



# DEVELOPING TOOLS FOR NANOMATERIALS AND ADVANCED MATERIALS THAT PROMOTE SAFETY FOR HEALTH AND FOR THE ENVIRONMENT.

## OECD's Nanosafety Programme

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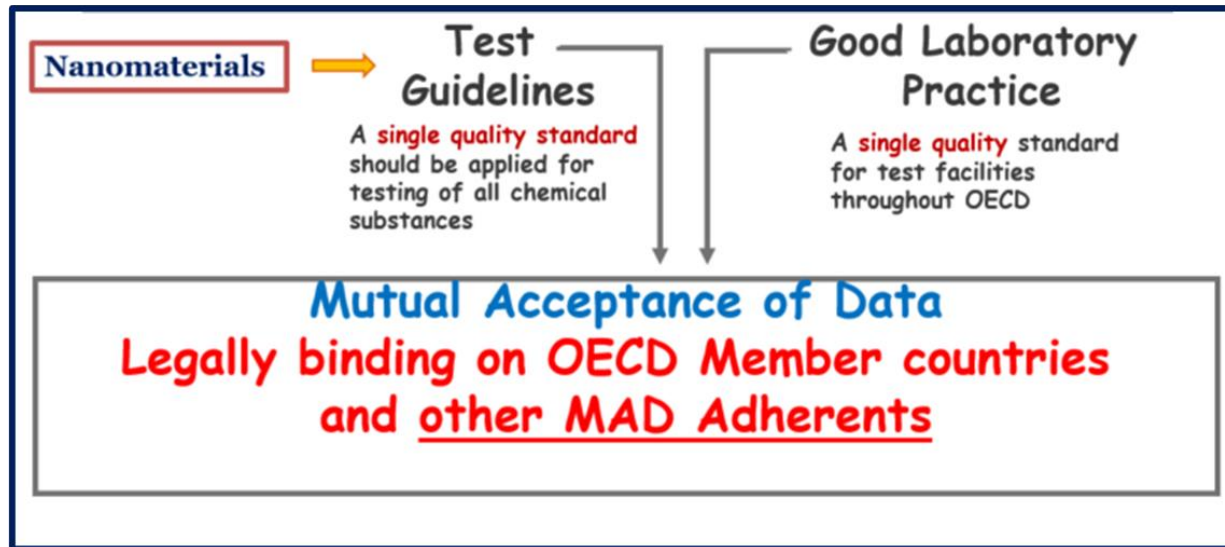
Harmonisation and Standardisation of test methods for nano and advanced materials



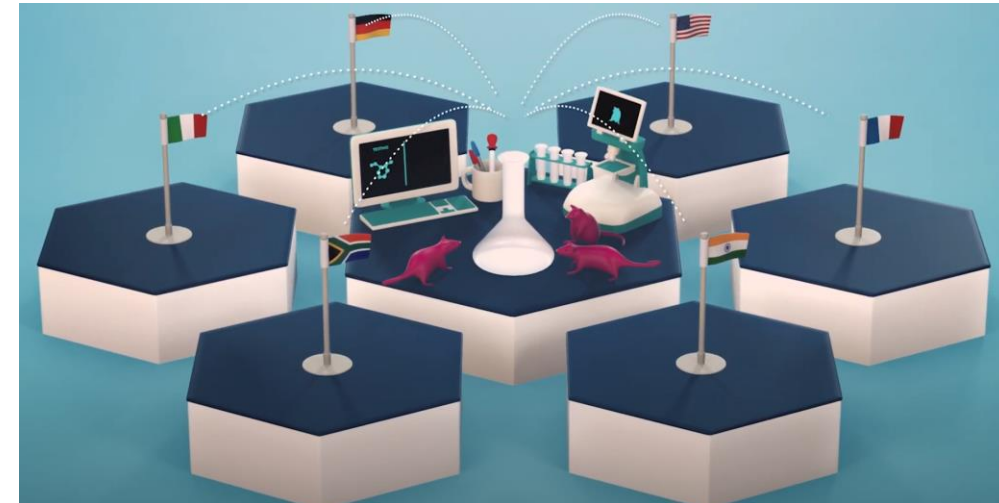
# THE MUTUAL ACCEPTANCE OF DATA SYSTEM



Data generated using **OECD Test Guidelines (TG)** under **Good Laboratory Practices (GLP)** are accepted across member countries and MAD adhering countries having the same data requirement



