

Governance brief **1**

IMPORTANCE OF STANDARDISATION AND HARMONISATION OF TEST METHODS AND OF A STREAMLINED KNOWLEDGE TRANSFER FROM SCIENCE TO REGULATION

Gaps and recommendations for safety and health
regulatory research concerning nanomaterials

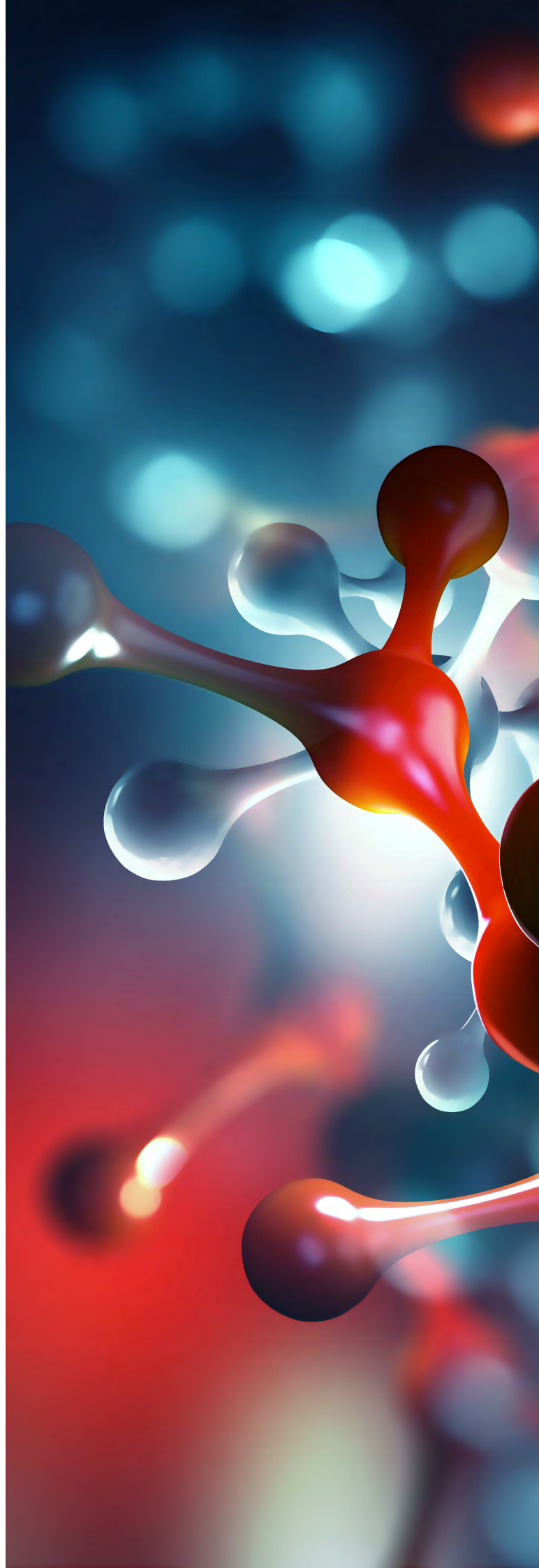


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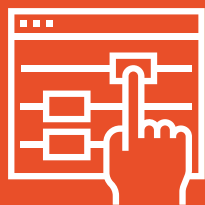
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INTRODUCTION



This brief provides a synthesis of critical gaps and roadblocks, and recommendations on ways forward about standardised and harmonised test methods for the safety of nanomaterials and nano-related products, intended for use by regulators, scientists, and industries. The ambition of this document is to inform about how a streamlined knowledge transfer from science to regulation and vice versa could look like and what is required for future-proof OECD Test Guidelines (TGs) and standards.

The brief is an outcome of four years of research activity on the topic of four European projects, including consultation of a wide range of experts in the field, including several health and safety authorities across Europe and worldwide. Details on the methodology are reported in Gov4Nano deliverable 5.6: Report on case studies for Risk Governance available on www.gov4nano.eu.

