

OECD Test Guidelines for Nanomaterials



Support and future steps towards TG development by
Malta Initiative and NanoHarmony

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NanoHarmony



Our vision



OECD Test Guidelines fit for the future



Safe and Sustainable Europe





Start of Malta Initiative in June 2017

To fill the gaps of missing Test Guidelines for nanomaterials in REACH.

- Ensuring that nanomaterial safety regulation keeps pace with innovation
- Strengthening European and international cooperation
- Setting priorities in TG developments
- Involving all stakeholders
- Initiating activities

What is the Malta Initiative?

- Malta Initiative – is a network of international experts that advocates for appropriate test methods (first step: for nanomaterials).
- Malta Initiative works on a voluntary basis without any official mandate.
- Malta Initiative addresses the importance of internationally harmonised and standardised testing and measurement methods.

European Test Methods Strategy



is promoted by the

Malta Initiative Position Paper to
Support safe and sustainable innovation
- Help overcome trade barriers - Make legislation enforceable

MALTA
INITIATIVE

and is supported by



Bundesanstalt für
Materialforschung
und -prüfung

Federal Ministry
Republic of Austria
Climate Action, Environment,
Energy, Mobility,
Innovation and Technology



Federal Ministry
of Labour and Social Affairs



National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

National Research Centre
for the Working Environment

Umwelt
Bundesamt

Federal Ministry
for Economic Affairs
and Climate Action



Department
for Environment
Food & Rural Affairs

b a u a :
Federal Institute for Occupational
Safety and Health

CESAM
CENTRE FOR
ENVIRONMENTAL AND
MARINE STUDIES

universidade
de aveiro

UNIVERSITY OF
BIRMINGHAM

NIA
Nanotechnology
Industries Association

BUSINESSatOECD

Ministry of Infrastructure
and Water Management
of the Netherlands

BUILDING
TRUST LNE

NanoFabNet
sustainable High-Tech Innovation

ecetoc
KEMI
Swedish Chemicals Agency

Status November 2023

The European Test Methods Strategy



includes:

- funding of researchers for the **development, validation and harmonization of test methods**
- an **international platform** for collaboration and exchange between stakeholders to:
 - identify endpoints, methodological gaps and related methods ready for validation and harmonisation,
 - support international collaboration between researchers, regulators and industry in Test Guideline development,
 - ensure the development of test methods that are operable and useful in (pre-) regulatory and scientific testing,
 - increase the likelihood of effective adoption and implementation by the OECD Member Countries.

The Malta Initiative Position Paper - Conclusions



- Adaptation and development of test methods require **intensive effort** (in terms of time, human and financial resources)
 - Individual researchers, industrial actors or EU Member States **cannot undertake the challenge of TG development alone**
 - A **coordinated approach** can be more effective and avoids duplication of work
- A **strong European financial support** is needed to support the validation and harmonisation of test methods and coordinate the efforts towards OECD Test Guideline development

The NanoHarmony project

NanoHarmony



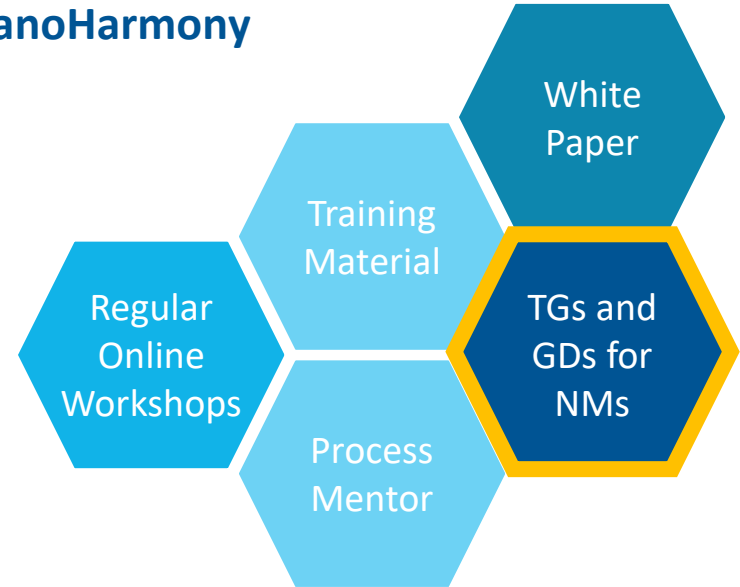
WP1: Develop and validate
Test Methods for
OECD TGs/GDs