**“tested once, accepted everywhere.”**



Saving Costs in Chemicals Management <https://oe.cd/chemicals-costs>



# From science to standards: Developing standardised methods to generate trustable safety data for nanomaterials

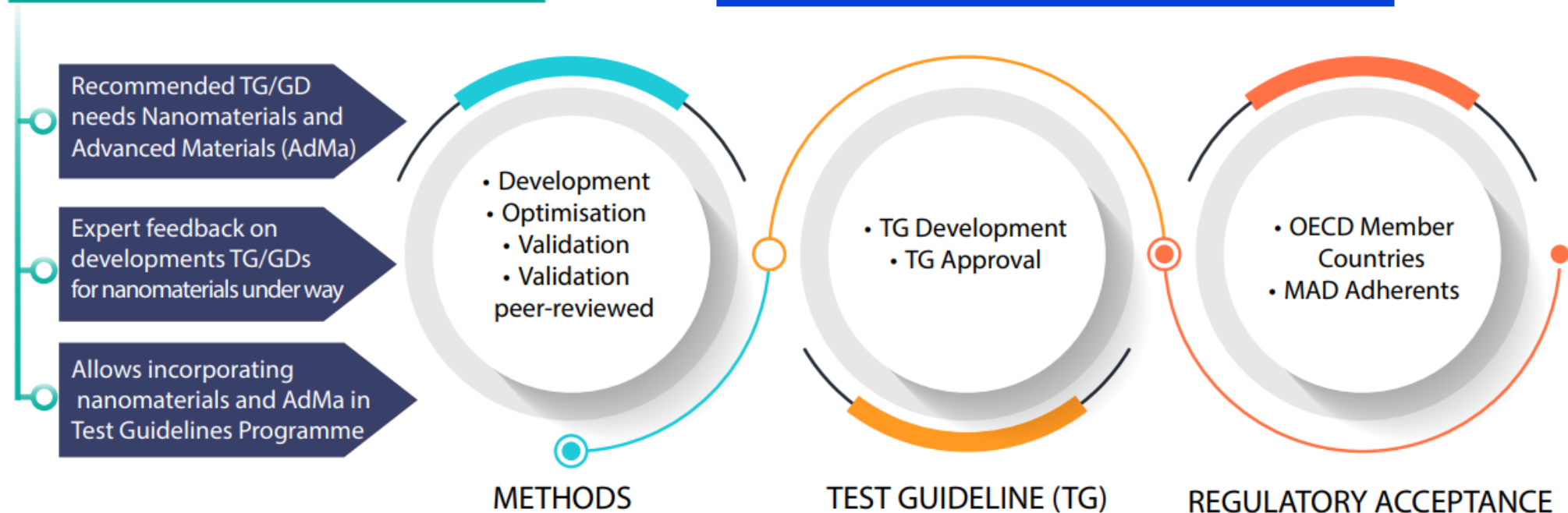


## Working Party on Manufactured Nanomaterials (WPMN)

- Policy discussions on innovative materials
- Assist in implementation of safety policies and regulatory preparedness

## The Working Party of the National Coordinators of the Test Guidelines Programme (WNT)

- A well established international programme for regulatory standard-setting.
- Oversees the development of Test Guidelines (TGs) and associated Guidance Documents (GDs).



# TG / GD / Review papers on NMs (PUBLISHED)



## Physical-chemical properties

- Determination of the (Volume) Specific Surface Area of Manufactured Nanomaterials (TG 124)
- Particle Size and Size Distribution of Manufactured Nanomaterials (TG 125)
- Determination of the hydrophobicity Index of Nanomaterials Through an Affinity Measurement (TG 126)



## Effects on Biotic systems

- Aquatic and Sediment Toxicological Testing of Nanomaterials (No. 317 OECD Series on Testing and Assessment)



