

# **OECD Working Party on Manufactured Nanomaterials (WPMN)**

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## The Business and Industry Advisory Committee to the OECD (BIAC)

### What is BIAC ?

An independent international business association devoted to advising government policymakers at the OECD and other related forums on the many diversified issues of globalization and the world economy.

Founded in 1962 – officially recognized by the OECD as being representative of the OECD business community

### What is BIAC's mission?

BIAC promotes the interests of business by engaging, understanding and advising OECD policymakers on a broad range of issues.

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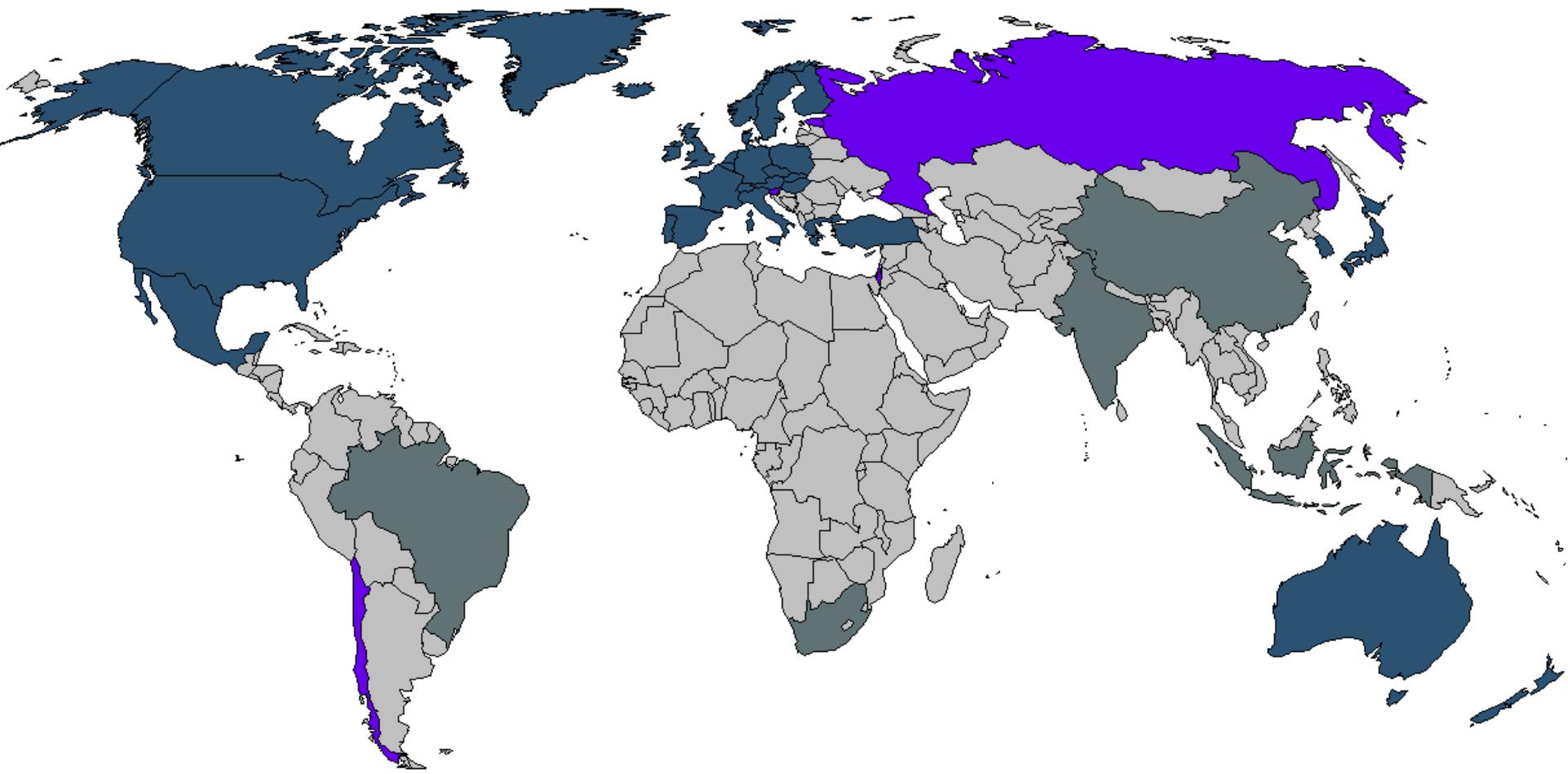
# **Organization for Economic Co-Operation and Development (OECD)**

