

**ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND
THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY**

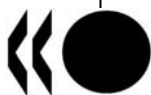
**Series on the Safety of Manufactured Nanomaterials
No. 27**

**LIST OF MANUFACTURED NANOMATERIALS AND LIST OF ENDPOINTS FOR PHASE ONE OF
THE SPONSORSHIP PROGRAMME FOR THE TESTING OF MANUFACTURED
NANOMATERIALS: REVISION**

This is a revised version of the List of Manufactured Nanomaterials and List of Endpoints for Phase One of the Sponsorship Programme for the Testing of Manufactured Nanomaterials, which was originally published in 2008 [ENV/JM/MONO(2008)13/REV].

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OECD Environment, Health and Safety Publications

Series on the Safety of Manufactured Nanomaterials

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ENDPOINTS FOR PHASE ONE OF THE SPONSORSHIP PROGRAMME
FOR THE TESTING OF MANUFACTURED NANOMATERIALS:
REVISION**

IOMC

INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

A cooperative agreement among **FAO, ILO, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD**

**Environment Directorate
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- No. 1, *Report of the OECD Workshop on the Safety of Manufactured Nanomaterials: Building Co-operation, Co-ordination and Communication (2006)*
- No. 2, *Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 1st Meeting of the Working Party on Manufactured Nanomaterials (2006)*
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- No. 25, *Guidance Manual for the Testing of Manufactured Nanomaterials: OECD Sponsorship Programme: First Revision (2010)*
- No. 26, *Current Development/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 7th Meeting of the Working Party on Manufactured Nanomaterials (2010)*

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ABOUT THE OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 33 industrialised countries in North and South America, Europe and the Asia and Pacific region, as well as the European Commission, meet to co-ordinate and harmonise policies, discuss issues of mutual concern, and work together to respond to international problems. Most of the OECD's work is carried out by more than 200 specialised committees and working groups composed of member country delegates. Observers from several countries with special status at the OECD, and from interested international organisations, attend many of the OECD's workshops and other meetings. Committees and working groups are served by the OECD Secretariat, located in Paris, France, which is organised into directorates and divisions.

The Environment, Health and Safety Division publishes free-of-charge documents in ten different series: **Testing and Assessment; Good Laboratory Practice and Compliance Monitoring; Pesticides and Biocides; Risk Management; Harmonisation of Regulatory Oversight in Biotechnology; Safety of Novel Foods and Feeds; Chemical Accidents; Pollutant Release and Transfer Registers; Emission Scenario Documents;** and **Safety of Manufactured Nanomaterials.** More information about the Environment, Health and Safety Programme and EHS publications is available on the OECD's World Wide Web site (www.oecd.org/ehs/).

This publication was developed in the IOMC context. The contents do not necessarily reflect the views or stated policies of individual IOMC Participating Organizations.

The Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) was established in 1995 following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. The Participating Organisations are FAO, ILO, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD. UNDP is an observer. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organisations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

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FOREWORD

The OECD Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology (the Joint Meeting) held a Special Session on the Potential Implications of Manufactured Nanomaterials for Human Health and Environmental Safety (June 2005). This was the first opportunity for OECD member countries, together with observers and invited experts, to begin to identify human health and environmental safety related aspects of manufactured nanomaterials. The scope of this session was intended to address the chemicals sector.

As a follow-up, the Joint Meeting decided to hold a Workshop on the Safety of Manufactured Nanomaterials in December 2005, in Washington, D.C. The main objective was to determine the “state of the art” for the safety assessment of manufactured nanomaterials with a particular focus on identifying future needs for risk assessment within a regulatory context.

Based on the conclusions and recommendations of the Workshop [ENV/JM/MONO(2006)19] it was recognised as essential to ensure the efficient assessment of manufactured nanomaterials so as to avoid adverse effects from the use of these materials in the short, medium and longer term. With this in mind, the OECD Council established the OECD Working Party on Manufactured Nanomaterials (WPMN) as a subsidiary body of the OECD Chemicals Committee. This programme concentrates on human health and environmental safety implications of manufactured nanomaterials (limited mainly to the chemicals sector), and aims to ensure that the approach to hazard, exposure and risk assessment is of a high, science-based, and internationally harmonised standard. This programme promotes international co-operation on the human health and environmental safety of manufactured nanomaterials, and involves the safety testing and risk assessment of manufactured nanomaterials.

This document is published under the responsibility of the OECD Chemicals Committee. It is intended to provide information on the outcomes and developments of the WPMN related to the safety of manufactured nanomaterials.

