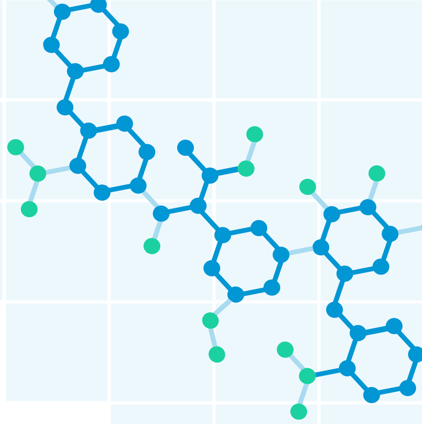
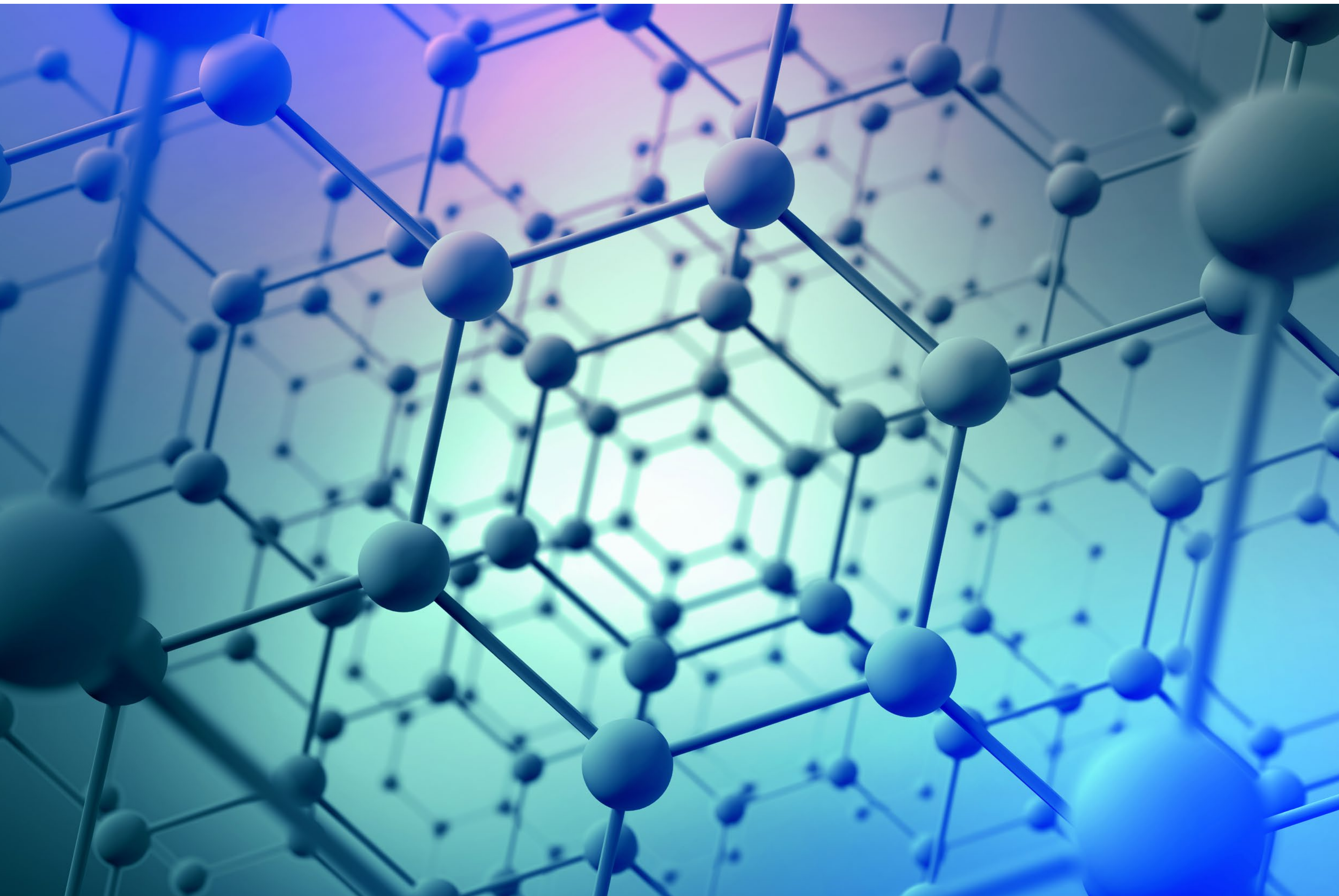


Making nano- and advanced materials safe for all

State of play of discussions at the OECD



January 2023

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Bund für Umwelt und Naturschutz Deutschland

BUND

FRIENDS OF THE EARTH GERMANY

The NanoTG project – making the voice of environmental protection heard

OECD working groups developing test guidelines are primarily composed of industry, academia, and national authority representatives. While civil society is not excluded per se, very few societal actors have the resources to participate in discussions and ensure that health and environmental concerns are prominent enough in the debates and adequately taken into account.

