

OECD Priorities and the Malta Project

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- Dedicated to **promoting chemical safety worldwide**
- The aims of its work on Environment, Health and Safety (EHS) are to **protect human health and the environment**, while **avoiding duplication of efforts**; and **ensuring efficiency** and **reduction of trade barriers**
- OECD develops **OECD Test Guidelines (TG)** for Chemicals and OECD Principles of **Good Laboratory Practice (GLP)**
 - Harmonised, common tools used by countries to test and assess the potential risks of chemicals
 - Accepted by all the member countries through the Council Decision on the **Mutual Acceptance of Data (MAD)**

The safety of nanotechnologies was first raised in the OECD Chemicals Committee in November 2004. This was followed by two events:

1. Special Session on the “potential implications of manufactured nanomaterials for human health and environmental safety (June 2005)
2. Workshop on the Safety of Manufactured Nanomaterials (December 2005)



WPMN established in 2006

Objective:

‘To promote **international co-operation** in human health and environmental **safety related aspects** of **manufactured nanomaterials (MNs)**, in order to assist in the **development of rigorous safety evaluation** of nanomaterials’

Established under the [OECD Chemical Committee](#)

Participants are experts from

- OECD Members
- Non-members (China, Israel, the Russian Federation, Singapore, South Africa, Thailand)
- Observers and invited experts from e.g. UNITAR, FAO, WHO, ISO, TUAC, environmental NGOs (ED, FOE, CIEL) and industry:
 - **BIAC (Business and Industry Advisory Committee to the OECD)**



- **Testing specific nanomaterials** for their human health and safety evaluation, while ensuring appropriate testing methods (in vivo & in vitro)
- **Promoting co-operation on voluntary and regulatory programmes**
- Facilitating **international co-operation on risk assessment** strategies
- **Developing guidance** on exposure measurement and exposure mitigation (workplace; consumers; and the environment)
- **Promoting the environmentally sustainable use** of nanotechnology through enhancing the knowledge base about life cycle aspects of manufactured nanomaterials

In 2013 the work was reorganised into the following Steering Groups:

- **SG-Testing and Assessment**
- **SG-Risk Assessment and Regulatory Programmes**
- **SG-Exposure Measurement and Exposure Mitigation**
- **SG-Environmentally Sustainable Use of Nanotechnology**

- Test a **selected list of manufactured nanomaterials for approximately 59 endpoints** (effects measurements and observations) relevant to environmental safety and human health
- Nanomaterial tested for (e.g.):
 - Nanomaterials Information/ Identification
 - Physical-Chemical Properties
 - Environmental Fate
 - Environmental Toxicology
 - Mammalian Toxicology
 - Material Safety
- **Lots of data generated and providing useful input for further activities**

More than 40 publications from WPMN since 2005 (e.g.):

- No. 40 - [ENV/JM/MONO\(2014\)1 ENV/JM/MONO\(2014\)1/ADD **Ecotoxicology and Environmental Fate** of Manufactured Nanomaterials: Test Guidelines](#)
- No. 38 - [ENV/JM/MONO\(2013\)18 Co-Operation on Risk Assessment: **Prioritisation of Important Issues on Risk Assessment** of Manufactured Nanomaterials - Final Report](#)
- No. 36 - [ENV/JM/MONO\(2012\)40 **Guidance on Sample Preparation and Dosimetry** for the Safety Testing of Manufactured Nanomaterials](#)
- No. 35 - [ENV/JM/MONO\(2012\)14 **Inhalation Toxicity Testing**: Expert Meeting on Potential Revisions to OECD Test Guidelines and Guidance Document](#)
- No. 33 - [ENV/JM/MONO\(2012\)8 **Important Issues on Risk Assessment** of Manufactured Nanomaterials](#)

[<http://www.oecd.org/env/ehs/nanosafety/publicationsintheseriesonthesafetyofmanufacturednanomaterials.htm>]

- **OECD is assisting member countries in implementing the UN Strategic Approach to International Chemicals Management (SAICM)**
 - Awareness-Raising Workshops on Nanotechnology/
Manufactured Nanomaterials
- OECD also co-ordinates its works with the **International Standards Organisation**

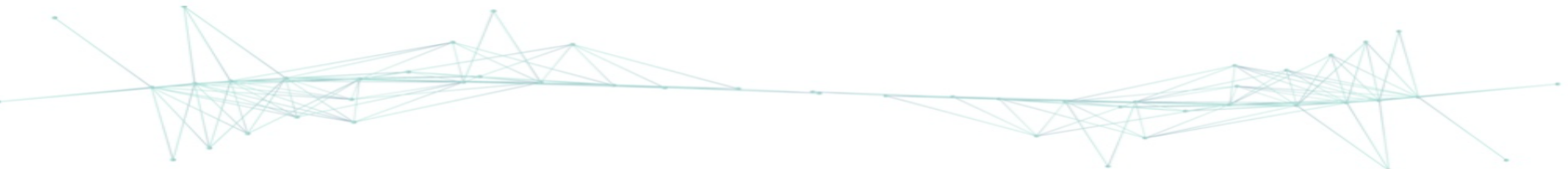
- Focus on **adaptation and/or development** of specific **testing methods** used for assessing human health and environmental safety
- **Developing guidance documents** for assessing manufactured nanomaterials adapted to their specificities.
- **Guidance on estimating exposure** (including fate and transport) on how to use results on physico-chemical endpoints in exposure assessment and mitigation measures to reduce exposure to safe levels

- Draft Guidance Documents/Technical Guidelines for discussion:
 - Determination of **solubility and dissolution rate** of nanomaterials in water and relevant synthetic biologically mediums
 - Identification and quantification of the **surface chemistry and coatings** on nano- and microscale materials
 - New TG on Determination of the **Dustiness** of Manufactured Nanomaterials
 - Applicability of the TG 442D *in vitro* **skin sensitisation** for nanomaterials
 - Aquatic (Environmental) **Transformation** of Nanomaterials
 - New TG on **toxicokinetics** or Amendments to OECD TG 417 to accommodate nanomaterials
 - New GD to TG 305 Bioaccumulation in Fish

- Malta project will work on the projects proposed for inclusion in the OECD WPMN work programme
- The Malta Project is run under work package 2 in the Gov4Nano (NMBP13) proposal that last week passed the first stage evaluation
 - Second stage proposal deadline is 28 June.
- NIA is part of the Gov4NANO

**NIA Members:
Act to become involved!**

- Biopersistent/Biodurable manufactured nanomaterials
- Decision Framework and Guiding Principles for Physical-Chemical Decisions
- Investigating the Different Types of RA, Tools available for RA Measurements and Uncertainties
- Compilation of Available Tools and Models Used for Assessing Exposure to MN
- Assessing the global readiness of regulatory and non-regulatory models for assessing occupational exposure to manufactured nanomaterials
- Assessment of biodurability of nanomaterials and their surface ligands



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