## Environmental fate and behaviour

- Dispersion stability of nanomaterials in simulated environmental media (TG 318)
- Testing of dissolution and dispersion stability of nanomaterials and use of data for further environmental testing and assessment strategies (No. 318 OECD Series on Testing and Assessment)
- Leaching in soil columns (No. 342 Series on Testing and Assessment)
- Removal of nanomaterials in wastewater treatment plants (No. 349 Series on Testing and Assessment)



## Human health

- Applicability of TG 487 *in vitro* micronucleus test (genotoxicity) for testing manufactured nanomaterials (No. 359 Series on Testing and Assessment)
- Applicability of TG 442D *in vitro* skin sensitization to manufactured nanomaterials (No. 382 Series on Testing and Assessment)
- Subacute inhalation toxicity: 28-day study (updated TG 412)
- Subchronic inhalation toxicity: 90-day study (updated TG 413)
- Guidance Document on Inhalation Toxicity Studies (No. 39 - Second Edition - Series on Testing and Assessment)

Available at: [www.oecd.org/chemicalsafety/testing/oecd-guidelines-testing-chemicals-related-documents.htm](http://www.oecd.org/chemicalsafety/testing/oecd-guidelines-testing-chemicals-related-documents.htm)

Other documents on NMs/AdMa: <https://www.oecd.org/chemicalsafety/nanosafety>  
& <https://www.oecd.org/chemicalsafety/nanomet/>

# Ongoing TG/GD projects on NMs



## Physical-chemical properties

- TGP Project 1.5: Determination of solubility and dissolution rate of nanomaterials in water and relevant synthetic biological media [2024]
- TGP Project 1.6: Identification and quantification of the surface chemistry and coatings on nano- and microscale materials
- TGP Project 1.8: Determination of the dustiness of manufactured nanomaterials
- TGP Project 1.10: Determination of concentrations of nanoparticles in biological samples for (eco)toxicity studies



## Environmental fate and behaviour

- TGP Project 3.10: Dissolution rate of nanomaterials in aquatic environment
- TGP Project 3.12: Assessing the apparent accumulation potential for nanomaterials
- TGP Project 3.16: Environmental abiotic transformation of nanomaterials
- WPMN Project: Tiered approach for reliable bioaccumulation assessment of MNs in environmental organisms minimising use of higher tier vertebrate tests



## Human health

- TGP Project 4.146: Toxicokinetics to accommodate testing of nanoparticles
- TGP Project 4.158: Integrated *in vitro* approach for intestinal fate or orally ingested nanomaterials



## Effects on Biotic systems

- WPMN Project: Adaptation of OECD TGs 201, 202 and 203 for the determination of the ecotoxicity of MNs



## Other Guidances

- Develop “Section 6.9 Grouping” [this is part of the OECD Guidance on Grouping (GD 194)]. [2024]
- Scoping review to consider a tiered approach to accurately determine the bioaccumulation potential of MNs [2024]
- Guidance on Release Tests for Manufactured Nanomaterials [2025]
- (**updating**) Guidance on Sample Preparation and Dosimetry [2024]

## WNT new SPSF submitted (Section Human health)



### Validating the *In Vitro* Micronucleus assay for Engineered Nanomaterials

- **Leads:** UK, Germany, France and Norway
- **Partners:** US, Luxembourg

#### Objective:

Proposes an inter-laboratory trial utilising the Standard Operating Procedure (SOP) already defined in the *Study Report and Preliminary Guidance on the Adaptation of the In Vitro micronucleus assay (OECD TG 487) for Testing of MNs*. Based on discussion with and preceding recommendations within the OECD expert group, it is agreed to conduct the necessary ring trial evidence to support and produce an **adaptation/update of OECD the preliminary GD 359 to include the methodological requirements that ensure the approach taken is appropriate for ENMs**. Based on the revised GD 359 an update of TG 487 will be developed



# OECD's WPMN strategy for addressing Advanced Materials\*

## Development of International Standards for regulatory enforcement and innovation enhancement

Integrate Advanced Materials when developing standards and associated tools. For example:

- OECD's Test Guidelines
- Guidance Documents
- Reports

See: <https://oe.cd/nanomet> & <https://www.oecd.org/chemicalsafety/testing/oecdguidelinesforthetestingofchemicals.htm>

