

OECD Working Party on Manufactured
Nanomaterials (WPMN):
International Rules for Nanosafety

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OECD activities

- 1. Working Party on Nanotechnology (WPN):** Subgroup of the Committee for Science and Technology Policy *established in March 2007*
Objectives: Advice upon emerging policy issues of science, technology and innovation related to the responsible development of nanotechnology.
→ Focus: **Fostering development of technology**
- 2. Working Party on Manufactured Nanomaterials (WPMN):**
Subgroup of the Chemicals Committee (Env. Directorate) *established in September 2006 (nanosafety first addressed in Chemicals Committee in 2004)*
Mandate for 3 + 3 years (until 2012)
→ Focus: **Nanosafety**

Why Safety of Nanomaterials?

- **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 production is expected (referred by National Nanotechnology Initiative (NNI))
- **Uncertainness of industrialized countries how to ensure safety**
 - Emerging data that manufactured nanomaterials behave different
 - Need for international co-operation.

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Objectives:

- International Co-operation regarding risks of manufactured nanomaterials (MN) for human health and environment
- Science based safety information is needed on
 - Effects of nanomaterials (testing)
 - Exposure Measurement (occupational, consumers and environment)
 - Hazard assessment
 - Risk assessment
- Sampling of data on positive and negative impacts of MN on the environment

Results:

- Results are published on the website www.oecd.org/env/nanosafety
- Tour de table of all participating delegations is published
- Co-operation with ISO und other international bodies (UNEP, FAO...)

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Current WPMN Projects

- OECD database on Manufactured Nanomaterials to Inform and Analyse EHS Research Activities (SG 1/2);
- Safety Testing of a Representative Set of Manufactured Nanomaterials (SG 3);
- Manufactured Nanomaterials and Test Guidelines (SG 4);
- Co-operation on Voluntary Schemes and Regulatory Programmes (SG 5);
- Co-operation on Risk Assessment (SG 6);
- The Role of Alternative Methods in Nano Toxicology (SG 7);
- Exposure Measurement and Exposure Mitigation (SG 8);
- Environmentally Sustainable Use of Manufactured Nanomaterials (SG 9).

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SG 1/2: OECD database on manufactured nanomaterials to inform and analyse EHS research activities

Objectives:

- To develop a global resource (Database), which details research projects and identifies research needs
- To inform scientists, the interested public and politicians
- To create new collaboration and networks
- To identify “hotspots” and gaps in nanosafety research
- To support other steering groups of WPMN
- Not: to develop a global research strategy or to coordinate international research activities

Status and next steps:

- Database was publicly launched (April 2009), and includes more than 760 research projects (July 2010)
<http://webnet.oecd.org/NanoMaterials>
- Improvement of functionalities
- Extending the contents of the database
- Identifying future research priorities

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SG 3: Safety testing of a representative set of manufactured nanomaterials

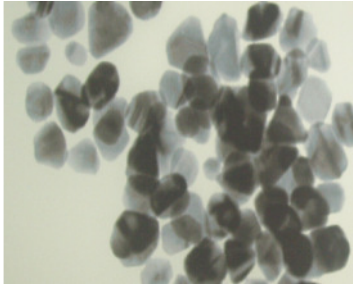
Objectives:

- To test a representative set of manufactured nanomaterials with regard to phys-chem. characteristics, toxicology, ecotoxicology and environmental fate
- To address knowledge gaps regarding the safety characteristics of MN
- To gain experience on sample preparation and testing methods with MN

Status and next steps:

- Originally 14 MN were selected,
- Member countries build sponsoring consortia financing determination of > 50 endpoints
- Only 9 (- 10) MN were sponsored. 7th WPMN decided to remove polystyrene and carbon black and to add nanogold (alumina and nanoclay will be investigated by US within their regulatory programme)