WP2: Formation of a network
to interact with
all relevant stakeholders

WP3: Develop a structure
to translate science into
test methods used in regulation



The NanoHarmony legacy



to support (future) OECD TG developments
also beyond the field of nanomaterials





Physical Chemical Properties

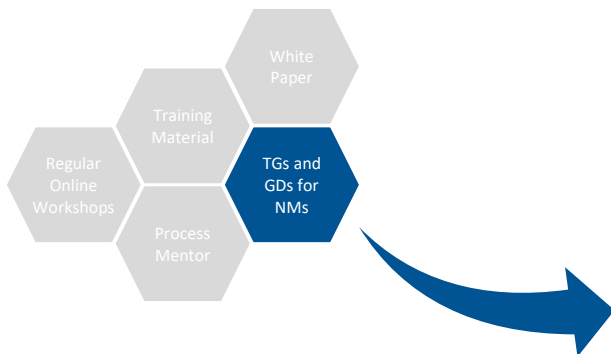
- GD on determination of **solubility and dissolution rate** of nanomaterials in water and relevant synthetic biological media **(DK/DE) TGP Project 1.5**
- GD on identification and quantification of the **surface chemistry** and coatings on nano- and microscale materials **(DK/DE) TGP Project 1.6**
- TG on determination of the **dustiness** of manufactured nanomaterials **(FR/DK) TGP Project 1.8**
- GD on the determination of **concentrations of nanoparticles in biological samples** for (eco)toxicity studies **(UK) TGP Project 1.10**

Human and Environmental Hazards

- Scoping review for a **tiered approach for reliable bioaccumulation assessment** of MNs in environ. organisms minimising use of higher tier vertebrate tests **(UK) WPMN project**
- TG on **toxicokinetics** to accommodate testing of nanoparticles **(NL/UK) TGP Project 4.146**
- Integrated **in vitro approach for intestinal fate** of orally ingested nanomaterials **(IT) TGP Project 4.158**
- Revision of GD 317 to provide **further guidance on conducting assays with manufactured nanomaterials** according to **OECD TG 201, 202, 203 (FR/ES) TGP Project 2.71**

→ NanoHarmony and NANOMET status report accessible via nanoharmony.eu and oe.cd/nanomet





- Validation studies and their implementation in the OECD documents will be finished
- Exchange with the OECD and expert group will be kept active
- Commenting rounds will be started

Section 1 Physical Chemical Properties	Section 2 Effects on Biotic Systems	Section 3 Env. Fate and Behaviour	Section 4 Health Effects
<p>GD on determination of solubility and dissolution rate of nanomaterials in water and relevant synthetic biological mediums (DK/DE) TGP 1.5</p> <p>GD on identification and quantification of the surface chemistry and coatings on nano- and microscale materials DK/DE) TGP 1.6</p> <p>TG on determination of the dustiness of manufactured nanomaterials (FR/DK) TGP 1.8</p> <p>Development of a new GD on the determination of concentrations of nano-particles in biological samples for (eco)toxicity studies (UK) TGP 1.10</p>	<p>Revision of GD 317 on Aquatic Toxicity Testing of Nanomaterials (ES/FR) TGP 2.71</p>	<p>Scoping review for a tiered approach for reliable bioaccu. assess. of manufactured nanomaterials in environ. organisms minimising use of higher tier vertebrate tests (UK) WPMN Project</p>	<p>New TG on toxicokinetics to accommodate testing of nanoparticles (NL/UK) TGP 4.146</p> <p>GD on integrated In vitro approach for intestinal fate of orally ingested nanomaterials (IT) TGP 4.158</p>

