OECD AND THE SAFETY OF NANOMATERIALS: HARMONIZED APPROACHES TO TESTING AND ASSESSMENT

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Areas covered by the OECD Programme

- Testing and Assessment
- Regulatory Programmes and Risk Assessment
- Exposure Measurement and Mitigation
- Environmentally Sustainable Use of Nanomaterials
Endorsed by the OECD Council on 19th September 2013, recommends that:

• Regulatory Frameworks are valid (might need to be adapted)
• Members, in the testing of manufactured nanomaterials, apply the OECD Test Guidelines, adapted as appropriate to take into account the specific properties of manufactured nanomaterials;
• the OECD Principles of Good Laboratory Practice;
• It is open to non-members.
Mutual Acceptance of Data (MAD)

Test Guidelines

Good Laboratory Practice

A single quality standard should be applied for testing of all chemical substances

→ Avoids duplication of testing: around Euros 150 million saved each year
→ Reduces use of animals
→ Reduces trade barriers

Mutual Acceptance of Data
Legally binding on OECD Member countries

A single quality standard for test facilities throughout OECD
International effort to share the testing of an agreed set of manufactured nanomaterials selected by WPMN

- test selected MNs for selected endpoints (completed)
- evaluation of data
<table>
<thead>
<tr>
<th>Material</th>
<th>Lead sponsor(s)</th>
<th>Co-sponsor(s)</th>
<th>Status of the Dossier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fullerenes (C60)</td>
<td>Japan, US</td>
<td></td>
<td>Completed</td>
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<tr>
<td>SWCNTs</td>
<td>Japan, US</td>
<td></td>
<td>Completed</td>
</tr>
<tr>
<td>MWCNTs</td>
<td>Japan, US</td>
<td>Korea, BIAC</td>
<td>Completed</td>
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<tr>
<td>Silver nanoparticles</td>
<td>Korea, US</td>
<td>Australia, Canada, Germany, Nordic Council of Ministers</td>
<td>Completed</td>
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<tr>
<td>Iron Nanoparticles</td>
<td>China</td>
<td>BIAC</td>
<td>Completed</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>France, Germany</td>
<td>Austria, Canada, Korea, Spain, US, EC, BIAC</td>
<td>Completed</td>
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<td>Cerium oxide</td>
<td>US, UK/BIAC</td>
<td>Australia, Netherlands, Spain</td>
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<td>Zinc oxide</td>
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<td>Silicon dioxide</td>
<td>France, EC</td>
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<td>Nanoclays</td>
<td>BIAC</td>
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<td>South Africa</td>
<td>Korea, US</td>
<td>Draft Completed</td>
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List of Endpoints Addressed by the OECD Testing Programme

- Nanomaterial Information/Identification (9 endpoints) substance name, chemical identity, uses, coating
- Physical-Chemical Properties and Material Characterization (17 endpoints) water solubility, particle size, agglomeration/aggregation
- Environmental Fate (15 endpoints) biodegradability, adsorption, accumulation
- Environmental Toxicology (6 endpoints) effects on aquatic and terrestrial organisms
- Mammalian Toxicology (9 endpoints) inhalative toxicity, reproductive toxicity, genotoxicity
- Material Safety (3 endpoints) flammability
Test Guidelines Applicability and Sample Preparation and Dosimetry

- a review of 115 OECD test guidelines (TGs)

Most TGs are suitable but that, in some cases, modifications are needed in order to apply them to manufactured nanomaterials.

- “Guidance on Sample Preparation and Dosimetry to assist in the safety testing of nanomaterials”
Test Guideline assessment: Expert workshops

• Inhalation toxicity (December 2011)
• Environmental fate and eco-toxicity (January 2013)
• Physical-chemical properties (in collaboration with ISO TC229) (March 2013)
• Nano genotoxicity (18-19 November, Canada)
• Toxicokinetics (26-28 February, Korea)
• Grouping of nanomaterials (September, United States)
Test Guideline Development: Proposals

• Amendments to the Inhalation Test Guidelines and Associated Guidance to Accommodate Nanomaterials (lead, the United States);
• Decision Tree Guidance on Aquatic (and Sediment) Toxicity Testing of Nanomaterials (leads, Canada and the United States);
• Guidance Document on Assessing the Apparent Accumulation Potential of Nanomaterials (leads, United Kingdom and Finland);
• Guidance Document for Dispersion and Dissolution of Nanomaterials in Aquatic Media – Decision tree (lead, Germany);
• Test Guideline for Dispersability and Dispersion Behaviour of Nanomaterials in Aquatic Media (lead, Germany);
• Test Guideline for Dissolution of Nanomaterials in Aquatic Media (lead, United States); and
• Test Guideline on Nanomaterial Removal from Wastewater (lead, United States).
Recent/ imminent publications

- Co-operation on Risk Assessment: Prioritisation of Important Issues on Risk Assessment of Manufactured Nanomaterials - Final Report;
- Current Developments on the Safety of Manufactured Nanomaterials - Tour de Table at the 10th Meeting of the Working Party on Manufactured Nanomaterials;
- Rome Workshop Report: Environmentally Sustainable Use of Manufactured Nanomaterials
- Workshop Report: Environmental fate and Ecotoxicity
- Workshop Report: Physical chemical properties (in declassification)
- Recommendation of the Council on the Safety Testing and Assessment of Manufactured Nanomaterials
- Available Methods and Models for Assessing Exposure to MNs (in declassification)
- Environmentally sustainable use of nanotechnology in types
Thank you

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www.oecd.org/env/nanosafety

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