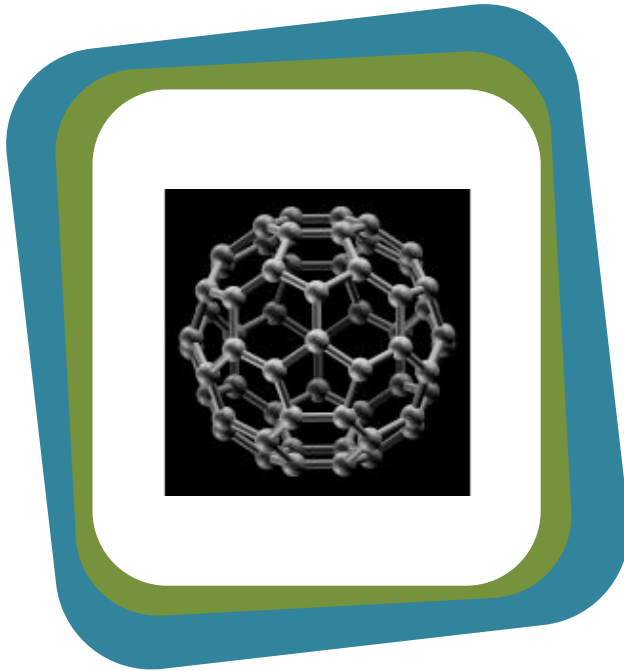


Nanosafety at the OECD: The First Five Years 2006-2010



BETTER POLICIES FOR BETTER LIVES

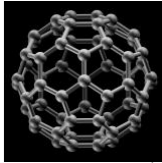
OECD
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Table of Contents

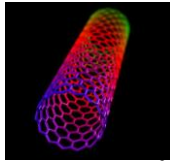
WHAT IS “NANO”?	3
WHY “NANOSAFETY”?	3
WHY OECD IS ADDRESSING THE SAFETY OF MANUFACTURED NANOMATERIALS?	4
1. Highlights of the WPMN's activities.....	4
2. Priority areas for the OECD' WPMN	7
3. Major outcomes of the WPMN's projects	8
4. Outreach.....	13
WHAT'S NEXT?	14
KEY PUBLICATIONS.....	14

What is “nano”?

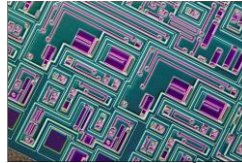
“Nano” comes from the Greek word for “dwarf”. It is used in the measurement systems to refer to a very small size. A nanometer (nm) is one billionth of a metre. A nm is about $1/50,000^{\text{th}}$ the width of a human hair and a sheet of paper is about 100,000 nm thick.



Fullerene (C60)¹



Carbon nanotube²



Nanoelectronics³

Why “nanosafety”?

On the nano-scale, typically within the range of 1-100 nm in at least one dimension, the properties of materials can be different from those on a larger scale. The novel properties of nanomaterials enable diverse application areas, such as in medicine, environment and energy production. These possibilities lead to a lot of benefits including:

- detection of genetic sequence using DNA-tagged gold nanoparticles
- effective waste-water treatment with carbon nanotube filters
- enhanced renewable energy sources from solar cells using silicon nanocrystals

Manufactured nanomaterials are already used in a number of commercial applications; which raise questions regarding potential unintended hazards to humans and the environment. A debate is taking place on whether nanomaterials need special regulation to deal with those potential risks. There is a need for a responsible and co-ordinated approach to ensure that potential safety issues are being addressed at the same time as the technology is developing.

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Why OECD is addressing the safety of manufactured nanomaterials?

OECD assists countries, amongst other things, in the implementation of national policies that guarantee the responsible development of nanotechnologies. As such, part of its work is focused on the safety evaluation and assessment of manufactured nanomaterials that ensure human health and environmental safety.

This work is overseen by the **OECD's Working Party on Manufactured Nanomaterials (WPMN)**. This body 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. Its programme seeks to promote international co-operation on the human health and environmental safety of manufactured nanomaterials, and involves the safety testing and risk assessment of manufactured nanomaterials.

