



# OECD Work on the Safety of Manufactured Nanomaterials

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Environment, Health and Safety Division  
Environment Directorate, OECD

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# I. Organisation for Economic Co-operation and Development



Australia



Austria



Belgium



Canada



Chile



Czech Republic



Denmark



Estonia



Finland



France



Germany



Greece



Hungary



Iceland



Ireland



Israel



Italy



Japan



Korea



Luxembourg



Mexico



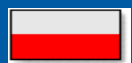
Netherlands



New Zealand



Norway



Poland



Portugal



Slovak Republic



Slovenia



Spain



Sweden



Switzerland



Turkey



UK



US

## II. Nano-enabled Applications

- **Nanotechnologies are likely to have a major impact across a range of economic sectors:**  
(e.g.) energy production, health industry, cosmetics, information technology, textiles
- **Global Market of Nanotechnologies has increased over time**
  - By 2015, 2 million jobs & 1 trillion USD production (National Nanotechnology Initiative(NNI))

# III. Human Health and Environmental Safety

## Safety information is needed on

- Exposure measurement  
(occupational, consumers and environment)
- Hazard assessment
- Risk assessment / risk management
- Broader environmental impacts



# IV. OECD Working Party on Manufactured Nanomaterials (WPMN)

- **Background**

- Safety of Nanotechnologies first addressed at OECD (Nov. 2004, Chemicals Committee)
- Special Session on the potential implications of manufactured nanomaterials for human health and environmental safety (June 2005)
- Workshop on the Safety of Manufactured Nanomaterials (Dec. 2005)

- **Establishment of the WPMN** (Sep. 2006)

- **WPMN Meetings**

- 1<sup>st</sup> WPMN (Oct. 2006) – 8<sup>th</sup> WPMN (March 2011)

## Participants to the WPMN

- **OECD Member Countries:**

- Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Estonia, Finland, France, Germany, Ireland, Israel, Italy, Japan, Korea, Mexico, Netherlands, New Zealand, Norway, Poland, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom, United States, European Commission.

- **Observers:**

- Brazil, China, Singapore, South Africa, Thailand, the Russian Federation;
- Inter-governmental Organisations: IOMC (FAO, UNEP, UNITAR and WHO); and
- Other Organisations: BIAC, ICAPO, ISO (TC 229), TUAC and Environmental NGOs

# Council

**ENVIRONMENT POLICY COMMITTEE (EPOC)**

**Working Party on Chemicals, Pesticides and Biotechnology**

**JOINT MEETING**

**CHEMICALS COMMITTEE**

**Working Party on Manufactured Nanomaterials**

Working Group on National Co-ordinators of Test Guidelines Programme

Working Group on Good Laboratory Practice

Working Group on Harmonisation of Regulatory Oversight in Biotechnology

Working Group on Chemical Accidents

Working Group on Pesticides

Task Force on Hazard Assessment

Task Force on Exposure Assessment

Task Force on Pollutant Release and Transfer Registers (PRTRs)

Task Force on Harmonization of Classification and Labelling

Task Force for the Safety of Novel Foods and Feeds

Task Force on Biocides

# V. WPMN Projects

**OECD Database on Manufactured Nanomaterials  
to Inform and Analyse EHS Research Activities**

**Safety Testing of a Representative Set  
of Manufactured Nanomaterials**

**Manufactured Nanomaterials and Test Guidelines**

**Co-operation on Voluntary Schemes  
and Regulatory Programmes**

**Co-operation on Risk Assessment**

**The Role of Alternative Methods in Nano Toxicology**

**Exposure Measurement and Exposure Mitigation**

**Environmentally Sustainable Use of  
Manufactured Nanomaterials**

**Note: Each Project is being managed by a Steering Group**

# OECD Database on Manufactured Nanomaterials to Inform and Analyse EHS Research Activities

- **Objective**

- To develop a global resource (Database), which details research projects and identifies research needs
- To provide opportunities to identify the similar fields, and lead to create new collaboration and networks

- **Status**

- The database was publicly launched in April 2009, and includes 794 research data (March 2011)
- A comprehensive compilation document “EHS Research Strategies on MNs” was published (May 2009)

- **Next Step**

- Consideration for linkage with other databases
- Further update/populate data as well as promote Database
- Develop a strategy to address incomplete entries

# Safety Testing of a Representative Set of Manufactured Nanomaterials: Sponsorship Programme

- **Objective**

- To test a representative set of Manufactured Nanomaterials (13)

- **Status/Next steps**

- **Stage 1 (completed)**

A list of MNs (based on materials which are now or soon to enter, commerce) and a list of endpoints

- **Stage 2 (July 2009~)**

Implementation of the Sponsorship Programmes for the Testing of Manufactured Nanomaterials