## Early Awareness and Action System for Advanced Materials (Early4AdMa)

Identify Actions needed and make recommendations, for example:

- the need for standardized methods
- Safety and sustainability issues of new materials and link this to innovation phase

## Anticipate safety + Sustainability issues at the earliest stage of Innovation

Bringing Safety and Sustainability consideration at the earliest stage of innovation



OECD's Safe(r) and Sustainable Innovation Approach (SSIA)

See: <https://oe.cd/ssia>

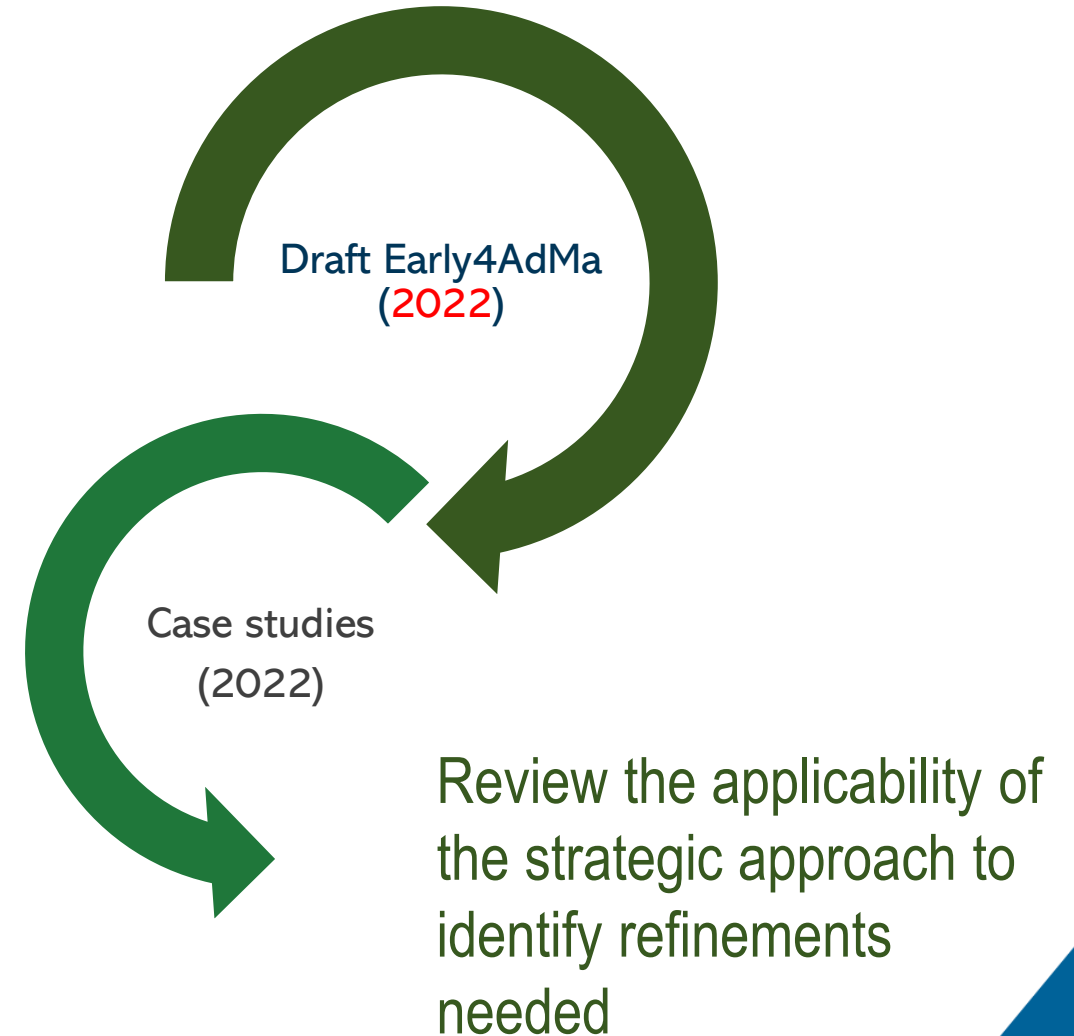
# 1st set of Case Studies



Antibacterial 2D  
Advance Nanomaterials  
(MXenes) Feb 2022



Fiber aerogel mat for  
façade insulation  
Nov. 2022 published







# Early Awareness and Action System for AdMa (Early4AdMa)

Tool in anticipatory risk governance approach to allow for timely decision-making

