

Making OECD Test Guidelines applicable for Nanomaterials and Advanced Materials – Activities by the Malta Initiative and MACRAMÉ

[Elisabeth Heunisch](#)¹, [Eric Bleeker](#)², [Dirk Broßell](#)¹, [Fanny Caputo](#)³, [Georges Favré](#)³, [Alberto Katsumiti](#)⁴, [Sean Kelly](#)⁵, [Iseult Lynch](#)⁶, [Marianne Matzke](#)⁷, [Anna Pohl](#)¹, [Isabel Rodríguez-Llopis](#)⁴, [Tommaso Serchi](#)⁸, [Blanca Suarez-Merino](#)^{5,9}, [Steffi Friedrichs](#)¹⁰

1. Introduction

Since 2017 the Malta Initiative has been working to update OECD Test Guidelines (TG) and Guidance Documents (GD). This work aims to ensure that TGs/GDs are applicable to nanomaterials and (other) advanced materials. OECD TGs are essential for industry and regulatory authorities involved in the testing and evaluation of chemicals. They help to ensure that legislation works.

2. The Malta Initiative Priority List

Ensuring that innovations in materials can come to the market and comply with regulations is important. This requires collaboration between experts from science, industry and authorities to set priorities for which test methods are required. In March 2024, the Malta Initiative released its Priority List¹¹. This list will help ensuring that the required harmonised methods will become available in the near future for nanomaterials and (other) advanced materials.

The Malta Initiative Priority List is a list of prioritised actions to support the development and amendment of OECD TGs for nanomaterials and (other) advanced materials. It has the following aims:

- Helping make legislation implementable and supporting industry in effective regulatory compliance;

¹ Federal Institute for Occupational Safety and Health, Germany (BAuA)

² National Institute for Public Health and the Environment, The Netherlands (RIVM)

³ French National Metrology and Testing Laboratory, France (LNE)

⁴ GAIKER Technology Centre, Basque Research and Technology Alliance (BRTA), Zamudio, Spain

⁵ Nanotechnology Industries Association aisbl, Belgium (NIA)

⁶ University of Birmingham, UK (UoB)

⁷ European Chemicals Agency, Finland (ECHA)

⁸ Luxembourg Institute of Science and Technology, Luxembourg (LIST)

⁹ TEMAS Solutions GmbH, Switzerland

¹⁰ AcumenIST, Belgium (AIST)

¹¹ <https://malta-initiative.org/what/#MI-Priority-List>

- Providing guidance to funders for the support required for the next generation of Test Guidelines;
- Encouraging scientists to develop the required methods and bring them through to OECD Test Guidelines; and
- Supporting the ongoing work of all Member Countries of the OECD relating to chemical safety.

3. MACRAMÉ contributions towards harmonisation and standardisation

The Horizon Europe project MACRAMÉ¹² develops advanced characterisation methodologies to assess and predict the health and environmental risk of advanced materials. MACRAMÉ focuses on inhalable carbon-based advanced materials, e.g. graphene-related materials and carbon nanofibers. The project aims to provide methodologies to assess the risk of these materials within a product matrix along the life cycle. MACRAMÉ identified 5 areas of test method development. For each of these roadmaps for harmonisation and standardisation were prepared.

The project therefore supports a number of the priorities identified in the Malta Initiative Priority List. Examples include the harmonisation and standardisation of specific dispersion protocols for graphene related materials for (eco-)toxicity testing. Other methods aim at detection of carbon-based materials in complex media, aerosol generation for inhalation studies, and in vitro/ex vivo models for inhalation toxicity testing.

4. Conclusions

The Malta Initiative Priority List clearly shows that the activities for making OECD TGs applicable for nanomaterials is still ongoing. Further research on safety testing for nanomaterials and (other) advanced materials is still needed. Researchers are encouraged to focus their attentions on the priorities identified. This should lead to advancing their research towards method validation, standardisation and harmonisation.

5. Funding

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¹² <https://macrame-project.eu/>