# Sponsorship Programme for the Testing of Manufactured Nanomaterials

**International effort to share the testing of an agreed set of manufactured nanomaterials selected by WPMN**

## **Two phases:**

- Phase 1: to test selected MNs for the selected endpoints (launched Nov 2007- continuing)
- Phase 2: consideration of those cross-cutting issues or tests that identified by phase 1 ( 2011-)

## Completing Phase 1

- Summary Matrices of the results of the Sponsorship Programme (March 2011): i) Matrix on the Testing Status; and ii) Matrix on Test Methods used
- Task Group on **Completing the Phase 1 Dossiers**
- Interim Report will be presented (Dec 2011, WPMN9)
- Completing the Phase 1 (June 2012, WPMN10)
- Preparing for Phase 2
  - Workshop on the Phase 2 of the Sponsorship Programme (Jan 2011)
  - Task Group on **Discussing Approaches for Phase 2**
  - Horizontal Expert Meeting on Inhalation Toxicity (SGs 3/4/6/7, Late 2011)

|                             | <b>Lead sponsor(s)</b> | <b>Co-sponsor(s)</b>   | <b>Contributors</b>  |
|-----------------------------|------------------------|--|--|
| <b>Fullerenes(C60)</b>      | <b>Japan, US</b>       |  | <b>Denmark, China</b>  |
| <b>SWCNTs</b>               | <b>Japan, US</b>       |  | <b>Canada, France, Germany, EC, China, BIAC</b>                |
| <b>MWCNTs</b>               | <b>Japan, US</b>       | <b>Korea, BIAC</b>   | <b>Canada, France, Germany EC, China, BIAC</b>                 |
| <b>Silver nanoparticles</b> | <b>Korea, US</b>       | <b>Australia, Canada, Germany, Nordic Council of Ministers</b> | <b>France, Netherlands, EC, China, BIAC</b>                    |
| <b>Iron nanoparticles</b>   | <b>China</b>           | <b>BIAC</b>  | <b>Canada, US, Nordic Council of Ministers</b>                 |
| <b>Titanium dioxide</b>     | <b>France, Germany</b> | <b>Austria, Canada, Korea, Spain, US, EC, BIAC</b>             | <b>Denmark, Japan, UK, China</b>                               |
| <b>Aluminium oxide</b>      |                        |  | <b>Germany, Japan, US</b>                                      |
| <b>Cerium oxide</b>         | <b>US, UK/BIAC</b>     | <b>Australia, Netherlands, Spain</b>                           | <b>Denmark, Germany, Japan Switzerland, EC</b>                 |
| <b>Zinc oxide</b>           | <b>UK/BIAC</b>         | <b>Australia, US, BIAC</b>                                     | <b>Canada, Denmark, Germany, Japan, Netherlands, Spain, EC</b> |
| <b>Silicon dioxide</b>      | <b>France, EC</b>      | <b>Belgium, Korea, BIAC</b>                                    | <b>Denmark, Japan</b>  |
| <b>Dendrimers</b>           |                        | <b>Spain, US</b>   | <b>Austria, Korea</b>  |
| <b>Nanoclays</b>            | <b>BIAC</b>            |  | <b>Denmark, US, EC</b>   |
| <b>Gold nanoparticles</b>   | <b>South Africa</b>    | <b>US</b>  | <b>Korea, EC</b>   |

## List of Endpoints for phase 1

▶ **Nanomaterial Information/Identification** (9 endpoints)

(e.g.) substance name, chemical identity, uses, coating

▶ **Physical-Chemical Properties and Material Characterization** (17 endpoints)

(e.g.) water solubility, particle size, agglomeration/aggregation

▶ **Environmental Fate** (15 endpoints)

(e.g.) biodegradability, adsorption, accumulation

▶ **Environmental Toxicology** (6 endpoints)

(e.g.) effects on aquatic and terrestrial organisms

▶ **Mammalian Toxicology** (9 endpoints)

(e.g.) inhalative toxicity, reproductive toxicity, genotoxicity

▶ **Material Safety** (3 endpoints)

(e.g.) flammability

# Manufactured Nanomaterials and Test Guidelines

- **Objective**

- To review existing OECD Test Guidelines (TGs) for adequacy in addressing MNs
- To identify need for new or revised Test Guidelines

- **Status**

- Consideration of OECD TGs for their applicability to MNs
  - ✓ Preliminary conclusions published in 2009: Most TGs are applicable (some need adjustment)
- Publication of Guidance Notes on Sample Preparation and Dosimetry (GNSPD) for Safety Testing of MNs (2010)

- **Next Steps**

- Update/revise/finalize GNSPD
- Prepare/develop Guidance Documents or TGs
- Coordinate with the WNT via SPSF

