



SIX YEARS OF OECD WORK ON THE SAFETY OF MANUFACTURED NANOMATERIALS:

Achievements and Future Opportunities

For more than 40 years OECD has had a key role in the safe use of chemicals and the protection of human health and the environment.

As part of its response to emerging issues, OECD identified the need to analyse the potential safety concerns caused by manufactured nanomaterials. As nanomaterials started to be used in commercial applications, OECD launched a programme of work in 2006 to ensure that the approaches for hazard, exposure and risk assessment for manufactured nanomaterials are of a high quality, science-based and internationally harmonised.

After six years of work, *the OECD and its member countries have come to the conclusion that 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.* As with other chemicals, it is clear that each nanomaterial may pose specific challenges, but in most instances, they can be addressed with existing test methods and assessment approaches. In some cases, it might be necessary to adapt methods of sample preparation and dosimetry for safety testing. Similarly, adaptations may be needed for certain Test Guidelines. But it will not be necessary to develop completely new approaches for nanomaterials. OECD continues to review all existing methodologies to identify and implement the necessary changes needed for their application to nanomaterials.

Manufactured Nanomaterials and their potential applications

Manufactured nanomaterials have been and are being developed to exhibit new characteristics in contrast to the same material without nanoscale features. Such characteristics can include increased strength of the material, its chemical reactivity or conductivity. These novel features offer possibilities for new applications in a broad range of sectors such as in; medicine (e.g. detection of genetic sequences using DNA-tagged gold nanoparticles); environment (e.g. waste-water treatment with carbon nanotube filters); and energy production (e.g. solar cells using silicon nanocrystals). At the same time, the use of manufactured nanomaterials in a number of commercial applications raises questions regarding potential unintended risks to humans and the environment.

Much research on new uses for nanomaterials is underway and, while currently the production volumes are not very large compared to chemicals that are not at the nanoscale, many other applications are foreseen in the near future and production volumes are expected to increase significantly over the coming decade.

Manufactured nanomaterials are chemicals at the nano-scale (1-100 nm typically), that can be:

- ✓ → materials with novel properties developed from old materials (carbon black; rubber and plastics products)
- ✓ → new materials (fullerenes; molecular therapies)
- ✓ → existing materials (TiO₂; photodegradation of pollutants)

Promoting the responsible development of Nanotechnologies/Manufactured Nanomaterials: Safety of Nanomaterials

There is much knowledge available regarding possible health and environmental effects of traditional chemicals. However, it was not clear this knowledge could be transferred directly to nanomaterials. For this reason, the OECD held a Special Session in 2005 on the Potential Implications of Manufactured Nanomaterials for Human Health and Environmental Safety. This was the first opportunity for governments to discuss human health and environmental safety related aspects of manufactured nanomaterials. At this meeting, OECD countries agreed to set up a new programme to assist countries in the implementation of national policies that guarantee the responsible development of nanotechnologies.

Manufactured Nanomaterials tested within OECD:

- Fullerenes (C60)
- Single Wall Carbon Nanotubes
- Multi Wall Carbon Nanotubes
- Silver nanoparticles
- Iron nanoparticles
- Titanium dioxide
- Aluminium oxide
- Cerium oxide
- Zinc oxide
- Silicon dioxide
- Dendrimers
- Nanoclays
- Gold.

Endpoints:





- physical-chemical properties
- environmental degradation and accumulation
- environmental toxicity
- mammalian toxicity

This programme on the safety of manufactured nanomaterials addresses all the different components needed for thorough risk assessments for human health and the environment.

OECD is testing certain specific nanomaterials for their physical chemical properties, environmental fate and behaviour, ecotoxicity and toxicity using appropriate testing methods. This activity builds upon the concept that much valuable information on the hazard of manufactured nanomaterials, as well as the methods used to assess hazards can be derived by testing certain nanomaterials for their properties. Through the **“Sponsorship Programme for the Testing of Manufactured Nanomaterials”**, member countries, as well as some non-member countries and other stakeholders agreed to pool expertise and to fund the safety testing of specific manufactured nanomaterials. Representative manufactured nanomaterials were selected, each of which is either in commerce or expected to be in the near future.




The results of the testing programme are currently being analysed in order to evaluate the need for amending existing test methods and/or guidance documents used for testing and assessing traditional chemicals. A preliminary analysis showed that most test guidelines are suitable, but that in some cases, modification is needed for their applicability to manufactured nanomaterials

Further reading:

-  *List of Manufactured Nanomaterials and List of Endpoints for Phase One of the Sponsorship Programme for the Testing of Manufactured Nanomaterials: revision*
-  *Guidance Manual for the Testing of Manufactured Nanomaterials: OECD Sponsorship Programme: First revision*
-  *Inhalation Toxicity Testing: Expert Meeting on Potential Revision to OECD Test Guidelines and Guidance Documents*
-  *Preliminary Guidance Notes on Sample Preparation and Dosimetry for Manufactured Nanomaterials (revised version to be available at the end of 2012)*


OECD complements the testing programme with the **development of guidance on exposure measurement (including sampling techniques and protocols) and on exposure mitigation**. These guidance documents address exposure at the workplace, exposure to consumers and exposure to the environment.