1. Highlights of the WPMN's activities

In June 2005, the OECD's Chemicals Committee held a *Special Session on the Potential Implications of Manufactured Nanomaterials for Human Health and Environmental Safety*. This was the first opportunity for governments to begin to identify human health and environmental safety related aspects of manufactured nanomaterials.

The *OECD's Working Party on Manufactured Nanomaterials (WPMN)* was established in 2006. It comprises delegates from those ministries and agencies which are responsible for the safety of human health and the environment, with support from the Secretariat. WPMN meetings have been held every 8 months since October 2006. Furthermore, Workshops, Expert Meetings and/or Conferences are organised between the meetings as needed, such as:

- OECD's Meeting on the Sponsorship Programme for the Safety Testing of Manufactured Nanomaterials and Test Guidelines (March 2011)
- OECD's Workshop on the 2nd Phase of OECD's Sponsorship Programme and Further Testing Strategies (January 2011)
- 2nd OECD's Expert Consultation Meeting on Alternative Test Methods (January 2011)
- OECD's Expert Workshop of the TiO₂ Sponsorship Group (January 2011)
- OECD's Meeting on the Sponsorship Programme for the Safety Testing of Manufactured Nanomaterials (July 2010)
- OECD's Meeting on Exposure Measurement and Exposure Mitigation (June 2010)
- 1st OECD's Expert Consultation Meeting on Alternative Test Methods (April 2010)
- UNITAR/ OECD/ IOMC Awareness-Raising Workshops for Developing and Transition Countries on Nanotechnology/ Manufactured Nanomaterials (November 2009-April 2010)
- OECD's Meeting on Risk Assessment of Manufactured Nanomaterials (September 2009)
- OECD Workshop on Risk Assessment of Manufactured Nanomaterials in a Regulatory Context (September 2009)
- OECD's Conference on Potential Environmental Benefits of Nanotechnology: Fostering Safe Innovation-Led Growth (July 2009)
- OECD's Meeting on the Sponsorship Programme for the Safety Testing of Manufactured Nanomaterials (March 2009)
- OECD's Workshop on the Safety Testing of Manufactured Nanomaterials (November 2008)

- OECD's Workshop on Exposure Assessment and Exposure Mitigation for Nanomaterials in the Workplace (October 2008)
- OECD's Workshop on the Sponsorship Programme for the Testing of Manufactured Nanomaterials (April 2008)
- NEDO, AIST and OECD International Symposium on the Risk Assessment of Manufactured Nanomaterials (April 2008)
- OECD's Meeting on EHS Research Activities, Safety Testing of a Representative Set of Manufactured Nanomaterials, and Test Guidelines (March 2007)
- OECD's Workshop on the Safety of Manufactured Nanomaterials (December 2005)
- OECD's Special Session on the potential implications of Manufactured nanomaterials for human health and Environmental safety (June 2005)



2. Priority areas for the OECD' WPMN

The OECD programme has focused in generating appropriate methods and strategies to ensure potential safety issues, through:

- Establishing an OECD database on manufactured nanomaterials to inform and analyse research activities and strategies on environmental, human health and safety issues;
- Testing specific nanomaterials for their human health and safety evaluation, while ensuring appropriate testing methods (*in vivo* & *in vitro*), in addition to promoting the development of alternative test methods to nano-toxicity testing;
- Promoting co-operation on voluntary schemes and regulatory programmes;
- Facilitating international co-operation on risk assessment strategies;
- Developing guidance on exposure measurement and exposure mitigation at the workplace, for consumers and for the environment; and
- Promoting the environmentally sustainable use of nanotechnology through enhancing the knowledge base about life cycle aspects of manufactured nanomaterials. This should be done at their different stages of development and applications regarding the impacts on human health and environmental safety.

Did you know?

The **Organisation for Economic Co-operation and Development (OECD)** is an intergovernmental organisation, whose aim is to promote policies for sustainable economic growth and employment. By "sustainable economic growth" the OECD means growth that balances economic, social and environmental considerations.

