

OECD WORK ON MANUFACTURED NANOMATERIALS

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What is the OECD?

Organisation for Economic Co-operation and Development

- Intergovernmental, 35 member countries + other partners, Brazil, China, India, Indonesia, South Africa
- Accession countries: Colombia, Cost Rica, etc
- Advice to governments, **information exchange**, Analyse/compare data, **harmonised practices and standards**, recommends policies

OECD
Council

Chemicals
Committee

**JOINT
MEETING**

WP
Chemicals,
Pesticides &
Biotechnology

- **Good Laboratory Practice**
- **Test Guidelines**
- **Manufactured Nanomaterials**
- **Hazard Assessment**
- **Exposure Assessment**
- **Pollutant Release and Transfer Registers**
- **Pesticides**
- **Biocides**
- **Chemical Accidents**
- **Biotechnology**
- **Novel Foods and Feeds**



COUNCIL RECOMMENDATION

*“... the approaches for the testing and assessment of traditional chemicals are in general appropriate for assessing the safety of nanomaterials, **but may have to be adapted to the specificities of nanomaterials.**”* Council Recommendation C(2013)107

OECD COUNCIL RECOMMENDATION ON NANO: Endorsed on 19th September 2013

- Existing Legal Frameworks are applicable (might need to be adapted)
- Members, in the testing of manufactured nanomaterials, apply the OECD TGs, adapted as appropriate to take into account the specific properties of MN;
- the OECD Principles of GLP;
- Includes an Annex; *Tools for the adaptation of the existing chemical regulatory frameworks or other management systems to the specific properties of manufactured nanomaterials;*
- It is open to non-members.

OECD PROGRAMME ON NANOSAFETY

TESTING AND ASSESSMENT

to assess the applicability and accuracy of existing test methods and to identify where technical adaptation were needed.

RISK ASSESSMENT

Guidance for risk assessors & address challenges different jurisdictions are facing with respect to regulating nanomaterials

REGULATORY PERSPECTIVE

ENV. SUSTAINABLE USE OF MN

life cycle assessment
Safe by Design

EXPOSURE MEASUREMENT AND MITIGATION

Workplace
Consumer
Environmental exposure



Testing and Assessment

- Review of 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 Documents for nanomaterials

“Guidance on Sample Preparation and Dosimetry to assist in the safety testing of nanomaterials ”

- Explore and advance on

grouping and read across methods for characterisation, hazard, in vitro.

Where are we heading?

Physchem Characterisation

- For regulatory purposes
- Identification of the material

Example of parameters supporting the physical identification of NM

- Particle size and particle size distribution
- Particle shape/Aspect ratio
- Aggregation/Agglomeration states
- Porosity and Specific Surface Area

Physico-chemical parameters in OECD Testing Programme

- Chemical composition
- Surface chemistry
- Crystallite size
- Crystalline phase
- Particle size distribution
- Specific surface area
- Porosity
- Water solubility / Dispersibility
- Aggregation/agglomeration
- Zeta potential
- Dustiness
- Redox potential
- Radical formation potential
- Photocatalytic activity

What they are

Where they go

What they do

Characterisation of nanomaterials enables the evaluation of their (toxicological) properties.

Toxicological evaluation

Example of processes determining fate:
aggregation
dissolution/precipitation
(bio)degradation
diffusion/sedimentation
nanoparticle coating,
aging/weathering

- Identify & characterize physical hazards to inform:
 - Toxicity testing
 - Ecotoxicity testing
 - Fate and environmental behaviour

Characterisation of nanomaterials enables the evaluation of their (toxicological) properties.



Categorisation

A chemical category is a group of chemicals whose properties are likely to be similar or follow a regular pattern, usually as a result of structural similarity.

- Physical Chemical properties
 - Human Health
 - Toxicological
 - Environmental Fate

Categorisation for Nanomaterials

- **Categorization of NMs is not the same as other chemicals** due to:
 - Unique p-chem properties of NMs
 - Differences among nanoforms of a chemical species
 - Differences between nano and non-nano forms
- To categorize NM, regulators need to distinguish substances based on **chemical/molecular identity** approach and to **properties**.
- **The devil is in the details!**



Read Across

- Limit the amount of necessary tests/measurements
- Prioritisation for further scrutiny
- Design of testing strategies
- Hazard / exposure / risk assessment

Get insight in predicting/modelling

- Exposure
- Fate
- Uptake
- Kinetics
- Toxicity

With minimal amount of information

What do we know, where are we going?

- **Behaviour** may differ from non-nanomaterials
 - Nanomaterials may end up at different places (in body and/or environment)
 - Nanomaterials may change during their life-cycle (also within body!)
 - Nanomaterials' behaviour is influenced by surroundings
 - Different underlying processes:
 - Passive diffusion / partitioning only minor role
 - More difficult to predict (no proxy)
- **Chemical identify/characterisation** alone not enough to group NMs

Which Phys-chem Endpoint?

Develop a **framework** to identify the appropriate methods for characterising physico-chemical endpoints for different manufactured nanomaterials, or types of nanomaterials, for regulatory purposes.

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DECISION TREES for each physico-chemical endpoint

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Each decision tree would identify (based on the specific type of MN and the type of assessment) the appropriate method(s) to be used for a physico-chemical endpoint

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Each decision tree would also **identify the methods** that are **not appropriate** for specific MN for a particular purpose (e.g., for use only in screening or need for use in a more robust risk assessment).

The proposal is expected to further support the identification of the regulatory relevance/ need for TG/GD on physico-chemical characterisation for nanomaterials

Where we are and where we are heading

- ✓ Physchem characterisation (endpoint / identify the necessary parameter)
- ✓ Toxicological evaluation (processes determining fate = Test Guidelines)
- Categorisation and Read Across



Main areas of work for 2018-2020

- **OECD Test Guidelines for hazard characterisation of MN**
- **Explore and develop**
 - novel and alternative methods such as *in vitro* testing for MNs;
 - grouping and read across methods for characterisation, hazard, and exposure of MNs;
 - risk assessment methodologies to MNs,
- **exposure assessment and exposure mitigation:**
 - 1. occupational settings;
 - 2. exposure to humans resulting from contact with consumer products; and from
 - 3. environmental releases.

Future Work

- **Applicability of OECD Test Guidelines (MAD)**
 - Further prioritise TG needs (i.e. validation, revision or new guidelines) in particular to **p-chem properties**, inhalation toxicity, environmental fate, aquatic toxicity, *in-vitro* test methods
- **Assessment methodology** –need to develop equivalence, grouping and read-across frameworks, alternative testing strategies and adverse outcome pathways. Need for guidance materials.
- **Exposure data** –lack of appropriate exposure data for risk assessment of NM, in particular in consumer and environmental sectors.
- **Guidance material to assist with interpretation of data.** Need to develop
 - a (harmonised) core set of test data required for regulatory risk assessments ,
 - criteria for acceptance/ non-acceptance of tests
 - Calculation aids (to assist with conversion of metrics)



MAIN OUTPUTS

- **Harmonised standards for Mutual Acceptance of Data (TGs, GLP, compliance monitoring procedures)**
- **Tools and guidance for assessment**
- **Streamlined chemical management practices**
- **Co-operative, internationally agreed hazard assessments**

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Publications

www.oecd.org/env/nanosafety

www.oecd.org/env/ehs/testing