

# OECD WPMN SG3

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***International Workshop on Documentary Standards for  
Measurement and Characterization in Nanotechnologies***

# Project 3: Safety Testing of a Representative Set of Manufactured Nanomaterials

- Objective: *to agree and test a representative set of manufactured nanomaterials (MN) using appropriate test methods.*
- Co-Chairs: USA and European Community
- Status:
  - Testing program agreed encompassing 14 nanomaterials and a range of endpoints.
  - Sponsorship program agreed to/guidance manual under development

# Representative Nanomaterials

Fullerenes (C60)

SWCNTs

MWCNTs

Silver nanoparticles

iron nanoparticles

carbon black

titanium dioxide

aluminium oxide

cerium oxide

zinc oxide

silicon dioxide

polystyrene

dendrimers

nanoclays

# Endpoints

- “Minimal Exploratory Dataset”:
  - Physical-chemical properties
  - Materials Characterization
  - Environmental fate
  - Environmental toxicity
  - Mammalian toxicity
  - Safety
- Alternative approaches and methods, including in vitro
- Investigation of different particle sizes, shapes, coatings and/or modifications
- End product of Phase 1 is a “dossier” with supporting data
- 2<sup>nd</sup> Phase envisioned

# Endpoints (2)

- **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)

# Endpoints (3)

- **Physical-Chemical Properties and Material Characterization**
  - Agglomeration/aggregation
  - Water solubility
  - Crystalline phase
  - Dustiness
  - Crystallite size
  - Representative TEM picture(s)
  - Particle size distribution
  - Specific surface area
  - Zeta potential (surface charge)
  - Surface chemistry (where appropriate)
  - Photocatalytic activity
  - Pour density
  - Porosity
  - Octanol-water partition coefficient, where relevant
  - Redox potential
  - Radical formation potential
  - Other relevant information (where available)

# Endpoints (4)

- **Environmental Fate**
  - Dispersion stability in water
  - Biotic degradability
    - Ready 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
    - Hydrolysis, for surface modified nanomaterials
    - Adsorption- desorption
    - Adsorption to soil or sediment
  - Bioaccumulation potential
  - Other relevant information (when available)

# Endpoints (5)

- **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
  - Other relevant information (when available)

# Endpoints (6)

- **Mammalian Toxicology**
  - Pharmacokinetics (ADME)
  - Acute toxicity
  - Repeated dose toxicity
- If available:
  - Chronic toxicity
  - Reproductive toxicity
  - Developmental toxicity
  - Genetic toxicity
  - Experience with human exposure
  - Other relevant test data

# Endpoints (7)

- **Material Safety**
  - Where available:
  - Flammability
  - Explosivity
  - Incompatability

# Next Steps

- **Sponsorship sign-up**
  - To date, C60, SWCNT, MWCNT and CeO sponsored
- **Task group to develop a guidance manual for sponsors established (BIAC and US co-chair)**
- **Tokyo Meeting of SG3, SG4, SG7 and sponsors on 23-25 April**
- **WPMN-4 to be held in Paris on 11-13 June**

# Documentary Standards Needs/Gaps

- **Prioritization challenges.** See Work Plan, meeting reports.
- **Fundamental knowledge issues:** Appropriateness of existing test methods or guidelines for listed endpoint. In vitro/alterative methods. Links to SG4 +SG7.
- **Measurement and characterization needs:** Test methods and guidelines, as above.
- **Supporting reference materials** will be needed in relation to parallel work with e.g. SG4 & SG7.
- **Pre- and co-normative research needs:** From SG2.
- **Market need/demand:** Uncertain.
- **Technical or policy issues:** Test materials. Relationship to national, other, research and testing programs. How or where to use existing data, decision logic.