OECD's WPMN is regularly engaging not just member countries - the major developed countries – but also key emerging economies, such as China, the Russian Federation, South Africa, and Thailand. In addition, the discussion benefits from the inputs from other stakeholders such as Environmental NGOs, labour, industry, Animal welfare and other international organisations.

3. Major outcomes of the WPMN's projects

The WPMN is addressing various areas. Background information and major achievements for each area are presented below:

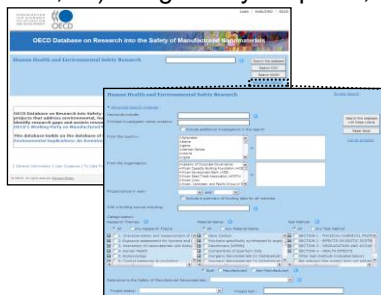
OECD Database on Manufactured Nanomaterials to Inform and Analyse EHS Research Activities

The objective of this project is to develop a **global resource for research projects** that address environmental, human health and safety (EHS) issues of manufactured nanomaterials. This database collects research information and allows to search by categories (e.g. nanomaterials, test methods, research areas, etc) and identifies research gaps.

On the other hand, it should assist researchers in future collaborative efforts. It is worth noticing that *Research* is defined in a broad sense. Thus, it includes not only experimental studies, but also projects relevant to EHS with regard to: i) Comprehensive risk assessments of specific substances; ii) Risk mitigation measures; iii) Regulatory aspects; iv) International standard setting; and v) Reports on public dialogues.

The OECD database was publicly launched in April 2009, and now includes data on more than 770 research projects. The database can be found at:

www.oecd.org/env/nanosafety/database



Safety Testing of a Representative Set of Manufactured Nanomaterials

A major outcome is the “**Sponsorship Programme for the Testing of Manufactured Nanomaterials**” which was launched in November 2007. This project builds upon the concept that much valuable information on the safety of manufactured nanomaterials, as well as the methods to assess safety, can be derived by testing certain nanomaterials for human health and environmental safety effects.

The Sponsorship Programme involves OECD member countries, as well as some non-member economies and other stakeholders to pool expertise and to fund the safety testing of specific manufactured nanomaterials. In initiating this programme, the WPMN agreed on a priority list of manufactured nanomaterials for testing, based on materials which are in, or close to, commerce (See box).

At the same time, a number of endpoints were selected for their relevance in providing crucial information for environmental and human health safety. Therefore, each selected manufactured nanomaterial will be tested for their physical-chemical properties, environmental degradation and accumulation, environmental toxicology and mammalian toxicology.



The outcomes of this Sponsorship Programme will provide information on the “intrinsic properties” of nanomaterials, that is, on properties of nanomaterials which are unique to the nanoscale dimension of these materials. Understanding intrinsic properties of nanomaterials is crucial in choosing existing risk evaluation and management strategies; or adapting them; or for creating new strategies.

As part of the programme, a *Guidance Manual for the Testing of Manufactured Nanomaterials* has been developed to assist Sponsors in the development of Dossier Development Plans (DDPs) and includes a *Data Sharing Template*; and a section on *Alternative methods*.

The Role of Alternative Test Methods in Nanotoxicology

This project addresses the use of alternative methods and Integrated Testing Strategies (ITS) for manufactured nanomaterials. As such, it is focused on those *in vitro* or other “**Alternative methods**” (for reduction, refinement or replacement of animals in tests) and ITS approaches that could be further explored in respect to manufactured nanomaterials. An outcome of this project will be a *Guidance on Integrated Testing*

Strategies, which will focus on those manufactured nanomaterials currently sponsored through the OECD's Sponsorship Programme.

Manufactured Nanomaterials and Test Guidelines

Through this project, OECD is carefully evaluating any concrete proposals for the **development or revision of test guidelines and/or guidance documents**, which takes into account existing information and results coming from the scientific community. A preliminary review of OECD test guidelines (TGs) has shown that most TGs are suitable but that, in some cases, modification will be needed for their **applicability to manufactured nanomaterials**. Because the information concerning the properties of nanomaterials and their effects is still being developed (for example, through the Sponsorship Programme), the process to move ahead is flexible and able to adapt new information.