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THE WORKING PARTY ON MANUFACTURED NANOMATERIALS (WPMN)

The Working Party on Manufactured Nanomaterials¹ was established in 2006 to help member countries efficiently and effectively address the safety challenges of nanomaterials. OECD has a wealth of experience in developing methods for the safety testing and assessment of chemical products.

The Working Party brings together more than 100 experts from governments and other stakeholders from: a) OECD Countries; b) non-member economies such as China, Israel, the Russian Federation, Singapore, South Africa, and Thailand; and c) observers and invited experts from UNITAR, FAO, WHO, ISO, BIAC², TUAC³, and environmental NGOs.

Although OECD member countries appreciate the many potential benefits from the use of nanomaterials, they wished to engage, at an early stage, in addressing the possible safety implications at the same time as research on new applications are being undertaken.

The Working Party is implementing its work through specific projects to further develop appropriate methods and strategies to help ensure human health and environmental safety:

- An 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 Nanotoxicology;
- Exposure Measurement and Exposure Mitigation; and
- Co-operation on Environmentally Sustainable Use of Nanotechnology

Each project is being managed by a steering group, which comprises members of the WPMN, with support from the Secretariat. Each steering group implements its respective “operational plans”, each with their specific objectives and timelines. The results of each project are then evaluated and endorsed by the entire WPMN.

This document was prepared as part of the project **Safety Testing of a Representative Set of Manufactured Nanomaterials**.

More information about the work of the WPMN, as well as OECD’s publications regarding safety issues of nanomaterials, is available at www.oecd.org/env/nanosafety.

¹ Updated information on the OECD’s Programme on the Safety of Manufactured Nanomaterials is available at: www.oecd.org/env/nanosafety

² The Business and Industry Advisory Committee to the OECD

³ Trade Union Advisory Committee to OECD.

PROJECT ON THE SAFETY TESTING OF A REPRESENTATIVE SET OF MANUFACTURED NANOMATERIALS

The WPMN project **Safety Testing of a Representative Set of Manufactured Nanomaterials** builds upon the concept that much valuable information on the safety of manufactured nanomaterials (MNs), as well as the methods to assess safety, can be derived by testing certain nanomaterials for human health and environmental safety effects. The objective of this project is to develop a programme to create an understanding of the kind of information on intrinsic properties that may be relevant for exposure and effects assessment of nanomaterials through testing.

At its inception, it was decided that the implementation of this project will take place in two stages. First, it will develop and agree on a priority list of representative manufactured nanomaterials now or soon to be in commerce for inclusion in a set of reference materials to support measurement, toxicology and risk assessment of nanomaterials. Second, it will develop a programme to create an understanding of the kind of information on intrinsic properties that may be relevant for exposure and effects assessment of nanomaterials by testing representative nanomaterials for human health and environmental effects as well as environmental fate for a specified set of endpoints (including *e.g.*, specific physical-chemical properties, environmental toxicity).

This document presents the completion of stage one: i) a list of representative manufactured nanomaterials; and ii) a list of endpoints for the hazard assessment of those nanomaterials.

The completion of stage one has now enabled the WPMN to discuss stage two, that is, to develop and implement a programme for testing those representative manufactured nanomaterials using the initial set of endpoints. Accordingly, the 3rd meeting of the WPMN agreed to move ahead with the stage two of the project through the launching of the **OECD's Sponsorship Programme⁴ for the Testing of Manufactured Nanomaterials**.

The "Sponsorship Programme" is a process to conduct specific tests for manufactured nanomaterials. It involves OECD member countries, as well as some non-member economies and other stakeholders solely or in partnership with other entities, to pool expertise and to fund the safety testing of specific manufactured nanomaterials.

In order to assist sponsors in the development of dossier development plans, which describes the testing programme for specific manufactured nanomaterials, the WPMN agreed to develop a *Guidance Manual for the Testing Manufactured Nanomaterials; OECD Sponsorship Programme; First Revision* [ENV/JM/MONO(2009)20/REV].

Information about the work of the WPMN, as well as publications and updates on efforts of governments and other stakeholders to address safety issues of nanomaterials is available at <http://www.oecd.org/env/nanosafety>.

⁴ www.oecd.org/env/nanosafety

This document presents an updated list of Manufactured Nanomaterials, based on discussion held at the 7th Meeting of the OECD Working Party on Manufactured Nanomaterials in July 2010. As originally agreed by the WPMN, the list was to be considered as a “snapshot” in time and it should be updated based on the commercial relevance.

LIST OF REPRESENTATIVE MANUFACTURED NANOMATERIALS

The list of representative manufactured nanomaterial has been selected by the WPMN for use in its work. The word “representative” refers to those manufactured nanomaterials now, or soon to enter into commerce, for inclusion in a set of reference materials to support measurement, toxicology and risk assessment of nanomaterials. Therefore, the list was mainly selected taking into account those materials which are in commerce (or close to commercial use), but other criteria were also considered: for example, production volume, the likely availability of such materials for testing and the existing information that is likely to be available on such materials.

