisations such as the World Health Organisation. It works closely together with global bodies, institutions and state entities, in Europe but also beyond.

Organised in five departments and a general services division, UBA amongst others employs experts such as biologists, chemists, economists, sociologists, lawyers and engineers from all ecology related disciplines. Currently around 2,050 people are employed (including trainees) at UBA, spread across 17 locations, including seven stations in its air quality monitoring network.

UBA has been dealing with the assessment of environmental implications of nanotechnology since 2007. UBA actively contributes to the provision of information on environmental hazards and risk of nanomaterials, closing knowledge gaps and identifying further needs for actions. One current main focus is the development of harmonised test methods for nanomaterials (i.e. OECD

test guidelines and guidance documents). Over the years, it has become increasingly clear that the considerations on material innovations cannot be limited to an upper limit of 100 nm. UBA has therefore broadened its perspective to include other advanced materials, fostering early detection of potential impacts on environmental health and sustainability, but also identifying regulatory action needs. UBA is currently leading the Steering Group on Advanced Materials within the OECD Working Party on Manufactured Nanomaterials.

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