- Relies on **existing data** and **expert assessment**
- **Step-wise approach:** in two tiers and seven steps
- **Outcome:** report describing the context, potential issues and suggested follow-up actions for a (group) of advanced materials

**Target audience:** Risk assessors and Regulators  
**Exploring** how to extend its use to Innovators and Researchers



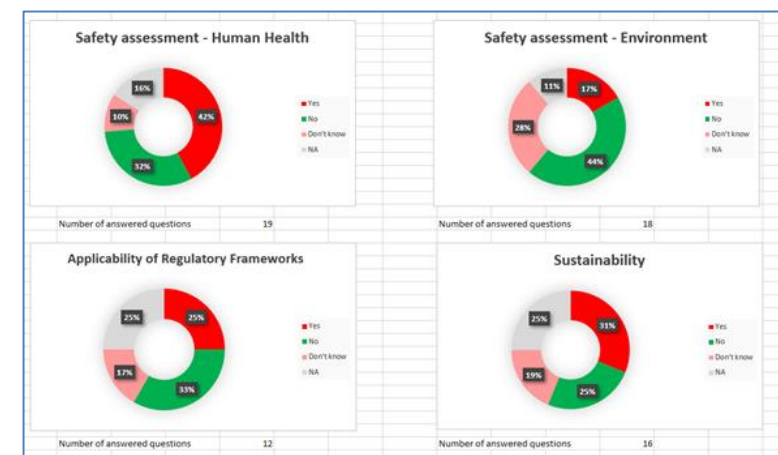
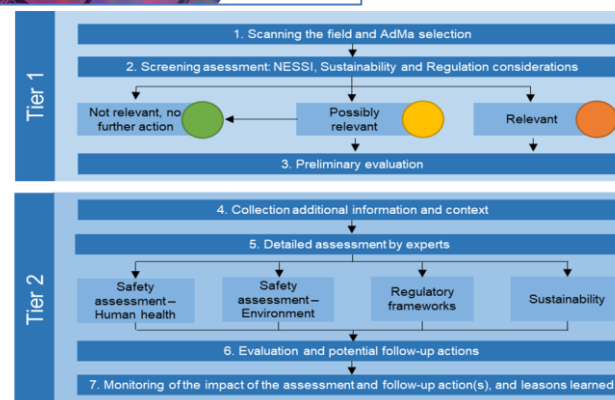
This is the Excel tool accompanying the OECD Early Awareness and Action System for advanced materials (Early4AdMa)\*

### Early Awareness and Action System for advanced materials (Early4AdMa)

#### Step 5: Detailed assessment by experts

Sheet					
1. Safety assessment - Human Health (HH)		The assessment is divided into four major topics (Safety assessment for Human Health, Safety assessment for Environment, Applicability of regulatory frameworks and Sustainability). Each topic is broken down into sub-topics with each sub-topic having multiple questions. Each question can be answered by 'Yes', 'No', 'Don't know' and 'NA'. Please include "X" in the answer box in the Excel sheet.			
2. Safety assessment - Environment (ENV)					
3. Applicability of Regulatory Frameworks					
4. Sustainability (Su)					
5. Summary					

	Sustainability	Yes	No	Don't know	NA	Comments
Raw Material and Resources	high energy, water, or land consumption and/or have an impact on global warming potential (emission of greenhouse gases)?					
	Is a technically feasible and established process for recycling the raw material missing?					
Manufacturing, production, transport and use	Does the process of manufacturing, production, transport, use or consumption require high energy, water or land consumption or have an impact on global warming potential (emission of greenhouse gases)?					
	Do the processes of manufacturing and production include the use of problematic substances?					
	Is waste generated during manufacturing, production, transport or use?					
	Are technically feasible and established possibilities for re-use and recycling of generated waste missing?					
	Does the waste generated during manufacturing, production, transport and use contain problematic					