It was also emphasised that certain nanomaterials not included in the list may become important in the future and certain nanomaterials currently on the list may have (over time) reduced production and/ or use. Accordingly, the list should be considered as a “snapshot in time” of those nanomaterials in commerce or likely to enter into commerce in the near term. At the same time, some nanomaterials on the list may have variants⁵ that the WPMN may wish to consider in detail in the future.

Based on the current state of knowledge regarding the use and production of manufactured nanomaterials, the WPMN decided at its 7th meeting to remove *carbon black* and *polystyrene* from the list and to add *gold-nanoparticles*. The revised list of manufactured nanomaterials was adopted as follows;

Nanomaterials

- Fullerenes (C60)
- Single-walled carbon nanotubes (SWCNTs)
- Multi-walled carbon nanotubes (MWCNTs)
- Silver nanoparticles
- Iron nanoparticles
- Titanium dioxide
- Aluminium oxide
- Cerium oxide
- Zinc oxide
- Silicon dioxide
- Dendrimers
- Nanoclays
- Gold nanoparticles

The order in which the nanomaterials are listed above does not indicate a priority.

⁵ For example, C60 could be broadened to other fullerenes as well as chemically modified varieties of C60; it may also be important to analyse chemically modified single- and multi- walled CNTs; and the influence of surface coatings of elemental and metal oxide nanomaterials, and/ or their different shapes – e.g., rods.

LIST OF ENDPOINTS FOR PHASE ONE TESTING

The list of endpoints⁶ is a set to take into account, when testing specific manufactured nanomaterials (MNs) for human health and environmental safety within phase one of the Testing Programme. Addressing this set should ensure consistency between the various tests to be carried out on specific nanomaterials. It should also lead to the development of dossiers for each nanomaterial describing basic characterization, environmental fate, environmental toxicity and mammalian toxicity information.

It is also expected that the list of endpoints be refined based on the practical results obtained through the testing programme. As such, phase one testing is expected to be of an exploratory nature, science-based and without any consequences for existing regulatory datasets.

Endpoints

Nanomaterial Information/ Identification

- Nanomaterial name (from list)
- CAS Number
- Structural formula/molecular structure
- Composition of nanomaterial being tested (including degree of purity, known impurities or additives)
- Basic morphology
- Description of surface chemistry (e.g., coating or modification)
- Major commercial uses
- Known catalytic activity
- Method of production (e.g., precipitation, gas phase)

Physical-Chemical Properties and Material Characterization

- Agglomeration/ aggregation
- Water solubility/ Dispersability
- Crystalline phase
- Dustiness
- Crystallite size
- Representative Electron Microscopy (TEM) picture(s)
- Particle size distribution – dry and in relevant media
- Specific surface area
- Zeta potential (surface charge)

⁶ Detailed information regarding these endpoints is provided in the document *Guidance Manual for the Testing of manufactured Nanomaterials: OECD's Sponsorship Programme; First Revision* [ENV/JM/MONO(2009)20/REV].

- Surface chemistry (where appropriate)
- Photocatalytic activity
- Pour density
- Porosity
- Octanol-water partition coefficient, where relevant
- Redox potential
- Radical formation potential
- Other relevant Physical-Chemical Properties and Material Characterization information (where available)

Environmental Fate

- Dispersion stability in water
- Biotic degradability
- Ready biodegradability
- Inherent biodegradability
- Simulation testing on ultimate degradation in surface water
- Soil simulation testing
- Sediment simulation testing
- Sewage treatment simulation testing
- Identification of degradation product(s)
- Further testing of degradation product(s) as required
- Abiotic Degradability and Fate
- Adsorption- desorption
- Adsorption to soil or sediment
- Bioaccumulation potential
- Other relevant environmental fate information (when available)

Environmental Toxicology

- Effects on pelagic species (short term/long term)
- Effects on sediment species (short term/long term)
- Effects on soil species (short term/long term)
- Effects on terrestrial species
- Effects on microorganisms
- Effects on activated sludge at WWTP
- Other relevant information (when available)

Mammalian Toxicology

- Pharmacokinetics/ Toxicokinetics (ADME)
- Acute toxicity

- Repeated dose toxicity

If available:

- Chronic toxicity
- Reproductive toxicity
- Developmental toxicity
- Genetic toxicity
- Experience with human exposure
- Other relevant test data

Material Safety

Where available:

- Flammability
- Explosivity
- Incompatibility