As relevant civil society stakeholders in Europe working on both standardisation and nanotechnologies, ECOS and BUND are conducting the project NanoTG, *putting nanomaterials to the test: methods, guidelines and transparent information for safer use. In German, Nanomaterialien auf dem Prüfstand - Methoden, Richtlinien und transparente Informationen für eine sicherere Nutzung.*

The project contributes to:

- Supporting the development and amendment of robust OECD Test Guidelines for nanomaterials, and facilitating their integration into EU and national policies regulating the use of nanomaterials in food, cosmetics, and other high-exposure applications;
- Supporting greater inclusion and impact of socio-environmental interests in the development of the regulatory framework for nanomaterials in Europe through the participation of civil society organisations.

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About ECOS: Environmental Coalition on Standards (ECOS) is an international NGO with a network of members and experts advocating for environmentally friendly technical standards, policies and laws. We ensure the environmental voice is heard when they are developed and drive change by providing expertise to policymakers and industry players, leading to the implementation of strong environmental principles.

About BUND: The Bund für Umwelt und Naturschutz Deutschland (BUND) is a major German environmental organisation with more than 2,000 volunteer groups and over 674,000 individual supporters. It is committed to protecting the environment and to ecologically and socially sustainable development.

Contents

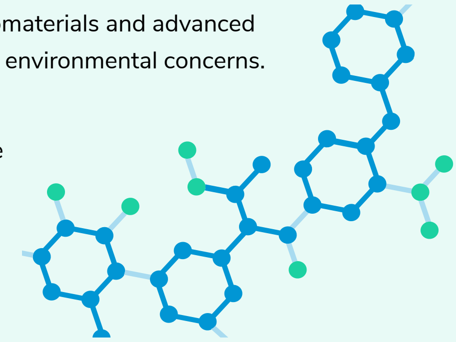
Summary

Nanomaterials are used every day for countless applications, yet their implications for health and the environment are not fully understood. At the OECD[1] level, member states work to develop a set of Test Guidelines and Guidance Documents to clarify how manufactured nanomaterials (MN) need to be tested to provide information and check their safety. This paper also addresses advanced materials (AdMa), which can have similar environmental, health and safety risks to nanomaterials. Currently, AdMa are covered by health and safety regulations for nanomaterials when their dimensions fit the definition of nanomaterials. However, not all AdMa are nanomaterials, and discussions are ongoing on how to regulate them better.

ECOS and BUND follow these discussions to ensure that socio-environmental interests are heard and support the development and amendment of robust OECD Test Guidelines. The ultimate goal is to facilitate their integration into EU and national policies.[2]

Our vision for the testing of nano- and advanced materials:

- EU member states and industry need to adopt a strong precautionary approach to nanomaterials and advanced materials, especially when uncertainties regarding their properties remain;
- National administrations and international organisations must set up the right governance framework. Among other things, this framework must ensure the industry shares information at the earliest stages in the design of new nanomaterials and advanced materials;
- Where OECD Test Guidelines exist but are not yet adapted to nanomaterials and advanced materials, this should be done, while fully addressing all health and environmental concerns. They should enable robust testing and result interpretation;
- The EU must update its regulations regularly to make full use of the OECD Test Guidelines. The use of OECD Test Guidelines must support the development of a more robust EU policy framework for nanomaterials, leading to dedicated regulatory measures.[3]