# Co-operation on Voluntary Schemes and Regulatory Programmes

- **Objective**
  - To develop a report on regulatory regimes; and to gather Information on the lessons learned from information gathering initiatives on MNs
- **Status**
  - Publication of Analysis of Information Gathering Initiatives (Nov 2009)
  - Publication of Report of the Questionnaire on Regulatory Regimes (May 2010)
  - Phase 1 of the Collaborative Workspace (Oct. 2010-)
- **Next steps**
  - Report on the Analysis of Information Gathering Schemes will be published(late 2011)
  - Report on Regulated Nanomaterials: 2006-2009 will be published (late 2011)
  - Phase 2 of the Collaborative Workspace (April or May 2011-)

## Co-operation on Risk Assessment

- **Objective**

- To evaluate risk assessment approach for MNs

- **Status**

- Workshop on Risk Assessment of MNs in a Regulatory Context (Sep 2009)
  - ✓ Report published in 2010

- **Next Steps**

- Report on Risk Assessment of Manufactured Nanomaterials: *Critical issues* will be finalised by the WPMN in a couple of weeks and then be published (late 2011)
  - ✓ This report introduce: current practices, challenges and strategies on risk assessment; the necessity of direct research towards Risk Assessment

# The Role of Alternative Methods in Nanotoxicology

- **Objective**

- To address the use of alternative test methods and testing strategies (in parallel with the Sponsorship Programme)

- **Status**

- 1<sup>st</sup> Expert Consultation Meeting on Alternative Test Methods (April 2010)
- 2<sup>nd</sup> Expert Consultation Meeting on Alternative Test Methods (incl. a special session on *in vitro* dispersion protocols) (Jan. 2011)
- Present draft status report for *in vitro* dispersion protocols for ZnO; and an ITS case study with a short term inhalation study (March 2011)

- **Next Steps**

- 3<sup>rd</sup> Expert Consultation Meeting will be held between WPMN9 & WPMN10
- Further Collaboration with SG4 (dispersion protocol) and WNT (GD 34, nano-specific validation requirements)

# Co-operation on Exposure Measurement and Exposure Mitigation

- **Objective**
  - To exchange information on guidance for exposure measurement and exposure mitigation for Manufactured Nanomaterials
- **Status**
  - Publication of Compilation and Comparison of Guidelines Related to Exposure to Nanomaterials in Laboratories (Dec. 2010)
  - Evaluating data and provide recommendation on measurement technologies and sampling protocols for determining concentrations of manufactured nanomaterials in air (ongoing, Australia)
- **Next Steps**
  - Developing Case Studies for exposure assessment on MNs (late 2009~)
  - Updating the following documents:
    - i) Comparison of Guidance on Selection of Skin Protective Equipment and Respirators for Use in the Workplace;
    - ii) Emission Assessment for Identification of Sources and Release of Airborne MSs in the Workplace

# Environmentally Sustainable Use of Manufactured Nanomaterials

- **Background – Nanobenefits conference July 2009**
- **Objectives**
  - ... enhance the knowledge base about life cycle aspects of nanomaterials, as well as positive and negative impacts on environment and health of certain nano-enabled applications at their different stages of development...
- **Status/ Next Step**
  - Publication of a report on national activities related to LCA and nanotechnology (2011)
  - A workshop and face-to-face meeting (September 2011)

## Recent Publications on Manufactured Nanomaterials (published in 2010)

- **Compilation and Comparison of Guidelines Related to Exposure to Nanomaterials in Laboratories**
- **List of Manufactured Nanomaterials and List of Endpoints for Phase One of the Sponsorship Programme for the Testing of Manufactured Nanomaterials: Revision**
- **Current Developments/Activities on the Safety of Manufactured Nanomaterials, Tour de Table at the 7th Meeting of the WPMN**
- **Guidance Manual for the Testing of Manufactured Nanomaterials: OECD Sponsorship Programme: First Revision**
- **Preliminary Guidance Notes on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials**

- **Report of the Questionnaire on Regulatory Regimes for Manufactured Nanomaterials**
- **OECD Programme on the Safety of Manufactured Nanomaterials 2009-2012: Operational Plans of the Projects**
- **Report of the Workshop on Risk Assessment of Manufactured Nanomaterials in a regulatory context**
- **Current Developments/Activities on the Safety of Manufactured Nanomaterials: Tour de Table at the 6th Meeting of the WPMN**

## Upcoming Publications (To be published in 2011)

- **Current Developments/Activities on the Safety of Manufactured Nanomaterials, Tour de Table at the 8th Meeting of the WPMN**
- **Risk Assessment of Manufactured Nanomaterials: Critical Issues**
- **Regulated Nanomaterials: 2006-2009**
- **Analysis of Information Gathering Schemes**

# More information

## **Safety of Manufactured Nanomaterials**

[www.oecd.org/env/nanosafety](http://www.oecd.org/env/nanosafety)

## **Contact OECD Secretariat**

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