**Intergovernmental organization founded in 1961- 30 major countries committed to democracy and the market economy**

**The OECD researches social changes and evolving patterns in science and technology, environment, trade, fiscal policy, education and more, with the overall objective to:**

- ◆ Support economic growth
- ◆ Boost employment
- ◆ Raise living standards
- ◆ Maintain financial stability
- ◆ Assist other countries' economic development
- ◆ Contribute to growth in world trade

**Major new focus on Outreach, Accession and Enhanced Engagement with the major transition economies**



 OECD member countries

 Countries invited to open talks on potential membership

 Countries to which OECD is offering enhanced engagement



# Major OECD Work Areas

- ◆ Economics
- ◆ Science and Technology and Innovation
- ◆ Employment and Education
- ◆ Environment and Sustainable Development
- ◆ Finance, Investment Policy, and Tax Policy
- ◆ Governance
- ◆ Development
- ◆ Trade and Competition
- ◆ Health



# OECD Structure

- ◆ OECD is led by Secretary-General Angel Gurría (Mexico)
- ◆ The work of OECD is conducted within departments, directorates, centers and agencies
- ◆ The two principle areas for nanotechnology work are contained within:

Environment Directorate (ENV)

Directorate for Science, Technology and Industry (STI)



# **OECD Work on Nanotechnology: 2 work streams**

## **ENV Directorate**

OECD Working Party on Manufactured Nanomaterials  
(WPMN)

## **STI Directorate**

OECD Working Party on Nanotechnology (WPN)



# OECD WPN

- ◆ Established in March 2007 under the Committee on Scientific and Technological Policy (CSTP) within the STI Directorate.
- ◆ The objective of this Working Party is to promote international cooperation that facilitates research, development, and responsible commercialization of nanotechnology in member countries and in non-member economies.
- ◆ The Working Party has initiated five projects to achieve its objectives:
  - Statistical Framework
  - Business Environments
  - Policy Roundtables
  - Monitoring and Benchmarking
  - Global challenges: water
- ◆ Next meeting December 1-2, 2009



## OECD WPMN

- ◆ OECD Chemical Committee established a Programme on the Safety of Manufactured Nanomaterials (2006).
- ◆ Objective: To promote international co-operation in human health and environmental safety related aspects of manufactured nanomaterials in order to assist in the development of rigorous safety evaluation of nanomaterials.
- ◆ To accomplish this work, the WPMN has established nine sub-groups.

# Working Party on Manufactured Nanomaterials (WPMN) Sub-groups

SG1: Development of an OECD database on EHS Research

Merged

SG2: EHS Research Strategies on Manufactured Nanomaterials

**(New SG1/SG2 – OECD Database on Manufactured Nanomaterials to Inform and Analyze EHS Research Activities)**

SG3: Safety Testing of a Representative Set of Manufactured Nanomaterials

SG4: Manufactured Nanomaterials and Test Guidelines

SG5: Co-operation on Voluntary Schemes and Regulatory Programmes

SG6: Co-operation on Risk Assessments ~~and Exposure Assessment~~

SG7: The Role of Alternative Methods in Nano Toxicology (Added Nov. 2007)

SG8: Exposure Measurement and Exposure Mitigation (Added Nov. 2007)

SG9: Co-operation on the Environmentally Sustainable Use of Nanotechnology  
(Added Mar. 2009)



## **OECD Database on Manufactured Nanomaterials to Inform and Analyze EHS Research Activities (WPMN Steering Groups 1 and 2)**

### **Original objectives of SG1(Development of an OECD Database on EHS Research)**

- ◆ Development of the OECD Database of Research into the Safety of Manufactured Nanomaterials
- ◆ Support of other SGs through identifying relevant research projects or storing information derived from the projects

### **Original objectives of SG2 (EHS Research Strategies on Manufactured Nanomaterials)**

- ◆ Exchange of information on research activities
- ◆ Identification of common research needs to address human health and environmental safety issues associated with manufactured nanomaterials.