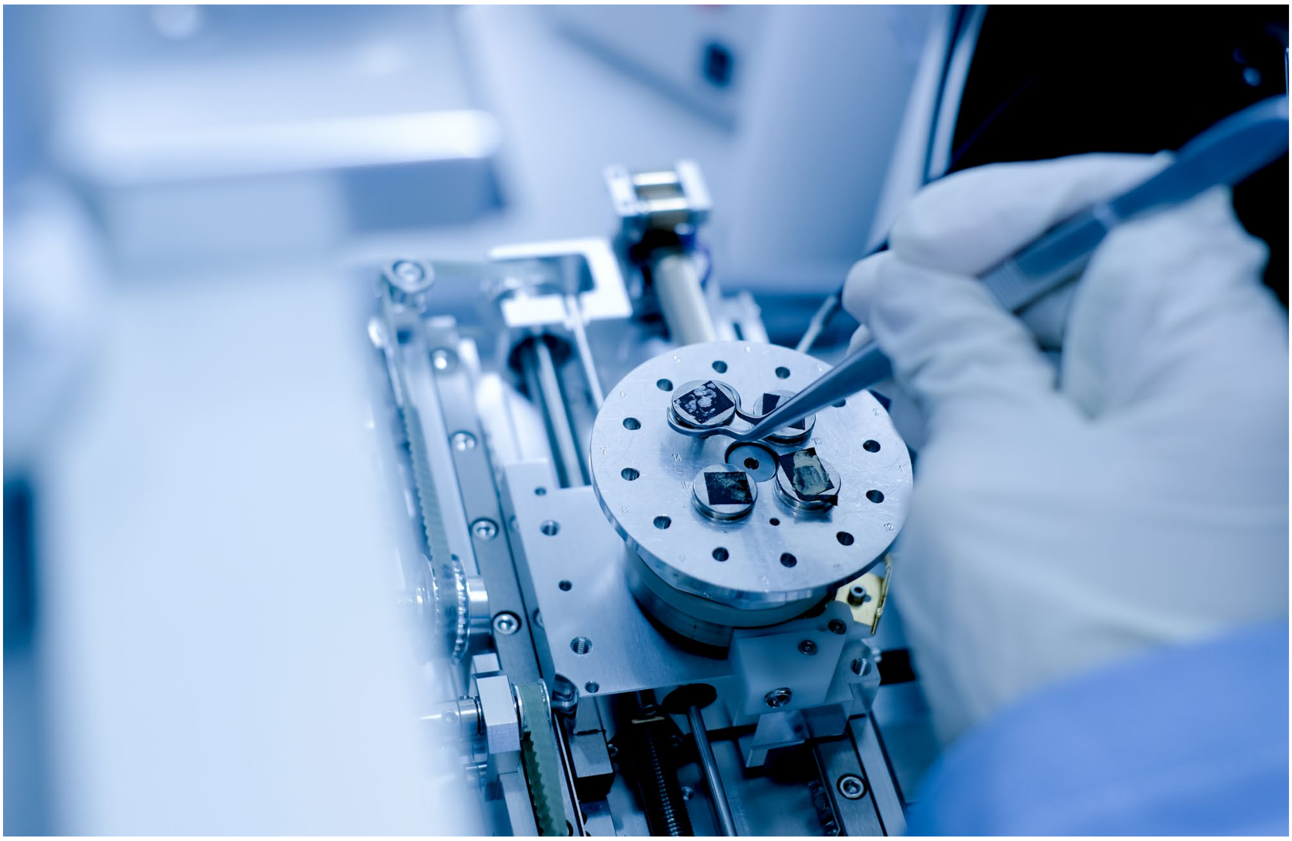


What needs to happen to achieve our vision?

- When developing new materials and products, manufacturers must keep safety and sustainability at the heart of the development process, including **ambitious life-cycle approaches**, where reusability, recyclability and waste management are also considered from the start.
- Regulators should implement an **early warning system,** which would support Regulatory Preparedness by allowing policymakers and regulators to anticipate material innovations for proper risk assessment.
- Regulators and industry should ensure traceability throughout the supply chain with a proper **information and labelling system** where all the material characteristics and health and safety data are included and shared throughout the whole life cycle of materials and products.
- Policymakers should improve regulatory frameworks, including at the EU level, to ensure that the precautionary principle is applied across the board in the face of uncertainty. **Regulatory frameworks should be transparent and involve relevant stakeholders and civil society** to ensure that innovation does not happen at the cost of safety and sustainability.

The OECD should develop:

- **A grouping strategy for nanomaterials** to facilitate their hazard assessment.
- Additional Test Guidelines and Guidance Documents for the **measurement of ecotoxicity and bioaccumulation** for nanomaterials and advanced materials, reproducing real-life situations and limiting animal testing.
- New guidance as well as validated and harmonised test methods for the **assessment of environmental, occupational and consumer exposure** to nanomaterials and advanced materials.
- A working definition for **advanced materials** and develop proper safety assessment tools. Advanced materials can have similar environmental, health and safety risks to nanomaterials, but they are currently not necessarily covered by health and safety regulations in place for nanomaterials if their dimensions do not fit the definition of 'nanomaterial'.



Introduction: Nanomaterials still slip through governance cracks

What are nanomaterials?

Nanomaterials are substances that are extremely small, including all particles and other morphologies such as sheets, needles or fibres, with one or more dimensions in the 1-100 nanometre scale.[4] There are many different types of nanomaterials with countless applications in food, cosmetics, construction materials, medical products... We use them every day, yet their implications for health and the environment are not easy to understand. Despite this, their use remains underregulated in the EU.

Nanomaterials in everyday life – The example of titanium dioxide

Titanium dioxide, also known as food additive E171, is an example of a material regularly added to consumer products and food, cosmetics and other items – mainly used for aesthetic purposes. In nanoscale, it is used as a UV filter in sunscreens.

Yet, uncertainty remains about its effects on human health when used as a nanomaterial. In 2017, the French government released a scientific assessment which found that titanium dioxide is a carcinogen when inhaled. In 2019, the European Chemicals Agency (ECHA) supported the French opinion and suggested classifying the material as a 'suspected carcinogen'.

The human health effects are clear: when titanium dioxide is in some nanoparticle forms, it is small enough to reach the alveoli of the lung. Yet at the end of 2022, after years of litigation and industry lobbying, the Court of Justice of the European Union issued a judgement annulling its classification as a suspected carcinogen by inhalation. An appeal may come in early 2023.

What is the problem with nanomaterials in the EU?