It is part of a series of initiatives organised by **Gov4Nano** in cooperation with the **RiskGONE** and **NANORIGO** projects with contributions provided by **NanoHarmony**, to discuss governance issues in the development of nanomaterials, with the goal to promote the safety and sustainability of innovation in nanomaterials in Europe.

BACKGROUND



Innovation is a key driver towards challenges facing humanity. Regulation has to keep pace with innovation to assure a safe and trustworthy development of new techniques and materials. In order to make regulation enforceable, standardised and harmonised test methods are essential. It is particularly important to have test methods ready and up to date that are applicable to the respective materials, usable to test for the required endpoints and operable by testing laboratories and industries.

Nanomaterials are a prime example for the need of applicable, usable and operable test methods. Nanomaterials possess new properties and pose challenges on existing test methods for the assessment of substance safety due to the complexity of the analysis and data interpretation. In the case of nanomaterials, it is known that existing test methods are not always applicable and methods to test for various endpoints are missing or should be updated.

When carried out in accordance with Principles of Good Laboratory Practice, OECD Testing Guidelines (TGs) are internationally accepted through the mutual acceptance of data (MAD) and, hence, one test is accepted everywhere by OECD Member countries and associated countries. A [status report](#) on OECD

TG and Guidance Document (GD) developments for nanomaterials was recently published by the NanoHarmony and NANOMET projects. These test methods provide businesses certainty of acceptance of test results, minimize animal tests and support further innovation in the development of safe chemicals and products.

Testing via standards enables to obtain experimental data that are comparable among different laboratories, allow for smooth international cooperation and facilitate the training on experimental setups by following the standardised and harmonised protocols.

The 'Malta Initiative', where 18 European countries, several Directorates-General of the European Commission, the European Chemicals Agency (ECHA), authorities, research institutions, NGOs, universities and industry work together on a voluntary and self-organised basis, has the aim to support OECD TG developments for nanomaterials. The need for additional TGs was addressed and funding towards the development of the scientific basis for new or amended TGs was provided within the Horizon 2020 NMBP-13 and NMBP-34 calls. The three projects Gov4Nano, RiskGONE and NANORIGO were funded within the NMBP-13 call. NanoHarmony and NANOMET were funded within the NMBP-34 call. One main objective of Gov4Nano, RiskGONE and NanoHarmony is to develop harmonised test methods for characterisation and testing of nanomaterials. This included the establishment of the scientific basis for several OECD documents and a series of interlaboratory comparison studies. Furthermore, overviews of ongoing regulatory and standardisation initiatives as well as gap analyses of missing test methods were developed in Gov4Nano and NANORIGO. However, there is still the need for additional test method developments, including New Approach Methodologies (NAMs), related to the characterisation, identification and hazard assessment of nanomaterials. Additionally, future, advanced materials will probably pose further, not yet foreseeable challenges on the test methods.

KEY ELEMENTS TOWARDS A STREAMLINED KNOWLEDGE TRANSFER



Besides the establishment of scientific knowledge that is of relevance for regulatory purposes, the experience in the three NMBP-13 and the two NMBP-34 projects showed that there are additional factors and requirements that are tremendously important for a successful development of standardised and harmonised test methods.

EXCHANGE BETWEEN SCIENTISTS, REGULATORS AND USERS OF TEST METHODS



Bringing all stakeholders together and assuring the regular exchange between them is of great importance for an improved knowledge exchange. Especially the communication between science and regulation is needed for bringing scientific developments to the regulatory arena and for informing about the regulatory needs. Regulators can inform about the regulatory needs and future topics to be addressed. This information can help safety research to define and explore new areas of research and can encourage scientists to work towards development of standards and TGs. The exchange of scientists and regulators with test methods users such as industries and especially testing laboratories furthers the mutual understanding, enables to develop test methods that are operable and fulfil the regulatory requirements.

INTERNATIONAL COOPERATION



When developing the scientific basis for standardised and harmonised test methods, international cooperation is essential. The exchange between international stakeholders ensures the test method to be applicable under different world-wide conditions and usable for different regulatory purposes. Especially the OECD TGs fall under the MAD agreement and thereby enable the acceptance of the obtained data in all OECD Member countries. For adoption of TGs, consent and acceptance by all OECD Member countries is mandatory.