**Report:** <https://www.oecd.org/chemicalsafety/safer-and-sustainable-innovation-approach/early-awareness-and-action-system-for-advanced-materials-pre-regulatory-anticipatory-risk-governance-tool.pdf>

## Early4AdMa Excel Tool:

<https://www.oecd.org/chemicalsafety/safer-and-sustainable-innovation-approach/early-awareness-and-action-system-for-advanced-materials-tool.xlsx>

Video: <https://youtu.be/Ys-V4C1zWCQ?feature=shared>

Presentation: <https://www.oecd.org/chemicalsafety/safer-and-sustainable-innovation-approach/presentation-webinar-on-early-awareness-and-action-system-for-advanced-materials.pdf>



# Case Studies

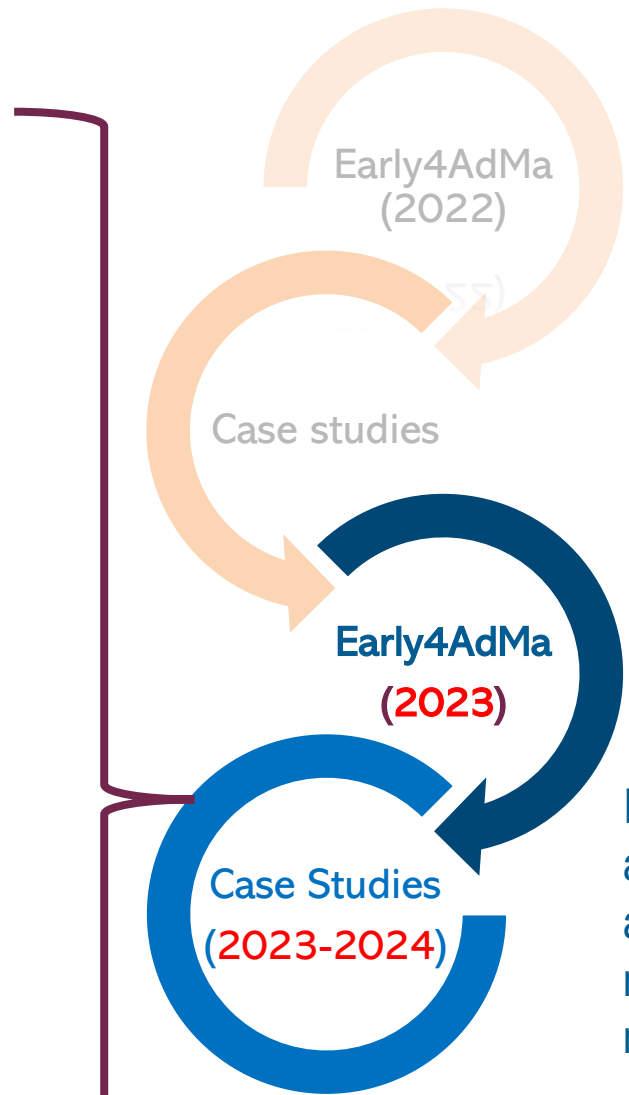
<p><b>WPMN new project: GFMs -Literature Review</b></p>	

**June 2023**  
 Report under review

**Underway**

**June 2024**

**Feb + Sept 2024**



Identification of information needs and warnings on specific AdMas and development of recommendations for action regarding safety and sustainability

- Need to differentiated considerations (carrier vs the cargo (active substance) & vs. those originating from the entirety of the Nanocarrier
- implications for safety mainly originate from the active substance while the contribution of the carrier remains low or unknown
- Need adequate reflection on the origin of the signals in the reporting
- Identified knowledge gaps include toxic potential of the carrier, change in fate/effect of the active substance due to the carrier, resource demand during the whole life cycle, waste considerations during production...
- Only a few regulatory frameworks consider the influence of nanocarrier within their obligations or provide sufficient guidance for assessment (differs between countries/regulatory areas)
- Test methods are needed to investigate and evaluate the extent to which transport/protection via a carrier can influence the fate and effect of (already well studied) active substances