In the EU, nanomaterials are regulated through the REACH Regulation, which is the main legislative tool to tackle chemical substances on the EU market. As such, unless they are specifically added to the list of substances that require authorisation (Annex IV of REACH), no prior authorisation is needed to use nanomaterials in products (except for biocides, plant protection products and pharmaceuticals). While the industry advocates new nanomaterials as advanced materials that can improve product performance, this lack of surveillance could lead to health and environmental safety problems. Nonetheless, nano-specific information requirements have entered into force recently as part of REACH.[5] While insufficient, they will hopefully improve our knowledge of the impacts of nanomaterials.

The main issue is that there are still many unknowns in the nanomaterial domain. To date, research on the environment, health and safety risks has focused only on a few types of nanomaterials. Meanwhile, the majority of commercialised nanomaterials remain under the radar of regulators, e.g. newly-developed applications containing graphene or carbon nanotubes which come in many different shapes and sizes, in many cases with possible adverse effects.

The fate and behaviour of nanomaterials remain problematic in the following cases:

- Many nanomaterials are inorganic carbon materials, metals or metal oxides that do not biodegrade.[6] However, how such materials accumulate in the environment is not understood.
- Coatings can disintegrate over time. Among other reasons, they are added to stabilise nanomaterials.
- Titanium dioxide is a widely used nanomaterial, for example, in cosmetics or paints and varnishes. There is emerging evidence that titanium dioxide accumulation as waste can cause environmental exposure, notably disrupting soil and aquatic microorganisms.[7,8,9,10]

OECD Guidelines: how do they work?

The Organisation for Economic Co-operation and Development (OECD) has developed a series of guidelines for the testing of chemicals, or OECD Test Guidelines (TGs). They are **a collection of about 150 of the most relevant, internationally agreed testing methods for chemicals** in general, used by industry professionals, academia and governments for the safety testing and assessment of chemicals. Some of them are notably used to comply with EU and national regulations. As such, Test Guidelines aim to standardise the testing of specific effects (for example, how to assess skin sensitivity), and not the testing of specific substances. Robust harmonised TGs are one way to ensure that regulatory obligations can be implemented in a reliable way, and that non-compulsory but useful tests are widely adopted.

Test Guidelines are split into four sections covering:
1) physical-chemical properties; 2) effects on biotic systems (e.g. ecotoxicity); 3) environmental fate and behaviour; and 4) health effects. The OECD Steering Group on Testing and Assessment of Manufactured Nanomaterials is in charge of the constant process of amending TGs, aiming to overcome persistent challenges in researching, regulating and governing nanomaterials.

Using OECD as the forum to develop guidelines, instead of standardisation committees at the ISO level, ensures that these **guidelines are freely available**. Indeed, standards are not published and need to be bought, while OECD guidelines are public and free of charge. It also provides a higher chance of acceptance by OECD Member countries when drafting regulations, as they are directly involved in drafting OECD guidelines, while national boards in ISO are primarily composed of industry associations. In fact, all OECD member countries have to approve TGs and Guidance Documents (GDs) before publication. Once they are approved, they fall under the OECD Mutual Acceptance of Data system, which enables OECD countries and the European Union to pool resources and develop the knowledge base faster, setting a common ground to then improve regulations. Considering the high pace of innovation in nanomaterials, speed is of the essence, and while this way of developing guidelines has helped improve the situation, there is now a recognition that regulators must act even earlier in the process. This is why the OECD is now working on the Safe Innovation Approach (which is described in page 12).

Developing the knowledge base to ensure appropriate governance – more nanomaterial-specific guidelines are needed

Test Guidelines and Guidance Documents are used for regulatory requirements, providing the **overall framework to regulate nanomaterials**. They are also the most widely used tools as a frame in international research. In Europe, these documents are developed at the OECD level, besides technical standards from international and European standardisers, ISO and CEN respectively, in addition to regulatory guidance from European Union bodies. They are written jointly by national and European regulators, with support from the industry and researchers, with some (but limited) input from civil society.

TGs and GDs are standardised tools and methods for assessing the potential effects of chemicals, including nanomaterials, on human health and the environment (for example, detecting endocrine-active substances or assessing skin sensitivity).[11,12] They are specified by legislators and regulators, such as ECHA[13,14], in order to indicate how to fulfil the legal information requirements mentioned above.

However, there is a continuous need to update these guidelines in order to fully address the impacts of nanomaterials and issues within tests, such as:

- Nanomaterial characterisation and intrinsic physicochemical properties;
- Nanomaterial aggregation and agglomeration;
- Degradation and persistence;
- Bioaccumulation and biotransformation.

The first two TGs for measuring some nanomaterials-specific physical-chemical properties were published in June 2022 (TG 124 and 125). However, more TGs are needed to measure other intrinsic properties such as chemical composition, particle shape or reactivity.

Finally, more information is necessary to interpret the results of tests undertaken as part of TGs, notably on ecotoxicity. Some TGs and GDs are available (see below on GD 317 and TG/GD 318), but more research must be done. At a minimum, more guidelines on how to conduct test and interpret test results must be developed or updated, and then applied by the industry, including through regulation when necessary.