### **Deliverables to date:**

- ◆ The SG1 database on publically-funded EHS research activities was launched on April 1, 2009.
- ◆ As of October 1, 2009, There are 732 projects in the database

<http://webnet.oecd.org/NanoMaterials/>



# Safety Testing of a Representative Set of Manufactured Nanomaterials (WPMN Steering Group 3)

## Objective

- ◆ Agree on and test a representative set of manufactured nanomaterials in accordance with the guidance manual for sponsors

## Activities

- ◆ Project will be in two stages, a project definition stage and an implementation stage. The project definition stage is now complete. The implementation stage is underway, and will test the substances selected through “Phase One” and “Phase Two” testing.
  - Phase 1 deals with gaining knowledge about the intrinsic characteristics of the material
  - Phase 2 will address hazard and risk assessment



# Manufactured Nanomaterials and Test Guidelines (WPMN Steering Group 4)

## Objective

- ◆ Review of OECD Test Guidelines for their Applicability to Manufactured Nanomaterials

## Activities

- ◆ The general finding was that in principle existing OECD Test Methods are capable to detect effects of Nanomaterials. In the area of physical-chemical data, some additional tests will be needed.

## The group's focus now includes:

- ◆ Finalizing the guidance notes for sample preparation and dosimetry
- ◆ Setting up communities of practice for the four test guideline-related areas (i.e., physical-chemical properties (materials characterization) ; effect on biotic systems; degradation and accumulation; and health effects)
- ◆ Developing a draft list of recommended changes to existing guidelines and new test guidelines to be developed.



# Co-operation on Voluntary Schemes and Regulatory Programs (WPMN Steering Group 5)

## Objectives

- ◆ To identify common elements of the various information-gathering initiatives, in place or planned
- ◆ To submit suggestions to countries on approaches and elements to consider for information gathering initiatives
- ◆ To identify applicable current and proposed regulatory regimes and how they address information requirements

## Activities

- ◆ Utilizing the results of a questionnaire, SG5 (led by Canada) has prepared a report on the current and proposed oversight for manufactured nanomaterials and how it addresses information requirements, hazard identification, risk assessment and exposure/risk management of nanomaterials



## Co-operation on Risk Assessment (WPMN Steering Group 6)

### Objectives

- ◆ The overall objective of this project is to evaluate risk assessment approaches for manufactured nanomaterials through information exchange and identify opportunities to strengthen and enhance risk assessment capacity

#### Detailed objectives include:

- ◆ Exchange, collate and synthesize information on risk assessment approaches for chemicals that may apply to manufactured nanomaterials
- ◆ Undertake a gap analysis of current risk assessment approaches as these apply to manufactured nanomaterials
- ◆ Make recommendations to WPMN for addressing and filling identified gaps

### Activities

- ◆ A workshop on risk assessment of Manufactured nanomaterials in a regulatory context, co-sponsored by SG6 and the Society for Risk Analysis (SRA), was held in Washington, D.C. on September 16-17, 2009.
- ◆ Completing the report on risk assessment critical issues as a “snapshot” of existing methodologies and without recommending specific risk assessment methodologies



# The Role of Alternative Methods in Nano Toxicology (WPMN Steering Group 7)

## Objectives

- ◆ Review and assess existing test methods, other than OECD test guidelines for bulk chemicals, for reliability and relevance, when applied to manufactured nanomaterials
- ◆ Perform coverage and gap analysis with regard to addressed endpoints
- ◆ Identify and describe need for development of new or adaptation of existing test methods and in cooperation with SG4 on adaptation or development of test guidelines
- ◆ Develop integrated testing strategies in support of the overall assessment plans

## Activities

- ◆ Developed text on alternative methods for the guidance manual for sponsors
- ◆ Started to develop an inventory of potential in vitro test methods with particular consideration to manufactured nanomaterials endpoints (mode of action)
- ◆ Plan to develop an information platform for methods and/or results including potential for manufactured nanomaterials to interfere with test system components
- ◆ Address reliability (repeatability/reproducibility) and relevance (predictability)
- ◆ Plan to prioritize accordingly for further method standardization, validation, and harmonization
- ◆ Coordinate activities with SG-3, SG-4 and SG-6 to develop guidance on an integrated testing strategy



# Exposure Measurement and Mitigation (WPMN Steering Group 8)

## Objective

- ◆ To exchange information on guidance for exposure measurement (including sampling techniques and protocols) and exposure mitigation for manufactured nanomaterials and to develop suggestions for further actions to be undertaken by the WPMN
- ◆ The first phase of work will focus on exposure in occupational settings