## With regard to the signals identified for Nanocarriers:

- Obtain an overview of ongoing research activities to (1) to fill data gaps and (2) to substantiate the identified signals
- Close remaining data gaps to provide information on
- the influence of the carrier on fate/effects of the active substance resource consumption over the whole life cycle and waste considerations during e.g., production
- Review and amend where necessary affected obligations and assessment guidance

## • **Establish harmonised test methods and analytical methods**

## With regard to the applicability of Early4 AdMa:

- Identify step 5 questions which may afford a differentiated response for the different building blocks of an AdMa to aid cases with similar challenges like for nanocarrier (i.e., cases for which signals are driven mainly by one [non-advanced] component)
- Propose solutions how to deal with such questions while ensuring that the overall assessment relates to the entirety



# Graphene Based Materials: Case Study

Review nature of inputs to be provided by contributors (Spain, Germany, Netherlands, South Africa + Experts involved in the Graphene Flagship)  
framing the case study

Online meeting to advanced material that will be circulated in advanced of the workshop  
February 2024 (6-8 TBC)

Workshop on GBM  
Sept/October 2024



# Nano TG/GDs related publications



<https://www.oecd.org/chemicalsafety/nanomet/>  
[www.oecd.org/env/nanosafety](http://www.oecd.org/env/nanosafety)

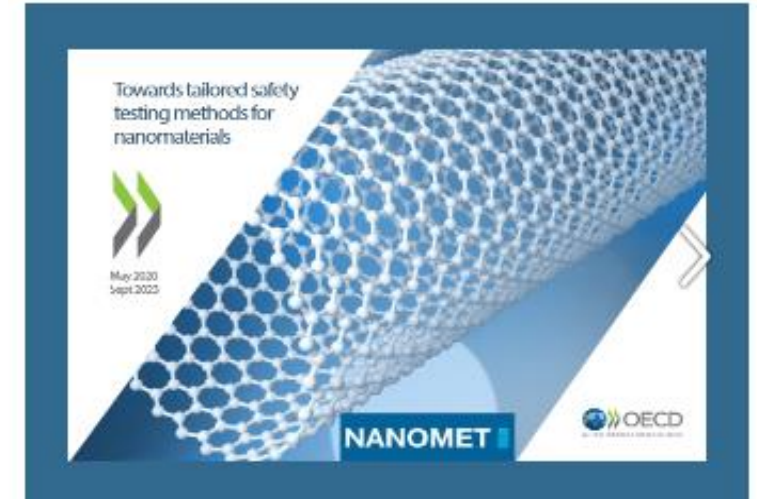
Test Guidelines and Guidance Documents on Nanomaterials

<p><b>TEST GUIDELINE</b></p> <p><b>Test No. 125: Nanomaterial Particle Size and Size Distribution of Nanomaterials</b></p> <p>This Test Guideline, covering nanomaterials spanning from 1 nm to 1000 nm, is intended for particle size and particle size distribution measurements of nanomaterials.</p>	<p><b>TEST GUIDELINE</b></p> <p><b>Test No. 124: Determination of the Volume Specific Surface Area of Manufactured Nanomaterials</b></p>	<p><b>TEST GUIDELINE</b></p> <p><b>Test No. 318: Dispersion stability in simulated environmental media</b></p>
<p><b>GUIDANCE DOCUMENT</b></p> <p><b>Guidance Document on testing Nanomaterials using OECD TG No. 312 "Leaching in soil columns"</b></p>	<p><b>GUIDANCE DOCUMENT</b></p> <p><b>Guidance document No. 318: Solubility and dissolution rate</b></p>	<p><b>GUIDANCE DOCUMENT</b></p> <p><b>Guidance document No. 317: Aquatic and sediment ecotoxicity testing</b></p>