This paper provides an overview of current discussions within the OECD on nanomaterials and what is at stake for the environment. The main work items at the WPMN are reported under the following sections:

- Testing and assessment
- Exposure measurement and mitigation: tools and models
- Safe Innovation approach
- Advanced materials

OECD WPMN – An overview of guidelines currently under development or update

The OECD Working Party on Manufactured Nanomaterials (WPMN), launched in 2006, leads an **ongoing evaluation of the suitability of existing OECD TGs**.[15] It first focused on a priority list of 11 manufactured nanomaterials, that were either already commercially available or soon to be on the market in the mid-2000s.[16] In 2015, the WPMN confirmed the specificities of nanomaterials. Now, it works to ensure that OECD TGs apply to nanomaterials.[17]

Currently, the WPMN identifies needs for either adapting existing TGs or developing new TGs and Guidance Documents specifically for nanomaterials. TGs and GDs notably include the list of endpoints that need to be tested, that is, the targeted outcomes tested when assessing the safety of a material, such as skin sensitisation, reproduction and neuronal development. TGs and GDs also include information about the method to be used and how to interpret results. Because of the particular properties and morphologies of nanomaterials, more or different endpoints might need to be tested, the method might need to be adapted, and the results will have to be interpreted differently.[18]

The development of TGs is then overseen by the Working Group of National Co-ordinators of the TGs programme (WNT).[19] The WNT is a group composed of regulatory authorities within OECD member countries, experts, and other stakeholders who take decisions on TGs. As such, the WNT represents regulatory authorities in OECD member states and countries adhering to the Mutual Acceptance of Data (MAD)[20] system. In collaboration with the WPMN, this group is currently updating or developing new Test Guidelines and Guidance Documents on testing and assessment, which should improve our understanding of the impact of nanomaterials on the environment. While a long list of projects is underway to improve the testing on environmental and health impacts, we present below the projects that are more directly linked to application in regulation.[21]

Projects related to testing and assessment

Measuring the ecotoxicity of chemicals

Several available Test Guidelines allow **measuring the ecotoxicity of chemicals**. In 2020, the OECD published GD 317 on aquatic and sediment toxicological testing of nanomaterials[22]. GD 317 gives comprehensive advice on how to perform appropriate testing of the ecotoxic effects of nanomaterials. Based on these recommendations, the WMT is currently developing more elaborate advice regarding the testing of specific effects of some nanomaterials.

In particular, the working group is creating specific advice for nanomaterials based on: the **freshwater alga and cyanobacteria growth inhibition test (TG 201), Daphnia sp. acute immobilisation test (TG 202), and acute toxicity tests in fish (TG 203)**. The main problem found is the lack of data about the performance of these three TGs when applied to nanomaterials, as they tend to provide results that are too different to enable comparison. Methods will therefore need to be adapted to give more guidance and improve comparability by aiming to reproduce real-life situations. Other measurement methods also need to be considered (e.g. computational modelling) to diminish the need for animal testing without compromising the assessment of ecotoxicity. Finally, GD 317 involves efforts to disperse NMs into laboratory media that may not always be realistic to environmental dispersal. Environmental realism is to be integrated with the exposure assessment component of the NM risk assessment (see specific section on NMs below) and is beyond the scope of this GD.

In the same frame, a scoping review has been initiated for a tiered approach to reliably assess the **bioaccumulation of manufactured nanomaterials in environmental organisms,** while minimising the use of higher-tier vertebrate tests. The overall purpose of this scoping exercise is to check if and how the usually applied TG 305 (which defines test for bioconcentration of traditional chemicals in fish) can be triggered or waived for nanomaterials. The traditional approach for triggering bioaccumulation testing is not appropriate for nanomaterials. Instead, alternative triggers based on the physico-chemical properties of nanomaterials should be used.

The Steering Group on Testing and Assessment of Manufactured Nanomaterials has started developing **a new Guidance Document on an integrated in vitro approach for understanding nanomaterials fate once ingested**. The SGTA is establishing a conceptual framework and procedures to simulate, thanks to a sequential approach, the two first steps of the digestion process, i.e. nanomaterials behaviour in the different digestive compartments (mouth, stomach, intestine) and their interactions with the intestinal mucosa. They will also identify the best analytical techniques for nanomaterial detection in biological matrixes, and they will inform on how to manage the data in a stepwise identification of hazards of nanomaterials. This guidance will support mutual acceptance of data between laboratories and avoid double testing among OECD countries, and is currently further developed at the WNT level.

Sample Preparation and Dosimetry

Another item, **the Guidance on Sample Preparation and Dosimetry,**[23] is a fundamental document developed by the Working Party on Manufactued Nanomaterials. It informs key preparatory steps in the investigation of nanomaterials, and is essential to the proper assessment of, *inter alia*, their environmental impact. It is currently being updated to include the latest scientific knowledge and ensure coherence with new Test Guidelines and Guidance Documents developed in parallel.