FLOW OF INFORMATION ON THE TEST METHOD DEVELOPMENT PROCESS



Since the process of test method development is a time consuming and complex succession of different steps, knowledge about the important steps and the potential challenges of these steps is pivotal. Knowledge of the OECD process for the development of TGs can be provided by the regulators as well as the OECD committees. Many scientists are new to the area of standardisation and harmonisation of test methods when they start getting involved in this field. Here a comprehensive training and a streamlined flow of information would help to accelerate the test method development and to assure that all essential steps are fulfilled, and all stakeholders are informed.

FUTURE ASPECTS AND THE WAY FORWARD



The progress in building a network and trusted environment made within the NMBP-13 and NMBP-34 projects, together with all stakeholders involved, is an important achievement to maintain and to expand on. Within the project Gov4Nano, it was shown that the developments of the scientific basis for new or amended harmonised test methods were strongly supported by the establishment of a close exchange between the different international stakeholders. This exchange also reduced potential language barriers between scientists and regulators. For future developments of standardised and harmonised test methods, a strong, long-lasting, world-wide network between all stakeholders supported by a permanent platform on risk governance is required.

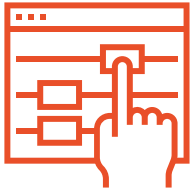
Coordination of the different test method developments and activities in the NMBP-13 and NMBP-34 projects towards OECD, showed a tremendous effect towards streamlining the process of OECD TG development. On the one side, potential overlaps or gaps in the development of the scientific

basis were identified and knowledge about topics that are of interest for many test method developments (e.g., solubility) was combined and shared between the test method developers. World-wide cooperation was established and thereby an effective knowledge transfer was built. On the other side, the coordination of the different TG developments facilitated the communication between the developers and the OECD committees, reduced the workload of the respective experts and committees and, thereby, sped up the process and clearly improved the acceptance by the OECD Member countries.

In Gov4Nano the development of the scientific basis for the respective test methods under development is led by the country, that is the lead for the respective project at OECD WNT level (working group of national co-ordinators of the TGs programme). Since Gov4Nano brought together many different partners involved in TG developments, exchange of experiences and knowledge on the TG development process was shared and communicated. Informing scientists about the complex process of TG developments and helping with the strategic and important steps of this process increased the willingness of scientists to work towards OECD TG developments. This improved the output of the EU projects towards OECD, while creating an additional value for European funding.

The experience within the different projects showed that three years of funding is not long enough to bring 'proof of concept' methods towards fully standardised and harmonised test methods. Funding for the development of harmonised test methods accepted by countries, e.g., in the framework of OECD, is seen essential.