## Activities

- ◆ Two phase 1 projects have been completed and declassified
  - Emission Assessment for Identification of Sources and Release of Airborne Manufactured Nanomaterials in the Workplace
  - Comparison of Guidance on Selection of Skin Protective Equipment and Respirators for Use in the Workplace
- ◆ A new phase 1 project on laboratory guidance has been started by the German Federal Institute for Occupational Safety and Health
- ◆ BIAC has invited SG 8 to become an associated partner for the planned conference “Workplace Aerosols” in Germany in June/July 2010



# Co-operation on the Environmentally Sustainable Use of Nanotechnology (WPMN Steering Group 9)

- ◆ Established at 5<sup>th</sup> meeting of WPMN (March 2009)
- ◆ Operational plan incorporated ideas generated at the OECD Conference on Potential Environmental Benefits of Nanotechnology held in July 2009

## Objective

- ◆ Develop tools and frameworks based on life cycle considerations for different nano-enabled applications that 1) directly address an environmental problem (i.e. water purification, remediation), or 2) indirectly contribute to environmental objectives (i.e. being more energy and/or resource efficient)

## Considerations behind the project

- ◆ Exchange information about “environmental benefits”
- ◆ Addressing data scarcity and resource issues – life cycle considerations
- ◆ Broad information about the impact of nano-enabled applications



# OECD Launches Program on Safety Testing of Nanomaterials (November 30, 2007)

## 3 Participation Levels

- ◆ **Lead Sponsor(s)** - volunteering to assume responsibility for conducting and coordinating all of the testing determined to be appropriate and feasible for a listed Nanomaterial
- ◆ **Co-Sponsor(s)** - volunteering to conduct some of the testing determined to be appropriate and feasible for a specific listed nanomaterial
- ◆ **Contributor** - volunteering to provide existing test data, reference or testing materials or other relevant information to the lead and secondary sponsors

# List of Manufactured Nanomaterials (Annex I)

- ◆ Fullerenes (C60)
- ◆ Single-walled carbon nanotubes (SWCNTs)
- ◆ Multi-walled carbon nanotubes (MWCNTs)
- ◆ Silver nanoparticles
- ◆ Iron nanoparticles
- ◆ Carbon black
- ◆ Titanium dioxide
- ◆ Aluminum oxide
- ◆ Cerium Oxide
- ◆ Zinc oxide
- ◆ Silicon dioxide
- ◆ Polystyrene
- ◆ Dendrimers
- ◆ Nanoclays

# List of Endpoints (Annex II)

- ◆ **Nanomaterial Information/Identification (9 endpoints)**
- ◆ **Physical-Chemical Properties and Material Characterization (17 endpoints)**
- ◆ **Environmental Fate (13 endpoints)**
- ◆ **Environmental Toxicology (6 endpoints)**
- ◆ **Mammalian Toxicology (9 endpoints)**
- ◆ **Material Safety (3 endpoints)**

# OECD Sponsorship Program Sponsorship Arrangements

	Lead Sponsor (s)	Co-sponsor (s)	Contributor
Fullerenes(C60)	Japan, United States		China, Denmark
SWCNTs	Japan, United States		Canada, France, Germany, EC, China, BIAC
MWCNTs	Japan, United States	Korea, BIAC	Canada, France, Germany, EC, China, BIAC
Silver nanoparticles	Korea, United States	Australia, Canada, Germany, Nordic Council	France, EC, China, <b>Netherlands</b>
Iron nanoparticles	China, BIAC		United States, Nordic Council, <b>Canada</b>
Carbon black			Germany, United States, Denmark, <b>Canada</b>
Titanium dioxide	Germany, France	Canada, Korea, Spain, Austria, EC United States, BIAC	China, Denmark, Japan, United Kingdom