Grouping of Chemicals

Finally, the Working Party on Hazard Assessment of the OECD has developed **Guidance on Grouping of Chemicals**[24] **to assess the hazards of chemical substances** while gaining efficiencies and improving animal welfare. The approach described in the guidance document is to consider closely related chemicals as a group, or category, rather than as individual chemicals. The first edition was published in 2007 and was further revised in 2014, adding a few initial considerations applicable to manufactured nanomaterials. The guidance is currently being updated. The WPMN has established an ad hoc group to support the current update regarding guidance on grouping possibilities of nanomaterials. Grouping applied to manufactured nanomaterials is a very delicate exercise and should be carefully developed since it can have important implications for the testing and assessment of nanomaterials. Unless the work results in extensive guidance with sufficient detail, it should not be used to provide recommendations on testing. It should especially not lead to the exclusion of certain groups from testing.

Exposure measurement and mitigation: tools and models

In 2017 and 2018, the Steering Group on Exposure Measurement and Mitigation at the OECD set up three projects to compile available tools and models for the **assessment of environmental, occupational and consumer exposure** to manufactured nanomaterials.[25] The projects aimed to analyse their applicability for use in regulatory exposure assessment by evaluating the models to determine their availability, reliability, user-friendliness and applicability to scenarios. The findings led to **new guidance for regulators on the use and specific application of all these exposure models** for nanomaterials.

Guidance on release tests for Manufactured Nanomaterials

A first step in the development of new guidance for exposure assessment is to **obtain data from release tests** for a broad range of processes and release mechanisms, as well as for a variety of manufactured nanomaterials (MNs) and products containing them. **Release of MNs from component materials, powders, composites or other products containing nanoforms is the first step towards exposure of workers, consumers or the environment to nanomaterials**. Validated and harmonised release test methods are therefore necessary to provide quantitative information about the amount of released MNs during a specific process. The conditions under which release tests are performed, the chosen parameters, and the output parameters of release tests, need to be harmonised and relevant to the requirements of exposure assessment tools. Although release tests are already available for several processes, additional test methods are yet to be developed and standardised, especially for environmental exposure.

So far, there is no detailed guidance on existing standardised release tests suitable for MNs. **A decision framework is urgently needed to help producers, processors and users of MNs and MN-containing products with the choice of appropriate tests**. This is important not only for nanomaterials, but also for other advanced and emerging materials (see section below).

Aggregation and agglomeration

Due to their specific intrinsic characteristics, such as reactivity or surface area, as well as surrounding conditions, nanoparticles can form loosely bonded agglomerates or more strongly bonded aggregates when released into the environment. The creation of these structures will strongly impact the physico-chemical properties of nanomaterials as compared to the pristine particles and can impact the environment, health, and safety. This means that **characterisation and exposure assessment of nanomaterial aggregates and agglomerates is crucial** to properly assess the (eco)toxicology of these nanomaterials. In this line, two guidelines were published in June 2022, **TG 124 (Determination of the Volume Specific Surface Area of Manufactured Nanomaterials) and TG 125 (Testing of Chemicals Particle Size and Particle Size Distribution of Nanomaterials)**. These are the first two TGs for measuring certain nanomaterials-specific physical-chemical properties. However, more are needed to measure other intrinsic properties such as chemical composition, the shape of the particles, or reactivity.

Dispersion stability is covered in TG and GD318, which provides guidance on how to measure if NMs are dispersed through sanitation and if the particles aggregate or agglomerate. The test method does not measure the agglomeration rate or the particle size over time.

Currently, there are no **legally binding regulations defining how to perform or assess exposure measurements to nanomaterials aggregates and agglomerates**. There are general regulatory requirements on how to assess the exposure to chemicals, but more detailed guidelines are not expected at the regulatory level due to the high number of substances that would have to be reviewed. The OECD is therefore filling this information gap with voluntary guidelines. Its project on aggregation and agglomeration aims to contribute to the harmonisation of exposure and risk assessment of these nanomaterials. There is an urgent need to define the appropriate metrics and evaluate the available test methods for these exposure measurements. It should result in the development of new Test Guidelines and Guidance Documents, forming the basis for a regulatory framework.

Towards a Safe Innovation Approach for sustainable nanomaterials and nano-enabled products

Beyond specific testing and assessment guidelines, the Working Party on Manufactured Nanomaterials is also working on the broader governance of manufactured nanomaterials. Indeed, beyond testing existing materials, **we need a framework that ensures that newly developed materials are safe for our health and the environment**.

At the end of 2020, the OECD published a first report on *Moving Towards a Safe(r) Innovation Approach (SIA) for More Sustainable Nanomaterials and Nano-enabled Products*. It states that:

> Technological innovations such as nanotechnology are being developed at such a rapid pace that they present a challenge to health and environmental risk assessment. Because of this rapid innovation, a gap can arise between technological innovations and the development of suitable risk assessment tools and frameworks.[26]

This creates the need to ensure human and environmental safety from the early stages of product development. The SIA approach has two main components: Safe and Sustainable by Design, and Regulatory Preparedness. The former refers to the need for industry to consider the safety of nanomaterials during their life-cycle processes. In contrast, the latter refers to the need for regulators to set up governance adapted to the pace of innovation.[27]

Safe and Sustainable by Design

In 2022, the OECD developed a Safe and Sustainable by Design (SSbD) approach.[28] Following this approach, **research and development in nanomaterials must fully address the safety and sustainability of materials, products and processes** needed to provide a certain function (or service) throughout their life cycle.[29] SSbD aims to guide the industry on how to identify risks and uncertainties regarding safety and sustainability during the early stages of the innovation process, ensuring safety and sustainability along the life cycle of a product or material.