As such, some of the outcomes are being publicised as “living documents” and they are expected to be revised as new information becomes available. For example, the document *Preliminary*

Guidance Notes on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials.

Furthermore, the WPMN has developed an IT collaborative platform called “**Communities of Practice**” (CoP), which refers to groups of experts who convene to discuss technical issues related to testing being conducted under the Sponsorship Programme.

Co-operation on Voluntary Schemes and Regulatory Programmes

Through this project, **various national voluntary reporting schemes and regulatory programmes have been analysed to assess the safety of manufactured nanomaterials**. To date, the main outputs of this project have been: i) *An analysis of Information Gathering Initiatives on Manufactured Nanomaterials*, which includes an information gathering schemes: table of comparison; and ii) *Regulatory Regimes for*

Manufactured Nanomaterials: questionnaire, which includes legislative features identified in legislations on regulatory oversight of nanomaterials/products.

Surveys are underway amongst national bodies with the aim: i) to update trends relating commercial activities and the regulatory oversight; as well as ii) to collect specific information on manufactured nanomaterials (such as types and volumes used). Thus, the surveys include questions regarding: i) Information gathering schemes; and ii) Regulated nanomaterials. In addition, national delegations can use a collaborative workspace as well as an “Information Sharing Database” to share information and ideas on voluntary information gathering schemes and regulatory systems.

Co-operation on Risk Assessment

The overall objectives of this project are to **evaluate risk assessment approaches for manufactured nanomaterials** through information exchange and to identify opportunities to strengthen and enhance risk assessment capacity. Through this project, it is expected that the outcomes of the work of the other WPMN projects be integrated into an overall framework within which risks of manufactured nanomaterials are assessed, ensuring good practice across OECD countries and other interested parties.



Co-operation on Exposure Mitigation and Exposure Measurement

Through this project the WPMN is **exchanging information on guidance for exposure measurement** (including sampling techniques and protocols) **and exposure mitigation for manufactured nanomaterials**. This is been achieved by addressing: i) Exposure in occupational settings; ii) Exposure to humans resulting from contact with consumer products and environmental releases of manufactured nanomaterials; and iii) Exposure to environmental species (including compartments water, air and soil) resulting from environmental releases of manufactured nanomaterials, including releases from consumer products.

A number of specific projects on occupational, consumer and environmental exposure have been identified and prioritised by the

WPMN. Currently, two projects are underway: i) Measurement techniques and sampling protocols for determining concentrations of manufactured nanomaterials in the air; and ii) Compilation of publicly available information and research activities related to disposal and treatment technologies of manufactured nanomaterials. Previous publications include:

- *Compilation and Comparison of Guidelines related to Exposure to Nanomaterials in Laboratories;*
- *Comparison of Guidance on Selection of Skin Protective Equipment;* and
- *Respirators for Use in the Workplace: Manufactured Nanomaterials.*

Furthermore, a number of case studies on the exposure assessment of manufactured nanomaterials will be developed. The first case study being on nano-silver.

Environmentally Sustainable Use of Nanotechnology

The aim of this project is to **investigate the potential benefits of applications based on the use of manufactured nanomaterials**. The expected outcome is to develop tools and frameworks based on **life cycle considerations for different nano-enabled applications** that: i) directly address an environmental problem; and ii) indirectly contribute to environmental objectives. As such, the project will address environmental benefits, sustainability and life-cycle related issues. Through this project, the WPMN focuses on the potential positive and negative impacts on environment and health of certain nano-enabled applications at their different stages of development. In this regard, this project is closely linked to green growth related work to address major environmental challenges.

This project builds on the outcomes of the OECD Conference on the *Potential Environmental Benefits of Nanotechnology: Fostering Innovation -Led Growth*, which was held on 15-17 July 2009.

Did you know?

Nanotechnology can offer a wide range of environmental benefits such as renewable energy production under the provision that potential safety issues are being addressed and as a result contribute to **promoting green growth**.