Further reading:

-  *Compilation and Comparison of Guidelines Related to Exposure to Nanomaterials in Laboratories*
-  *Comparison of Guidance on Selection of Skin Protective Equipment and Respirators for Use in the Workplace: Manufactured Nanomaterial*
-  *Emission Assessment for Identification of Sources and Releases of Airborne Manufactured Nanomaterials in the Workplace: Compilation of Existing Guidance*

OECD has also been **analysing risk assessment strategies for manufactured nanomaterials**, including a review of current practices, challenges and strategies for assessing risks in circumstances where data are limited. This has led to the identification of a number of risk assessment issues for which further work or research are needed.

Further reading:

 *Important Issues on Risk Assessment of Manufactured Nanomaterials*

OECD supports an **environmentally sustainable use of nanotechnology** through enhancing the knowledge base about life cycle aspects of manufactured nanomaterials. The focus is given to potential applications to address major environmental challenges such as climate change, pollution of water, soil, and air, and natural resource depletion, as well as the potential negative impacts that such new technologies may have on environment and health. This will help inform decision makers early in the process on how novel applications can be exploited in a safe and sustainable manner and how potential negative impacts can be addressed in the early stages.

OECD has begun an **analysis on whether current waste management practices are adequate to address waste containing nanomaterials**. This analysis is focused on existing initiatives/approaches to address nanowaste management, as well as on related regulatory issues.







Information on **research projects that address environmental, human health and safety issues of manufactured nanomaterials** can be

found at www.oecd.org/env/nanosafety/database. This database collects information on research projects that are relevant to human health and environmental safety aspects. It includes projects that are completed, underway or planned. It allows users to search by a variety of categories such as the nanomaterial being investigated, the test methods used and the scope of the research area. Research is defined in a broad sense, thus, it includes not only experimental studies, but also projects addressing: i) comprehensive risk assessments of specific substances; ii) risk mitigation measures; iii) regulatory aspects; iv) international standard setting; and v) reports of public dialogues.

An analysis of existing voluntary schemes and regulatory programmes in OECD member countries provided information on legislative features used to manage manufactured nanomaterials. Through this analysis it has been possible to understand which data requirements are appropriate for assessing the safety of nanomaterials in a regulatory framework and which information is needed for defining manufactured nanomaterials.

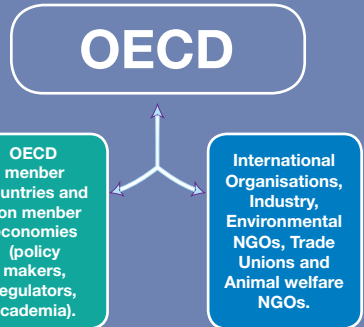
Further reading:

-  *Information Gathering Schemes on Nanomaterials: Lessons Learned and Reported Information*
-  *Regulated Nanomaterials: 2006-2009*
-  *Regulatory Regimes for Manufactured Nanomaterials*
-  *Analysis of Information Gathering Initiatives on Manufactured Nanomaterials*

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation, whose aim is to promote policies for sustainable economic growth and employment.

By "sustainable economic growth" the OECD means growth that balances economic, social and environmental considerations.

OECD is regularly engaging not just its member countries but also key emerging economies, other international organisations and stakeholders such as environmental NGOs, labour, industry, and animal welfare groups.



International Co-operation

OECD is one of nine Participating Organisations of the *Inter-Organisation Programme for the Sound Management of Chemicals (IOMC)*. The aim of the IOMC is to strengthen co-operation and increase co-ordination in the field of chemical safety among international organisations (www.who.int/iomc). OECD is also engaged bilaterally with other intergovernmental organisations addressing the safety of manufactured nanomaterials, such as UNITAR, FAO and WHO.

OECD is assisting member countries in implementing the UN Strategic Approach to International Chemicals Management (SAICM). Within this context, OECD and UNITAR jointly held Awareness-Raising Workshops on Nanotechnology/ Manufactured Nanomaterials during 2009-2010. The workshops informed the participants of the potential applications and risks from nanotechnologies and manufactured nanomaterials and identified opportunities for awareness raising activities to be undertaken in those countries.

<http://www.unitar.org/cwm/nano>

The OECD also co-ordinates its works with the International Standards Organisation, especially in the context of the evaluation of test methods for physical-chemical properties of nanomaterials.

What's next?

There is still much to learn before our understanding of the safely use of manufactured nanomaterials is sufficient. However, the work achieved so far allows a better understanding of the remaining "unknowns". Knowing that the general approaches for the testing and assessment of traditional chemicals are in general appropriate for assessing the safety of nanomaterials, OECD will now focus on those specific aspects of manufactured nanomaterials, which require the adaptation and/or development of specific testing methods used for assessing human health and environmental safety; as well as on developing guidance documents for assessing manufactured nanomaterials adapted to their specificities. This will include guidance on estimating exposure (including fate and transport) on how to use results on physico-chemical endpoints in exposure assessment and mitigation measures to reduce exposure to safe levels (defining appropriate exposure metrics). At the same time, as R&D on manufactured nanomaterials/nanotechnologies is increasing, OECD remains vigilant in order to address emerging issues in a timely and resource efficient way.

If countries continue to work together, as they have until now, this will ensure that the human health and environmental safety aspects of manufactured nanomaterials are addressed appropriately and efficiently at the same time as the economic opportunities of the technology advances.



More Information on OECD's work on Manufactured Nanomaterials

www.oecd.org/env/nanosafety

All OECD outputs concerning chemical safety and related topics (Test Guidelines, Guidance Documents, Reports, Databases, Software etc.) are available for downloading free of charge on the OECD website:

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