The SSbD approach looks at three pillars of design: safe(r) and sustainable material/product, safe(r) and sustainable production, and safe(r) and sustainable use and end-of-life.[30] To implement this approach, the OECD has developed working descriptions for 'sustainability' and 'safe and sustainable by design', which are necessary to make inventories of frameworks or criteria in the frame of the Safe(r) Innovation Approach. Thereby, careful considerations need to be made for the use of raw materials and products, ensure traceability along the value chain and sustainable production processes, as well as safeguarding sustainability through the entire life cycle of the product, maximising its lifetime including the repairability, reuse, and recycling of materials and products.

Regulatory Preparedness

On the regulatory side, policymakers and the industry are discussing Regulatory Preparedness as **a way to reconcile the slower pace of regulation with the much faster pace of innovation**. While this concept was developed for nanomaterials, it is also needed for emerging and advanced materials for current and future innovations to deal with potential safety issues. Here as well, working definitions for Regulatory Preparedness need to be established. Regulatory Preparedness can be seen as a way of applying the precautionary principle in a proactive and time-efficient way. Regulators acquire information about a new technology, its characteristics, and potential safety concerns early enough, while the technology is still in development, so that the necessary regulatory tools, such as adapted legislation and appropriate safety assessment methodology, can already be in place when industry is ready to seek market approval.

Trusted Environments – how to overcome the barriers to their creation and include civil society

To bring the Safe Innovation Approach (SIA) closer to practical applicability, a number of barriers, constraints and limitations were analysed by the OECD WPMN, as well as possible incentives to overcome these.[31] A major barrier for the implementation of the Safe(r) Innovation Approach is the lack of dialogue between innovators and regulators. Work is now focusing on the creation of **Trusted Environments that could help adapting the current regulatory systems.**

A Trusted Environment (TE) is a useful tool to share knowledge confidentially during the innovation process. A TE can, for instance, be set up between regulators or between regulators and innovators. It provides a space for industry to provide information to regulators beyond what they would normally disclose to protect trade secrets.[32] Trusted Environments exist in other domains (such as in food and medicine safety), and the concept has been explored for its applicability to nanomaterials.

According to Soeteman-Hernández et al.,[33] the main motivation for both regulators and industry to develop these spaces is the need to 'understand each other's concerns and together develop solutions to anticipate and address safety issues whilst also facilitating the development of sustainable and socially beneficial innovations'.

Such spaces could only work if trust is ensured, and for this it needs to be based on a number of key values: **public interest intent, competence, respect, integrity, fairness, openness, and inclusion**. Several EU-funded projects have explored how to set up Trusted Environments (NanoReg2 notably),[34] and all have pointed at the benefits of opening the dialogue to civil society and researchers to ensure the uptake of societal and environmental needs as early as possible in the innovation process, promote common understanding, and improve the general acceptability of the governance framework.[35]

However, the current OECD working description of Trusted Environment[36] only focuses on the protection of information shared by industry to regulators. Unfortunately, the **discussions fail to address the inclusion of civil society actors**. As a result, **consumer and environmental interests will continue to lag behind** even though they are primarily concerned stakeholders regarding the impacts of nanomaterials. Civil society will not be able to raise concerns soon enough in the regulatory process and will remain in a reactive position instead of being able to truly contribute.

Another related barrier is the **lack of knowledge and awareness-raising around the Safe(r) Innovation Approach and its elements**. This is impeded by the data gaps that exist for emerging and advanced materials in general and nanomaterials in particular. The current regulatory systems are not designed to deal with the fast pace of innovations. More guidance and standardisation efforts are urgently needed, notably to compensate for the lack of resources to do this at the national level by pulling efforts at the OECD level. Furthermore, environmental, health and safety risk assessment is resource intensive, and more specific funding is needed for the implementation of Regulatory Preparedness.

To properly implement SIA, it is crucial to develop an **information platform to share knowledge on R&D at an early stage** of the development of safe-by-design materials and processes. For this, the development of thorough Test Guidelines and Guidance Documents is needed to assess environmental health and safety risks properly.

Besides dialogue and information platforms, several tools and frameworks need to be set up to assist in the assessment and development of safer and sustainable: (i) materials and products; (ii) production processes; and (iii) use and end-of-life of products. In this line, the OECD has already set up two inventories of available frameworks and tools, both existing and under development. In addition, the OECD is reviewing the inventories to incorporate additional tools covering other aspects of sustainability such as environmental, social and economic impacts – in addition to safety. With this review, the OECD aims to identify and analyse the applicability of frameworks and tools for different aspects of SIA, SSbD and Regulatory Preparedness.[37] Criteria will ensure that these tools cover different safety and sustainability aspects along the material life cycle, including human and environmental hazards, worker and consumer exposure, as well as environmental release during production, use and end-of-life processes. Notably, the structure and physicochemical properties must be considered for proper risk assessment at the design stage.