FINAL REMARKS



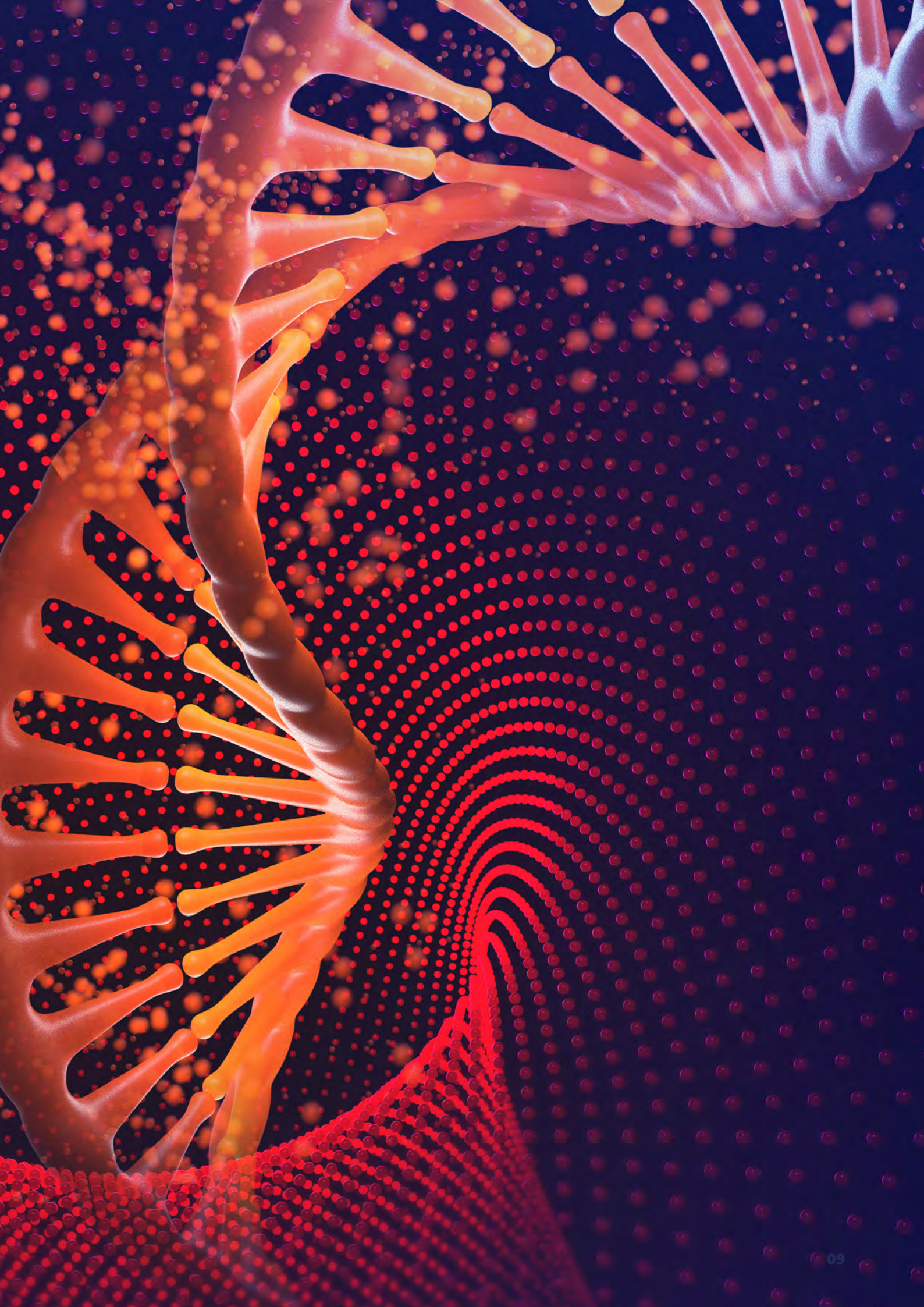
In summary, to keep standardised and harmonised test methods up to date and ready for future needs, the following is needed:

- **Dedicated funding to validate and standardise/ harmonise test methods.**
- **Continuous efforts in TG updating and development to cover new approaches and materials in test methods.**
- **A platform on risk governance for sharing knowledge and information between international stakeholders.**
- **Easy accessible information on the standardisation and harmonisation processes to prepare for the time-consuming process from Standard Operating Procedures (SOPs) to accepted OECD TGs and standards.**

KEY REFERENCES



- **Organisation for Economic Co-operation and Development (OECD)**
<https://www.oecd.org/>
- **Malta Initiative webpage**
<https://malta-initiative.org/about/>
- **Mutual Acceptance of Data (MAD)**
<https://www.oecd.org/chemicalsafety/testing/mutualacceptanceofdatamad.htm>
- **OECD Test Guideline Programme**
<https://www.oecd.org/chemicalsafety/testing/oecd-guidelines-testing-chemicals-related-documents.htm>
- **OECD Guidelines for the Testing of Chemicals**
https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals_72d77764-en
- **Series on the Safety of Manufactured Nanomaterials**
<https://www.oecd.org/chemicalsafety/nanosafety/publications-series-safety-manufactured-nanomaterials.htm>
- **Status report on OECD TG and GD developments for nanomaterials was recently published by NanoHarmony and NANOMET**
<https://nanoharmony.eu/2022/10/18/report-available/>



Brief: Importance of standardisation and harmonisation of test methods and of a streamlined knowledge transfer from science to regulation

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Other briefs of the series available on: www.gov4nano.eu



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