Tools, Validation and Study Reports

<p><b>STUDY REPORT</b></p> <p><b>Study Report on Applicability of the Key event-based TG 442</b></p>	<p><b>INTERLABORATORY</b></p> <p><b>Study Report on a test for removal in wastewater of treatment plants of gold manufactured nanomaterial</b></p>	<p><b>INTERLABORATORY</b></p> <p><b>Report of the interlaboratory comparison testing for the GD to support implementation of Test Guideline No. 312 for Nanomaterial safety testing</b></p>
<p><b>VALIDATION REPORT</b></p> <p><b>Validation report supporting Test Guideline 318</b></p>	<p><b>VALIDATION REPORT</b></p> <p><b>Validation report supporting TG 125</b></p>	<p><b>TOOL</b></p> <p><b>Tool accompanying guidance document No. 318</b></p>
<p><b>STUDY REPORT</b></p> <p><b>Study Report and Preliminary Guidance on the Adaptation of the In Vitro micronucleus assay (OECD TG 457)</b></p>	<p><b>Missed our past events? Watch the video recordings</b></p> <ul style="list-style-type: none"><li>› Webinar: Particle Size and Size Distribution of Nanomaterials: OECD Test Guideline 125 (7 February 2023) Access the presentations.</li></ul> <p>The recording is available in Spanish.</p> <ul style="list-style-type: none"><li>› International NanoHarmony and NANOMET Workshop on nano-related OECD Test Guideline Development (29 and 30 June 2022) Watch the live stream (Day 1 - Day 2).</li><li>› Webinar: Assessing the dispersion stability and dissolution rate of nanomaterials in the environment (25 February 2021) Presentations:<ul style="list-style-type: none"><li>- Introduction</li><li>- Test Guideline No. 318: Dispersion Stability of Nanomaterials in Simulated Environmental Media and its accompanying Guidance Document</li></ul>The recording is available in Spanish.</li><li>› Webinar: Guidance document No. 317 on aquatic &amp; sediment ecotoxicity testing of nanomaterials (26 January 2021) Presentations:<ul style="list-style-type: none"><li>- Introduction</li><li>- Guidance Document 317 on Aquatic and Sediment Ecotoxicity Testing of Nanomaterials</li></ul>The recording is available in Spanish.</li></ul>	

Read our brochure



**Webinar on Test Guideline No. 126: Determination of the Hydrophobicity Index of Nanomaterials Through an Affinity Measurement**

**WHEN: 20 September 2023**  
**14:00 - 15:30 CEST**  
**08:00 - 09:30 EDT**



# Safe(r) and Sustainable Innovation Approach

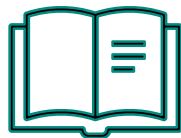
Dedicated public page: <https://oe.cd/ssia>

The screenshot shows the OECD website interface. At the top, there is the OECD logo and navigation menus for 'OECD Home', 'About', 'Countries', 'Topics', and 'COVID-19'. A search bar is also visible. The main content area features a large image of a hand holding a glowing orb with icons, titled 'Safe and sustainable innovation approach for advanced materials'. Below this, there is a 'Latest news' section with a smaller version of the same image and a 'Download the brochure (PDF)' link. A paragraph at the bottom describes the development of advanced materials and the need for suitable risk assessment tools.

The infographic is titled 'Safe(r) and Sustainable Innovation Approach (SSIA)'. It includes a section 'WHAT IS SSIA?' which states that the approach seeks to enhance the ability of all stakeholders to address safety and sustainability assessment of innovations. It lists two key concepts: 'Safe(r)-and Sustainable-by-Design (SSbD)' and 'Regulatory Preparedness (RP)'. A central diagram shows a cycle between 'Safe(r) and Sustainable by Design (SSbD)', 'Safety, Sustainability, Innovation', and 'Regulatory Preparedness (RP)', all leading to a 'Trusted Environment' at the bottom.

Webinar on Safer and Sustainable Innovation Approach for More Sustainable Nanomaterials and Nano-enabled Products  
WHEN: 3 November 2022  
14:30 - 16h30 CET  
09:30 - 11h30 EDT  
OECD

Webinar on Early Awareness and Action System for Advanced Materials (Early4AdMa)  
WHEN: 4 October 2023  
13:30 - 15:30 CEST  
07:30 - 09:30 EDT  
OECD



[OECD \(2022\) Sustainability and Safe and Sustainable by Design: Working Description for the Safer \(and Sustainable\) Innovation Approach.](#)  
[OECD \(2020\) Moving Towards a Safe\(r\) Innovation Approach \(SIA\) for More Sustainable Nanomaterials and Nano-enabled Products](#)



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**Thanks**