

# From Science to Regulation – The NanoHarmony White Paper on Test Guideline Development

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## 1. Introduction

International agreement on harmonised and standardised methodologies to test and characterise chemicals and innovative, advanced (nano)materials is essential to protect human health and the environment as well as to ensure sustainability. The OECD Mutual Acceptance of Data (MAD) agreement [1] has clearly demonstrated the benefits of such an international approach. An important cornerstone under the MAD agreement is a set of OECD Test Guidelines for Chemicals (TGs) [2]. These TGs are referred in several legislations (e.g. in Europe [3]).

The European project NanoHarmony ([www.nanoharmony.eu](http://www.nanoharmony.eu)) supported the development and adaption of several different OECD TGs to ensure applicability for nanomaterials. The team also analysed processes in TG development to identify hurdles and (unnecessary) delaying factors. This analysis identified issues in OECD TG development in general. The main output is collected in the NanoHarmony White Paper [4].

## 2. Ensure OECD TGs remain up to date

For the MAD agreement to remain effective, OECD TGs need to remain up to date and fit for purpose. They need to keep pace with new scientific and/or industrial developments and innovations. Also new and future regulatory needs may require new/adapted test guidelines. To allow up-to-date TGs requires an effective strategy for

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prioritising, initiating, and coordinating TG developments and the funding for these activities.

In a Position Paper [5] the Malta Initiative (MI) identified the need for a formal and continuous structure to accommodate this. They proposed to continue and expand their activities in a so-called 'European Test Methods Strategy'. The MI advocated that such a strategy should include funding of researchers for the development, validation, and harmonisation of test methods. At the same time, it can provide an international (global) platform for collaboration and exchange between stakeholders (researchers, regulators, industry, etc.).

#### **NanoHarmony recommendations to ensure OECD Test Guidelines remain up-to-date**

- Establish a formal structure for stakeholder engagement to allow a continuous early identification of required new or adapted OECD Test Guidelines.
- The European Commission, Member States and stakeholders should support the Malta Initiative's European Test Methods Strategy as proposed in its position paper.

### 3. Engage the scientific community

Many methods developed in the scientific domain will not reach the status of a harmonised and standardised test method. This limits or even prevents their use in regulatory setting.

Awareness of the steps and timing of the OECD process is an obvious benefit for projects aiming to deliver OECD TGs. An educational process is recommended to accommodate this. Such education could also provide broader skills on metrology and documentation.

TG development generally takes 5-7 years, resulting in a substantial risk of scientists moving out of the project and the specific field. Improvement on the FAIRness of research and data (including descriptions of methods used) can mitigate against the potential loss of knowledge and data.

#### **NanoHarmony recommendations to engage the scientific community**

- OECD Member Countries should encourage universities, professional societies, industry sector bodies and other relevant stakeholders to include Test Guideline development in their curricula and training to help raise awareness of the role and importance they play in society.
- Funding agencies in OECD Member Countries should encourage and support the scientific community to improve the FAIRness of their research and data.

### 4. Validation of methods

Validation is key to the successful development of new methods. It enables confidence and trust in the methods and the data generated by using these methods. This requires that once methods are developed, they need extensive validation. OECD Guidance Document No. 34 [6] provides information on these validation aspects. Nevertheless, many stakeholders have difficulties in finding the relevant information.

#### **NanoHarmony recommendations on validation of methods**

- OECD and its Member Countries should encourage and support the validation of scientific research, e.g. by providing guidance and tools for researchers over and above that contained in OECD Guidance Document 34.

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- The National Coordinators of lead countries for a Test Guideline in development should help ensure effective and efficient communication with all relevant stakeholders during validation and ensure that discussions and decisions are captured and shared.
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## 5. Funding TG development

Obviously, test method development requires funding. While finding funding will remain challenging, investments now can save resources in the future.

Many of the projects on method development finish before (pre-)validation activities or further formalisation into a harmonised TG can actually start. Consequently, many (financial) efforts in method developments may have been in vain.

Apart from funding for validation, additional resources are needed as well. These include reaching agreement with experts and drafting a TG. Such resources may not be immediately available under current financing schemes.

### NanoHarmony recommendations on funding TG development

- OECD Member Countries should provide long-term, dedicated additional funding to help ensure that TGs are kept up-to-date and relevant to regulatory requirements, especially for new chemicals and materials, ensuring a prioritised and focussed approach.
  - OECD Member Countries should encourage and (financially) support the translation of scientific progress into making Test Guidelines more effective and efficient, including addressing the 3Rs principles.
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## 6. Conclusions

The NanoHarmony project has provided recommendations to ensure engagement of all the relevant stakeholders.

Furthermore, educational material has been developed that aims to help making the process of TG development more effective. This includes the “NanoHarmony OECD TG/GD Process Mentor” ([www.testguideline-development.org](http://www.testguideline-development.org)) that facilitates easy access to the relevant information. This online tool also provides access to the NanoHarmony Training Material ([www.testguideline-development.org/useful-resources](http://www.testguideline-development.org/useful-resources)). This set of slides provides a low-level entry into the topic of standards and harmonised OECD TGs and how science can contribute to this.

## 7. References

- [1] OECD Mutual Acceptance of Data (MAD): [www.oecd.org/chemicalsafety/testing/mutualacceptanceofdatamad.htm](http://www.oecd.org/chemicalsafety/testing/mutualacceptanceofdatamad.htm).
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- [4] E.A.J. Bleeker, et al. (2023), From Science to Regulation – The NanoHarmony White Paper on Test Guideline Development: [nanoharmony.eu/white-paper](http://nanoharmony.eu/white-paper).
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- [6] OECD Series on Testing and Assessment, No. 34: [one.oecd.org/document/ENV/JM/MONO\(2005\)14/en/pdf](http://one.oecd.org/document/ENV/JM/MONO(2005)14/en/pdf).