➤ **Finish the OECD documents for NMs testing by 2025**



The NanoHarmony project

NanoHarmony



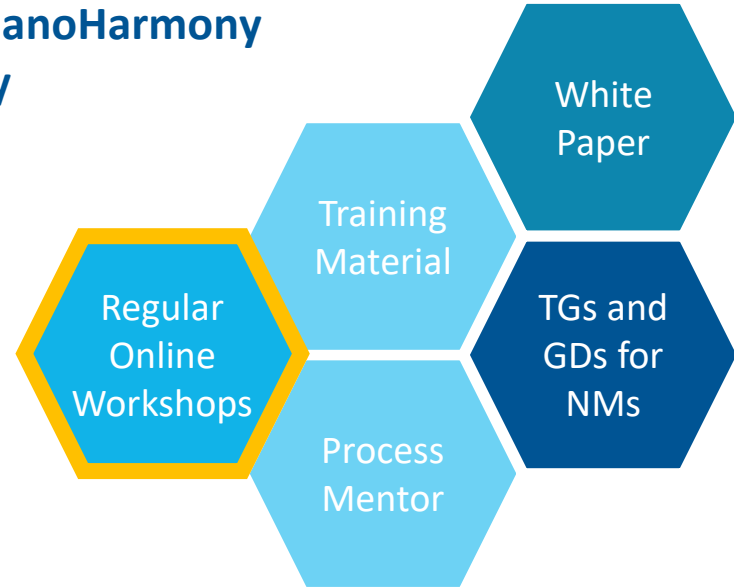
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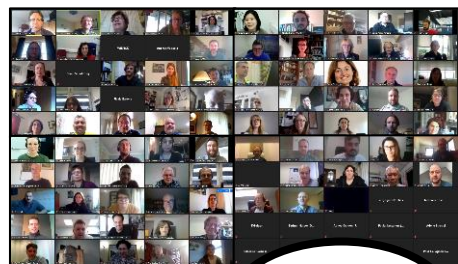
The NanoHarmony legacy



to support (future) OECD TG developments
also beyond the field of nanomaterials



Formation of a network to interact with all relevant stakeholders



1st online Workshop

2nd online Workshop

Joined Workshop at OECD

NanoHarmony Policy Meeting

3 Webinars

2 Webinars

3 Webinars

3rd online Workshop

4 6 8 10 12 2 4 6 8 10 12 2 4 6 8 10 12 2 4 6 8

2020

2021

2022

2023



Continuing the NanoHarmony NANOMET journey:
**Harmonisation & Standardisation of Test Methods
for Nanomaterials and Advanced Materials**

Two Days focused on the Standardisation Roadmaps for *in vitro* Models and Graphene

*** ONLINE ***

22. – 23. November 2023, 10:00 – 15:15 CET

The NanoHarmony project

NanoHarmony



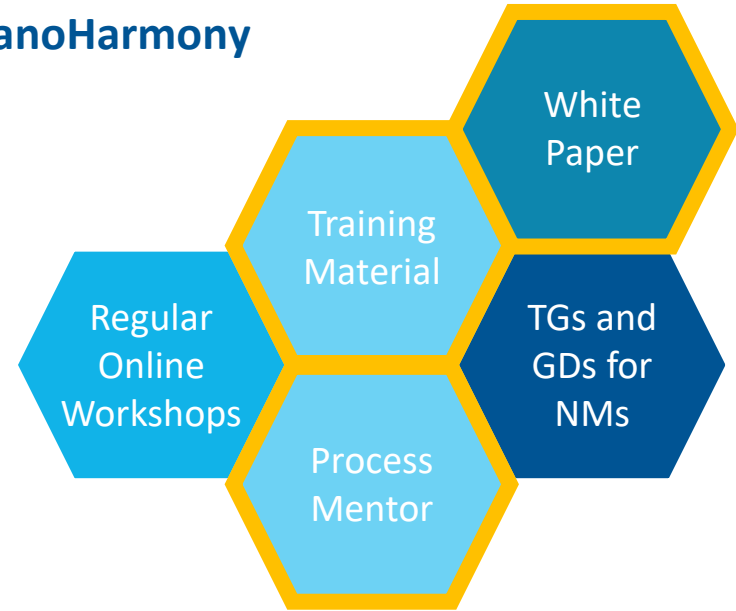
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to support future OECD TG developments
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Objectives of the Process Mentor and the Training Material



- Raise awareness for the importance and the **benefits of harmonised test methods**
- Inform about essential steps throughout the **OECD Test Guideline development process**
- Inform on the **OECD, its relevant committees**, and the importance of the National Coordinators
- Show possibilities and **benefits for active participation of various stakeholders**
- Provide insights in the **scientific and political barriers** of this process
- Provide an understanding of the **complexity and time scales**
- Help users and trainees understand how they can contribute to the OECD Test Guideline process, either by using Test Guidelines in their work, contributing to Test Guidelines under development or by **bringing their science forward** as a new or updated Test Guideline



The NanoHarmony Training Material One Training – Four Modules



1. Importance of standardised and harmonised test methods

What are harmonised test methods, why are they relevant and what are resulting benefits?
How can my science contribute to an OECD Test Guideline?
How are standards and harmonised test methods used?
How does OECD fit in with other standardisation activities?