Nanomaterial	Lead sponsor(s)	Co-sponsor(s)	Contributors
Fullerenes(C60)	Japan*, US*		Denmark, China
SWCNTs	Japan*, US*		Canada, France, Germany , EU, China, BIAC
MWCNTs	Japan*, US *	Korea, BIAC	Canada, France, Germany , EU, China, BIAC
Silver nanoparticles	Korea, US	Australia, Canada, Germany , Nordic Council of Ministers	France, EU, China
Iron nanoparticles	BIAC, China		Canada, US Nordic Council of Ministers
Gold nanoparticles (new)	South africa	US, Korea	EU, Netherlands, Thailand
Titanium dioxide	France, Germany	Austria, Canada, Korea, Spain, US*, EC, BIAC	China, Denmark, Japan*, UK, Thailand
Aluminium oxide	will be part of a US programme		
Cerium oxide	US*, UK, BIAC	Australia, Netherlands, Spain	Denmark, Germany , Switzerland, EU, Japan*
Zinc oxide	UK, BIAC	Australia, Spain, US, BIAC	Canada, Denmark, Japan*
Silicon dioxide	France, EU	Belgium, Korea, BIAC	Denmark, Japan*
Polystyrene / Carbon black	deleted		
Dendrimers		Spain, US*	
Nanoclays	will be part of a US programme, BIAC		Denmark, EU



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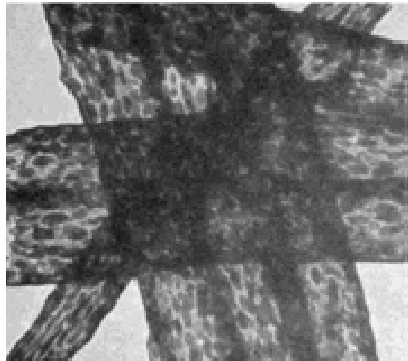
SG 3: Sponsorship programme

Two phases:

- Phase 1: to test selected MNs for the selected endpoints (launched Nov 2007- continuing until 2011)
- Phase 2: consideration of those cross-cutting issues or tests that identified by phase 1 (2011-1012), e.g. long-term testing, investigation of SAR, open questions regarding risk

Example:

- Germany and France are jointly sponsoring nano-TiO₂
- Collecting existing data and drafting a dossier development plan (DDP)
- Selecting 5 test materials differing in diameter, crystal form, coating etc. – distribution to participating laboratories
- Quality assurance of existing test results
- Starting and coordinating of research programmes of phase 1 of sponsors and co-sponsors
- Final assessment and proposing tests for phase 2



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List of endpoints of phase 1

- ▶ Nanomaterial Information/Identification (9 endpoints), e.g. substance name, chemical identity, uses, coating
- ▶ Physico-chemical Properties and Material Characterization (17 endpoints), e.g. water solubility, particle size, surface characteristics, 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, toxicogenetics
- ▶ Material Safety (3 endpoints), e.g. flammability

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SG 4: Manufactured nanomaterials and test guidelines

Objectives:

- To review existing OECD test guidelines for adequacy in addressing MNs
- To identify the need for modification or revision of existing test guidelines
- To review the need of new test guidelines
- To develop appropriate test strategies for MN
- To develop guidance for appropriate testing of MN

Status and next steps:

- 4 subgroups (Phys-chem, biotic systems, degradation and accumulation, health effects) established for revision and elaboration of a work plan – set up of Communities of Practice
- Preliminary result: most guidelines are appropriate
- Close co-operation with WNT
- Guidance on sample preparation and dosimetry

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SG 5: Co-operation on voluntary schemes and regulatory programmes

Objectives:

- To review voluntary and regulatory approaches in OECD member countries (e.g. national programmes for gathering information on production and use)
- To analyse national approaches for appropriateness and effectiveness (*inter alia*: analyse non CBI information of notifications of MN)
- To identify appropriate and applicable measures

Status and next steps:

- Report of the Questionnaire on Regulatory Regimes for Manufactured Nanomaterials (April 2010)
- Development of Follow up surveys and analysis of compiled data
- Establishment of a “collaborative workspace” for information exchange

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SG 6: Co-operation on risk assessment

Objectives:

- To evaluate risk assessment approaches for MN
- To identify specific features of risk assessment of MN.

