



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

Peter Kearns, PhD  
OECD, ENV/EHS  
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# Areas covered by the OECD Programme

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- Testing and Assessment
- Regulatory Programmes and Risk Assessment
- Exposure Measurement and Mitigation
- Environmentally Sustainable Use of Nanomaterials



# OECD COUNCIL RECOMMENDATION

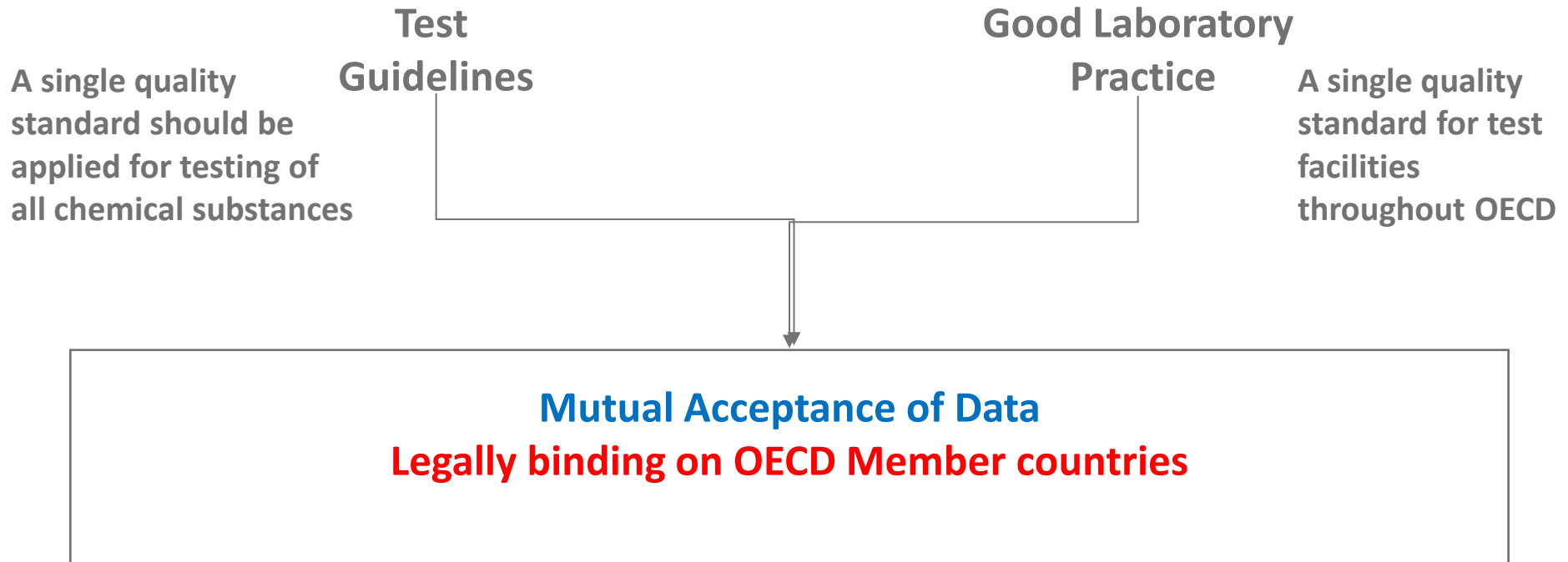
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Endorsed by the OECD Council on 19<sup>th</sup> September 2013, recommends that:

- 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)



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



# TESTING AND ASSESSMENT

## Sponsorship Programme for the Testing of Manufactured Nanomaterials

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



	Lead sponsor(s)	Co-sponsor(s)	Status of the Dossier
Fullerenes (C60)	Japan, US		<i>Completed</i>
SWCNTs	Japan, US		<i>Completed</i>
MWCNTs	Japan, US	Korea, BIAC	<i>Completed</i>
Silver nanoparticles	Korea, US	Australia, Canada, Germany, Nordic Council of Ministers	<i>Completed</i>
Iron Nanoparticles	China	BIAC	<i>Completed</i>
Titanium dioxide	France, Germany	Austria, Canada, Korea, Spain, US, EC, BIAC	<i>Completed</i>
Cerium oxide	US, UK/BIAC	Australia, Netherlands, Spain	<i>Completed</i>
Zinc oxide	UK/BIAC	Australia, US, BIAC	<i>Completed</i>
Silicon dioxide	France, EC	Belgium, Korea, BIAC	<i>Completed</i>
Dendrimers		Spain, US	<i>Completed</i>
Nanoclays	BIAC		<i>pending</i>
Gold Nanoparticles	South Africa	Korea, US	<i>Draft Completed</i>



# List of Endpoints Addressed by the OECD Testing Programme

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- 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

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- a **review** of 115 OECD test guidelines (TGs)

 Most TGs are suitable but that, in some cases, modification 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

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- 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

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- 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

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- 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



# OECD Nanosafety Team

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## Thank you

Peter Kearns, Mar Gonzalez, Asako Aoyagi,  
Hoseok Song, Jihane El Gaouzi, Mika Hosokawa.

[www.oecd.org/env/nanosafety](http://www.oecd.org/env/nanosafety)

[peter.kearns@oecd.org](mailto:peter.kearns@oecd.org)