Advanced materials – work at the WPMN Steering Group

Beyond nano

A whole new class of **emerging and advanced materials**, not necessarily falling under the EU definition of a nanomaterial, **are increasingly being developed** and brought into our lives. Just like nanomaterials, they can be designed for a variety of sectors, from electronics to construction materials. This creates an urgent need for Regulatory Preparedness for a class of materials not covered by current regulation, but which could bring about unknown environmental, health, and safety risks. Regulators must develop a new strategy to deal with this new class of rapidly evolving materials within a circular economy.[38] In this framework, the WPMN has created a steering group to discuss the safety and sustainability aspects of advanced materials.

Describing the playing field of advanced materials within WPMN

Advanced materials are generally considered to have novel or enhanced properties over conventional products and processes (e.g. higher connectivity, lighter weight, highly resistant, enhanced chemical performance, etc.). While many nanomaterials are considered advanced, **not all advanced materials contain components in the nanoscale.**[39] In this context, **the steering group developed a working description** of their playing field.

In parallel to the OECD WPMN, a project of the **International Organisation for Standardisation (ISO)** is looking at the possibility of **developing a working definition of 'advanced materials'**. Since this new class involves possibly hazardous materials that go beyond the current definition of 'nano', there is a clear need to further standardise what is meant by advanced materials. That way, they can be included in the discussions on environmental, health and safety risk assessment, as it is currently the case for nanomaterials.

The discussion at ISO, taking place within a Strategy Group on advanced and emerging materials under the technical committee ISO/TC 229 'Nanotechnologies', is followed by the Working Party on Manufactured Nanomaterials to ensure coherence between the definition of 'advanced materials' (by ISO) and the description of their playing field (by WPMN). These three elements (playing field, categorisation method and definition) will assist in defining, assessing and managing environmental safety and occupational and consumer health risks associated with advanced materials.

A strategic approach to support SSbD and Regulatory Preparedness in advanced materials – we need early warning systems

The WPMN steering group is developing a strategic approach to address advanced materials in coherence with the work of the OECD Chemicals Committee. This strategic approach aims to **identify safety and sustainability issues of advanced materials**, namely to identify knowledge gaps on safety and sustainability, TG/GD adaptation needs, missing regulatory coverage, and possible concerns, aiming to develop action needs and recommendations.

This approach should outline the focus, goals and purpose of the WPMN work on advanced materials and enhance Regulatory Preparedness and SSbD by identifying and engaging all the relevant stakeholders. This project should result in a set of criteria to classify a given material as advanced. It will also **develop a clear and user-friendly categorisation method** to operationalise this for technology developers and risk assessors so that they can categorise materials unambiguously.[40]

The steering group has **already developed a working description for 'advanced materials'**.[41] There is now a clear need to develop further guidance to encompass more materials than are currently defined under nanomaterials. The field of environmental safety and consumer and occupational health has no unified process or protocol for addressing advanced materials, nor determining the necessity for risk assessment of such materials with advanced or emergent properties.[42] Considering the necessity to assess the potential environmental implications of advanced materials, such unified processes and protocols might be needed to ensure that assessments are conducted from the early stages of material development and commercialisation.[43] Also, it is crucial to create **a framework for Regulatory Preparedness in order to be ready for new materials that will be developed in the future**.

The steering group now plans to apply the strategic approach to selected advanced materials case studies to identify issues (as mentioned above) and come up with recommendations but also identify possible refinement needs to the approach.

To support this, ECOS and BUND consider that **early warning systems are needed when developing new materials**. That way, adequate tests can be developed and ensure that innovation is environmentally sound, especially when innovation is meant to support sustainable policies such as the energy transition. Early warning systems support Regulatory Preparedness by allowing policymakers, decision-makers and regulators to anticipate material innovations.

In this context, the Dutch National Institute of Public Health and the Environment (RVIM),[44] and German public bodies Federal Institute for Risk Assessment (BfR),[45] Federal Institute for Occupational Safety and Health (BAuA)[46], and UBA (German Environmental Agency)[47] have developed a joint early warning system to identify, describe and prioritise alerts related to the safety and sustainability of advanced materials.[48, 49] The system aims at the early identification of potential human health, environmental and sustainability issues. It should support the development, production, use, and end-of-life treatment of advanced materials. This warning system also links back to the work of the SIA steering group. The system helps to assess different warnings systematically. In addition, the system will support the identification of gaps in regulatory frameworks. Finally, it allows to examine whether the development of new materials is in line with other policy goals, such as the European Green Deal[50] and the European Chemical Strategy for Sustainability,[51] where SSbD, circularity and life-cycle approaches (including reuse and recyclability) play the most important role.

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WeWork
Rue du Commerce, 31
1000 Brussels · Belgium
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Deutschland eV (BUND)
Federal office
Kaiserin-Augusta-Allee 5
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