4. Outreach

OECD is a Participating Organisation (PO) of the *Inter-Organisation Programme for the Sound Management of Chemicals (IOMC)* to strengthen co-operation and increase co-ordination in the field of chemical safety amongst international organisations. OECD is also engaged bilaterally with other intergovernmental organisations addressing the safety of manufactured nanomaterials, such as FAO, UNITAR and WHO.

Recently, OECD and UNITAR jointly held *Awareness-Raising Workshops on Nanotechnology/ Manufactured Nanomaterials for Developing and Transition Countries*. These workshops were organised in conjunction with the *Strategic Approach to International Chemicals Management (SAICM)* UN regional meetings during 2009-2010. The workshops informed on potential applications and risks from nanotechnologies and manufactured nanomaterials as well as looked for opportunities for awareness raising activities to be undertaken in those countries.

The workshops were held as follows:

- Asia-Pacific Region: 27 November 2009, in Beijing, China
- Central and Eastern Europe Region: 11 December 2009, in Lodz, Poland
- Africa Region: 25-26 January 2010, in Abidjan, Cote d'Ivoire
- Latin America-Caribbean Region: 12 March 2010, in Kingston, Jamaica
- Arab Sub-Region: 11-13 April 2010, in Alexandria, Egypt



The OECD's WPMN co-ordinates its programme with other activities addressing nanotechnologies. Co-ordination has two main levels: i) internal co-ordination, which includes the activities of other OECD's programmes, such as OECD's Working Group on National Co-ordinators of Test Guidelines Programme (WNT) and the OECD's Working Party on Nanotechnology (WPN); and ii) co-ordination with other international and/or national initiatives. With this in mind, OECD is strengthening communication with other international organisations such as the IOMC participating organisations (i.e. FAO, ILO, UNEP, UNIDO, UNITAR and WHO), as well as with the International Standards Organisation Technical Committee 229 (ISO TC/229).








What's next?

OECD's research and development programme regarding manufactured nanomaterials is progressing rapidly, so the programme remains flexible in order to address emerging issues in a timely and resource efficient way. There is still much to learn to fully understand how to work safely with some nanomaterials. However, if countries continue to work together in the OECD, as they have started to do, this should ensure that the human health and environmental safety aspects are addressed appropriately and efficiently at the same time, as the economic opportunities of the technology advance.

Key publications

All publications are available for free of charge at the OECD public website: www.oecd.org/env/nanosafety

-  Compilation and Comparison of Guidelines related to Exposure to Nanomaterials in Laboratories (2010)
-  List of Manufactured Nanomaterials and List of Endpoints for Phase One of the Sponsorship Programme for the Testing of Manufactured Nanomaterials: Revision (2010)
-  Current Developments/Activities on the Safety of Manufactured Nanomaterials, Tour de Table at the 7th Meeting of the Working Party on Manufactured Nanomaterials (2010)
-  Guidance Manual for the Testing of Manufactured Nanomaterials: OECD Sponsorship Programme: First Revision (2010)
-  Preliminary Guidance Notes on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials (2010)
-  Regulatory Regimes for Manufactured Nanomaterials (2010)
-  Analysis of Information Gathering Initiatives on Manufactured Nanomaterials (2009)

-  Manufactured Nanomaterials: Work Programme 2009-2012 (2009)
-  Preliminary Review of OECD Test Guidelines for their Applicability to Manufactured Nanomaterials (2009)
-  Report of an OECD Workshop on Exposure Assessment and Exposure Mitigation: Manufactured Nanomaterials (2009)
-  Comparison of Guidance on Selection of Skin Protective Equipment and Respirators for Use in the Workplace: Manufactured Nanomaterials (2009)
-  EHS Research Strategies on Manufactured Nanomaterials: Compilation of Outputs (2009)
-  Manufactured Nanomaterials: Programme of Work 2006-2008 (2008)
-  Report of the OECD Workshop on the Safety of Manufactured Nanomaterials: Building Co-operation, Co-ordination and Communication (2006)



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