Status and next steps:

- Report of the Workshop on “Risk Assessment of Manufactured Nanomaterials in a Regulatory Context” in Washington 2009 published in April 2010
- Development of a report on “critical issues” to risk assessment focussed on selective MN of the “representative set”

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SG 7: The role of alternative methods in nanotoxicology

Objectives:

- To analyse the appropriateness and informative value of non-animal / *in vitro* tests
- To identify the need for adaptation and development of methods
- To develop guidance for integrated testing strategies

Status and next steps:

- Review of existing methods
- Development of Annexes on alternative methods to be included in the Guidance manual for the Testing of Manufactured Nanomaterials and the Guidance Manual on Sample Preparation and Dosimetry
- Work will be closely linked to nanospecific issues and to the sponsorship programme (case studies)

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SG 8: Exposure measurement and mitigation

Objectives:

- To exchange information on guidance for exposure measurement and exposure mitigation for MN
- To identify methods for sampling and analysis of MN
- To identify methods for exposure mitigation of MN

Status and next steps:

- Report on measurement and mitigation in occupational settings (finished)
- Evaluating data and provide recommendation on measurement technologies and sampling protocols for determining concentrations of MN in air (led by Australia)
- Comparing exposure mitigation guidance for laboratories (led by Germany)
- Developing Case Studies for exposure assessment on MN (consumers and environment)

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SG 9: Environmentally sustainable use of manufactured nanomaterials

Background:

OECD Conference on Potential Environmental Benefits of Nanotechnology: Fostering Safe Innovation-Led Growth (15 - 17 July 2009, Paris) – started only in 2010

Objectives:

- To develop case studies on nano-enabled applications regarding positive and negative impacts on health and environment
- To determine the relationship between risks and benefits applying lifecycle considerations

Status and next steps:

- Phase 1: Screening and selection of appropriate cases
- Phase 2: Case studies
- Phase 3. Evaluation and report

OECD WPMN: Recent Publications

(published in 2009-2010)

- Manufactured Nanomaterials: Roadmap for Activities 2009-2010
- Current Developments in Delegations and other International Organizations on the Safety of Manufactured Nanomaterials - Tour de Table
- Manufactured Nanomaterials: Work Programme 2009-2012
- Preliminary Review of OECD Test Guidelines for their Applicability to Manufactured Nanomaterials
- Guidance Manual for the Testing of Manufactured Nanomaterials: OECD Sponsorship Programme (1st revision: June 2010)
- Report of an OECD Workshop on Exposure Assessment and Exposure Mitigation: Manufactured Nanomaterials
- Comparison of Guidance on Selection of Skin Protective Equipment and Respirators for Use in the Workplace: Manufactured Nanomaterials

OECD WPMN: Recent Publications

(published in 2009 – 2010)

- Emission Assessment for the Identification of Sources and Release of Airborne Manufactured Nanomaterials in the Workplace: Compilation of Existing Guidance
- Identification, Compilation and Analysis of Guidance Information for Exposure Measurement and Exposure Mitigation: Manufactured Nanomaterials
- EHS Research Strategies On Manufactured Nanomaterials: Compilation Of Outputs
- Preliminary Analysis of Exposure Measurement and Exposure Mitigation in Occupational Settings: Manufactured Nanomaterials
- Analysis of Information Gathering Initiatives on Manufactured Nanomaterials
- Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 6th Meeting of the Working Party on Manufactured Nanomaterials

OECD WPMN: Recent Publications

(published in 2009 – 2010)

- Report of the Workshop on Risk Assessment of Manufactured Nanomaterials in a Regulatory Context
- OECD Programme on the Safety of Manufactured Nanomaterials 2009-2012: Operational Plans of the Projects
- Report of the Questionnaire on Regulatory Regimes For Manufactured Nanomaterials
- Preliminary Guidance Notes on Sample Preparation and Dosimetry

OECD WPMN: Final Remarks

- WPMN is the most dynamic forum to develop internationally harmonised rules for a safe development of nanotechnologies.
- WPMN will provide a basis of valid test results which allow to estimate which hazardous properties nanomaterials may have in contrast to coarse materials.
- WPMN will enable to build up their regulatory approaches in a science-based manner.
- WPMN will also regard potential benefits for environment and health from MN.

More information about OECD WPMN?

www.oecd.org/env/nanosafety

Thank you for your
kind attention

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