2. The OECD and its relevant committees

What is the OECD and which committees are relevant?
What is the political structure of the OECD?
Who are National Coordinators?

3. The different documents in the OECD Test Guidelines Programme

What are the different OECD documents?
What are advantages of getting involved in their development?

4. The process of development of OECD documents

How is the OECD Test Guideline development process structured?
Which stakeholders are involved in the development/revision/adaptation of OECD TG/GDs?
How can stakeholders get engaged in the process?

Slides from different modules can be combined and thereby the Training Material presentation can be tailored according to the purpose.



The NanoHarmony OECD TG/GD Process Mentor



www.testguideline-development.org

Web based tool with multiple entrance paths:

- By roles or institutions
- By phases or processes
- By useful resources

NanoHarmony
OECD TG/GD Process Mentor

About Roles Institutions Phases Processes Useful resources Q

NanoHarmony OECD TG/GD Process Mentor

The NanoHarmony Process Mentor provides guidance and understanding on developing OECD Test Guidelines (TGs) and Guidance Documents (GDs), including when and how to prepare for required activities, highlighting key start and finish dates of the development process, plus who to involve in which activities and when.

TG/GD developers can enter the tool by using the navigation menu (always displayed at the top of the web pages) or by clicking directly on the clickable items of this home page and other pages. Links and interlinks will then allow you to navigate within the tool toward relevant information.

An introduction to the process at the OECD is available from the "Useful resources" section of the tool (link below). Enjoy your learning journey on the key phases, roles and institutions involved in the OECD standards development process.

Find out more →

Roles in OECD TG/GD Process

Lead as Member Country
Project Lead Institution
Participate & Comment

- 1 Standardisation Bodies
- 2 General Public & NGOs
- 3 Governmental Bodies
- 3 Academia
- 2 Industry & Service Providers

Useful resources

- Introduction to OECD & standardization
- FAQ
- Key links
- Glossary

The NanoHarmony White Paper - From Science to Test Guidelines

NanoHarmony



Issues addressed:

- Communication and exchange of information
- Ensure up to date OECD Test Guidelines
- Engage the scientific community in the process, besides others
- Validation of new test methods
- Funding for activities towards Test Guidelines development



<https://nanoharmony.eu/white-paper/>



The NanoHarmony White Paper – Recommendations Summary



NanoHarmony recommendations are aimed at

- **a greater support** towards a more efficient OECD Test Guidelines development process
 - improving **managing the greater pace of innovation** in new chemicals and materials with appropriate TGs
-
- Need for **interactions** between all different stakeholders **in a structured way**
 - Need for **easily accessible information and education** on the Test Guidelines development process
 - Need for **a more structured funding** to allow up-to-date Test Guidelines that are fit-for-purpose



And now...



- There is no direct follow up project after NanoHarmony
- "The development and adaption of OECD TGs for nanomaterials is a marathon. We only covered 1/4 so far." *Wim de Coen (ECHA)*
- New challenges are upcoming due to new/ advanced materials
- We need to integrating new methods into Test Guidelines

We need your support to keep and increase the effort in TG developments for nano and advanced materials!



Malta Priority List



Defining priorities for making OECD TGs/GDs applicable for nano and advanced materials:

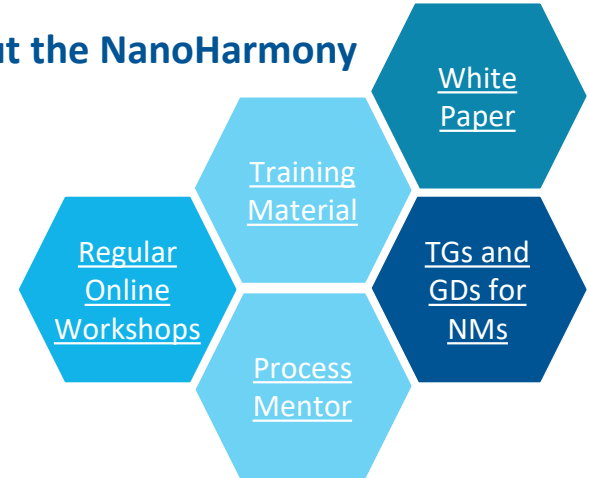
- Highlight the importance of these activities
- Provide guidance for decision makers towards funding
- Guide and encourage scientists to support work towards OECD
- Collect sources to support the activities
- Support the work at OECD

[LINK to survey](#)

Thank you to the NanoHarmony team!



Check out the NanoHarmony legacy...



... and contribute to the survey!