# OECD Sponsorship Program Sponsorship Arrangements

	Lead Sponsor (s)	Co-sponsor (s)	Contributor
Aluminum oxide			Germany, United States, Japan
Cerium oxide	United States, United Kingdom, BIAC(NIA)	Netherlands, Australia, Spain	Germany, EC, Denmark, Switzerland, Japan, Netherlands
Zinc oxide	United Kingdom, BIAC(NIA)	Australia, Spain, BIAC(CEFIC), United States	Canada, Japan, Denmark, Germany, Netherlands
Silicon dioxide	EC, France	Korea, Belgium, BIAC(CEFIC)	Denmark, Japan
Polystyrene			Korea, Austria
Dendrimers		Spain, United States	
Nanoclays			United States, Denmark, EC



# Sponsorship Program Tools and Guidance

**Guidance Manual for Sponsors** – objective is to assist sponsors in the development of dossiers including the design and conduct of the testing program

**Dossier Development Plan Review Group** - work with sponsors to help ensure the adequacy of the dossier developed for each material

**Reporting Template** – provides guidance on how to report testing results

# Industry Association Nano Activities



<http://www.americanchemistry.com>



<http://www.cefic.be>



<http://www.nikkakyo.org/English>

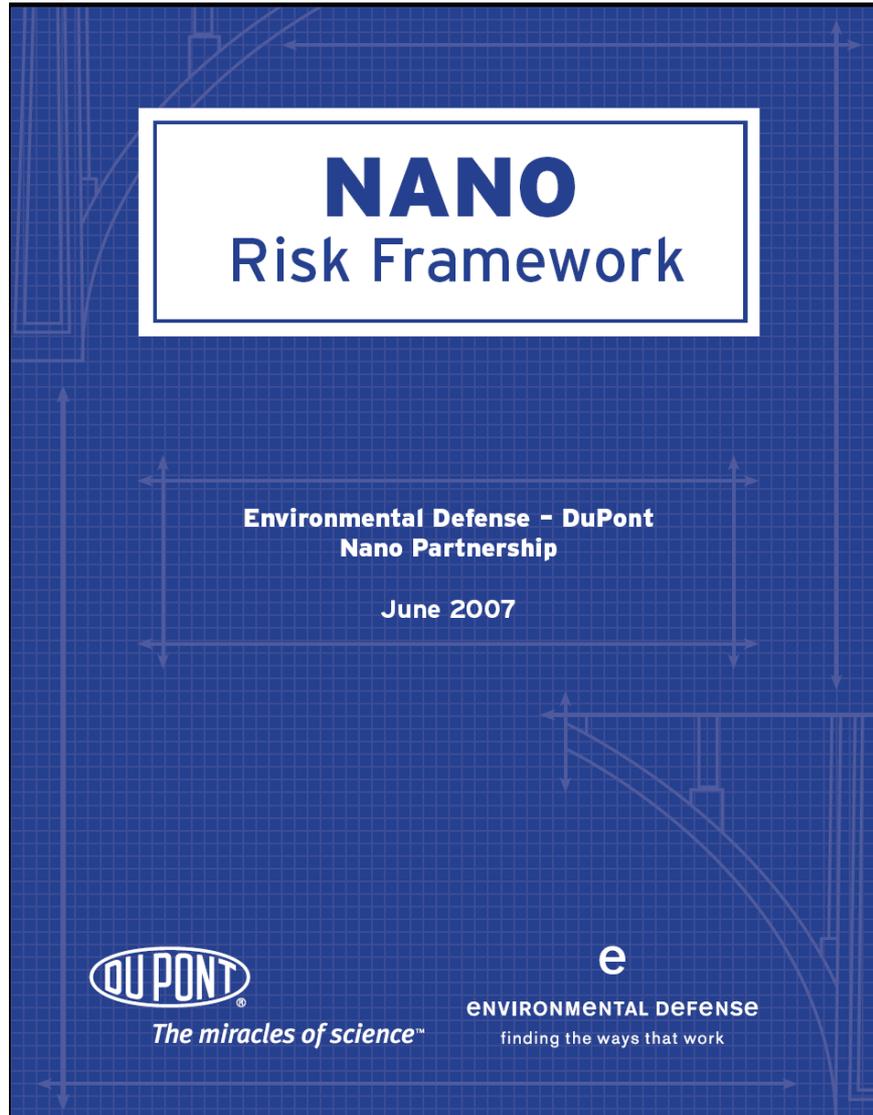


<http://www.nanotechia.org>



<http://www.vci.de>

# EDF and DuPont Partnership



[www.NanoRiskFramework.com](http://www.NanoRiskFramework.com)

**Thank You**

**Questions ?**