

The Malta Initiative: Activities, Aims, Collaboration Perspective with INISS

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**Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation
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Status, Gaps, Needs and the Role of INISS”**

Global needs for comparable research results

- We act in a global market.
- We need research for sustainable innovation and legal requirements.
- Research results must be comparable and reproducible.
- Therefore we need international standards eg. ISO/OECD/Metrology.
- OECD Test Guidelines (TG) are internationally harmonised.
- The advantage of using OECD TGs with Good Laboratory Praxis (GLP) is the Mutual Acceptance of Data (MAD) for OECD member countries.

Mutual Acceptance of Data (MAD) Principle

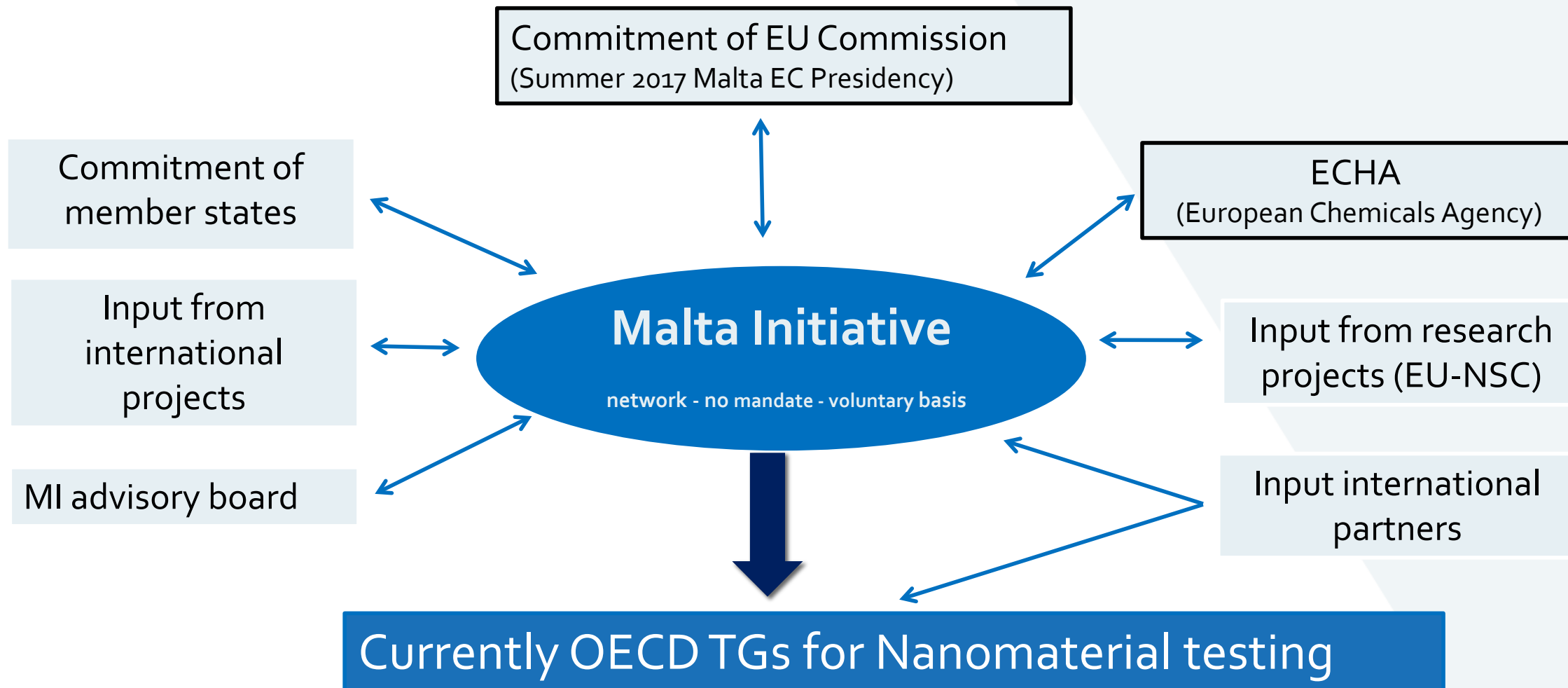
- Ensures that test results generated in accordance with OECD TGs and the OECD Principles of Good Laboratory Practice are accepted in all OECD and adherent countries
- Data generated according to OECD TGs are internationally comparable for research and development as well as regulation
- used by industry
- gives rise to considerable cost savings for industry and government and prevents many unnecessary tests being carried out
- reduces trade-barriers

OECD Chemical Programme

- OECD has established 150 Test Guidelines:
 - Physical Chemical properties , Bio-degradation and accumulation ,Eco toxicity, Health Effects
 - Other Test Guidelines
- International cooperation is unique.
- OECD works on the basis of consensus.
- OECD Test Guidelines and GLP lead to Mutual Acceptance of Data (MAD).
- Everyone has free access to the OECD Documents.
- Challenging task for experts: Adoption to technical progress – currently for nanomaterials

What is the Malta Initiative?

- Malta Initiative (MI) – during the European Council Presidency in Malta 2017 the idea became concrete to build a network that advocates for appropriate testmethods (first step: for nanomaterials).
- MI is a network of international experts.
- MI works on a voluntary basis without any official mandate.
- MI addresses the importance of internationally harmonised and standardised testing and measurement methods.



Aims of the Malta Initiative

- We want to strengthen trust in sustainable innovation and enforceable legislation.
- Therefore clear and **enforceable** legislation is needed (= one of the key factors for long term investments of industry – **safe and sustainable innovation**).
- International standards help to **overcome trade barriers**.
- EU funded research projects strengthen the international cooperation of experts from research, industry and regulation.
- Starting point **was** the adoption of Test Guidelines to nanomaterials.
- Short term: Calls within EU funding programme for research and innovation
- Long term: EU Testmethod Strategy

Achievements of the Malta Initiative

- MI spotlighted the importance of internationally harmonised tools and their adoption to technical progress.
- MI initiated calls under the EU Research Programme.
- MI is supporting the development or adoption of more than 20 OECD Testguidelines
- MI better understanding between researchers and regulatory needs – rules of OECD (role of national coordinators, SPSF, WNT)

Malta Initiative Position Paper- main messages

- OECD TGs support innovation and reduce trade barriers!
- OECD TGs support sustainable innovation and thus strengthens the UN SDG!
- OECD TGs are essential for legislation and its enforceability!
- OECD TGs need to be continuously amended and developed!
- Constant funding is needed within a European Test Method Strategy!

A European Test method strategy includes

- 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 TG development
 - ensure the development of test methods are operable and useful in (pre)regulatory and scientific testing
 - Increase the likelihood of effective adoption and implementation by the OECD Member Countries

A European Test method strategy includes

- Funding of researchers for the development, validation and harmonization of test methods

A coordination approach can be more effective and helps avoiding duplication of work!

Conclusions

- We need **safety research for sustainable innovation that is in line with legal requirements.**
- **OECD Test Guidelines make research results comparable and reproducible.**
- Malta Initiative is one example how to bring stakeholders together.
- Only international cooperation leads to sustainable success.
- The work on OECD TG/GDs and work on other standards needs a **systematical approach underpinned with financial solutions.**
- **We need a long-term and adequately funded EU Testmethod Strategy!**

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