



EuroNanoForum 2019

Session: Governance and Standardization

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The



Initiative –

A European Action to Develop OECD Test Guidelines for Nanomaterials

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baua:

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Aims of the Malta Initiative

- **Strengthen trust in innovation and legislation**
- **Ensuring that legislation keeps pace with innovation!**
- **Clear and enforceable legislation is one of the key factors for long term investments of industry**
- **Focussing on test guidelines and guidance documents which are not yet fully available for European legislation**
 - **Examples REACH, Novel Food, Cosmetics, Biocides ...**



Aims of the Malta Initiative

- **Bringing stakeholders together (e.g. Nano Safety Cluster – researchers and regulators)**
- **Setting thematic priorities**
- **Coordination of the needed exchange**
- **Strengthen national and international cooperation – global challenges**
- **Focus: OECD Chemical Program**



TGs/GDs for Enforceability of Legislation

Starting point: Revision of REACH Annexes for nanomaterials

- **Nanomaterials explicitly included into the Annexes**
- **New information requirements for nanomaterials**
- **Application January 2020 – but not enforceable – TG/GD missing, not adopted, not appropriate**
- **Update / Development of guidance (e.g. ECHA guidance) to align it with the legal text**



OECD TGs



- **tool for assessing effects of chemicals on human health and the environment**
- **internationally accepted standards for safety testing**
- **used by industry, academia and regulators**
- **updated by expertes from OECD member countries**



OECD TGs



→ Approximately 150 Test Guidelines:

- Physical and chemical properties
- Bio-degradation and bioaccumulation
- Ecotoxicity
- Health Effects
- Other Test Guidelines

→ TGs have to be adapted for nanomaterials



Benefits of OECD TGs



OECD TGs



Good Laboratory Practice



Mutual Acceptance of Data

OECD Council Decision: "...the data...**must** be accepted by other OECD countries for assessment purposes."



Mutual Acceptance of Data

“tested once, accepted for assessment everywhere”

- **Safe** – saves lives and costs
- **Comm** – shows how to address **relevant** environment and
- **Good Laboratory Practice** – testing is performed

**saves governments and industry around
€ 3 Million each year**



Mutual Acceptance of Data

Starting point: Focus on OECD TGs with REACH relevance

Revision of REACH Annexes for nanomaterials

- nanomaterials explicitly included into the Annexes
- new information requirements for nanomaterials
- Foreseen into application January 2020
- Update / Development of guidance to align it with the legal text



OECD TG



Approval



WNT

Endorsement



JM

Endorsement



EPOC

Adoption

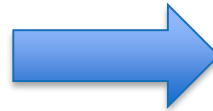


Council

Publication



Mutual acceptance of data



EU Regulation

REACH
Regulation

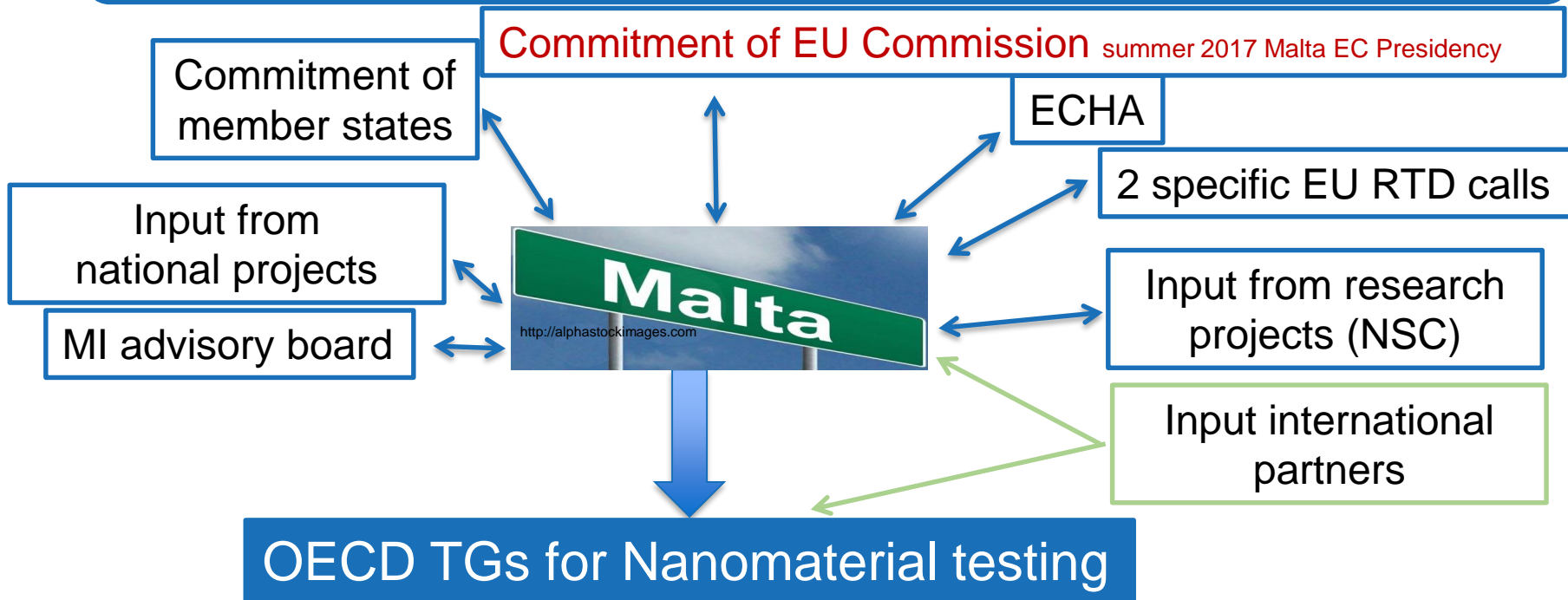


REACH Test Method
Regulation (based on
OECD TGs)

Malta Initiative
(2 projects)



The Malta Initiative





The Malta Initiative

Commitment of
member states

Commitment of
EU Commission

ECHA

Input from
national projects

MI advisory board



Members of MI

- Researcher
- Regulator
- Industry -BIAC
- OECD repres.
- MS repres.
- JRC
- NGO
- ...

OECD TGs/GDs for Nanomaterial testing



The Malta Initiative



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is supported by
18 European States
+
Industry/ECHA/JRC

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Conclusions

- **We need more common understanding how important the OECD work is**
- **Test guidelines are necessary for researchers, industry and regulators regarding MAD**
- **Legislation must be enforceable – common binding TG/GD standards/methods are the basis for that**



Conclusions

- **OECD is the right place (MAD) - but the work is voluntary: time/money/actions of member countries are restricting factors!**
- **Only international cooperation leads to accepted results**
- **Malta Initiative is an example how to bring stakeholders together to make legislation enforceable – without financial and political support the work is not possible**



Thank you for your attention!

Legislation has to keep pace with innovation!

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