Test guidelines for manufactured nanomaterials

Ensuring harmonised testing for safe and sustainable manufactured nanomaterials

What are nanomaterials?

Nanomaterials are extremely small - they are made up of particles at nanoscale (between 1 and 100 nm). There are many different types of manufactured nanomaterials with countless applications: food additives, toothpaste whiteners, water filters... We use them every day, yet their impacts on our health and the environment are not easy to understand. Despite this, their use remains underregulated in the EU.

What is the problem with nanomaterials in the EU?

The EU regulates nanomaterials through a number of chemical regulations, including REACH, the main legislative tool to identify and regulate chemical substances on the market. However, unless nanomaterials are specifically added to the list of substances that require authorisation, no prior permission is needed to use them in products. Manufacturers simply need to follow a set of specific information requirements.

To fulfil legal information requirements, adequate and harmonised guidelines are needed. That would improve the situation where legal obligations exist.

OECD guidelines: how can they help?

'OECD Guidelines for the Testing of Chemicals', or 'OECD Test Guidelines' (TGs) are commonly-used reference documents in chemicals testing. They are standardised methods for assessing the potential effects of chemicals on human health and the environment (for example, detecting endocrine active substances or assessing skin sensitivity). OECD TGs are accepted internationally, and used by professionals in industry, academia and governments.

The OECD works to ensure these guidelines also cover nanomaterials. The Working Party on Manufactured Nanomaterials is a dedicated group dealing with safety issues of nanomaterials and beside others supports the development of OECD TG on chemicals so that they can also be applied to nanomaterials. Amendments consider the characteristics of nanomaterials, which often require additional tests as their special size impacts the way they interact with living organisms or how they behave inside them.

In the EU, the European Chemicals Agency (ECHA) provides regulatory guidance to companies on how to identify and test nanomaterials in their chemical products, to ensure they meet information requirements under REACH. For this, ECHA takes part in the development of OECD TGs and updates its own regulatory guidance whenever new or amended OECD TGs are available.

ecos

Bund für Umwelt und Naturschutz Deutschland
BUND
FRIENDS OF THE EARTH GERMANY

Umwelt Bundesamt

Supported by:
Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection
based on a decision of the German Bundestag

This project is funded by the German Federal Environment Agency and the Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection. The funds are made available by resolution of the German Bundestag.

The publisher is responsible for the content of this publication.

What needs to be done next

The OECD process helps improve the understanding of nanomaterial characteristics, but it is still a work in progress. Analyses of the environmental, health and safety risks have yet to be performed for the majority of nanomaterials currently on the market. Only a handful of nanomaterials are being studied, and even for these, important aspects remain unknown to the scientific community.

Environmental impacts of nanomaterials - a few telling examples:

- Many nanomaterials are inorganic carbon materials, metals or metal oxides that do not biodegrade. But we do not understand how such materials accumulate in the environment.
- Coatings added to isolate nanomaterials from the environment and keep them safe can disappear over time.
- Titanium dioxide is a widely used nanomaterial, for example, in cosmetics or paints and varnishes. There is emerging evidence that its accumulation as waste can cause environmental deterioration.

At the very least, more guidelines are needed with regards to bioaccumulation, but also nanomaterials transformation, degradation and persistence. We need common testing references and information to interpret test results.

NanoTG project

– the environmental voice in nanotechnology

The Working group developing TGs is primarily composed of national authorities representatives supported by academia and industry. While civil society is not per se excluded, very few societal actors have the resources and expertise to take part in these discussions and ensure that societal concerns regarding health and the environment are prominent in the debates.

Having represented European civil society in standardisation and nanotechnologies for years, ECOS and BUND have now joined forces to lead the project NanoTG: Putting nanomaterials to the test - methods, guidelines, and transparent information for safer use.

The project contributes to:

- **Supporting the robust development and amendment of OECD TGs for nanomaterials**. The project facilitates the integration of guidelines into EU and national policies regulating the use of nanomaterials in food, cosmetics, and other high-exposure applications;
- **Supporting greater inclusion of socio-environmental interests** in the development of the regulatory framework for nanomaterials in Europe.

Our vision for nanomaterials testing – in an ideal world...

- **EU member states and the industry adopt a strong precautionary approach to nanomaterials**, especially when uncertainties regarding their properties remain, following the 'safe and sustainable by design' principle;
- **OECD Test Guidelines are adapted to nanomaterials** and fully address all health and environmental concerns. They enable robust testing and result interpretation.
- **The EU systematically updates its regulations to make full use of OECD TGs**, ensuring a harmonised system across Europe. The use of OECD TGs should support the development of a more robust EU policy framework for nanomaterials, leading to dedicated regulatory measures.

ecos

Environmental Coalition on Standards
Mundo-b, the Brussels Sustainable House
Rue d'Edimbourg, 26, 1050 Brussels,
Belgium, +32 2 894 46 68
ecostandard.org

Bund für Umwelt und Naturschutz Deutschland
BUND
FRIENDS OF THE EARTH GERMANY

Bund für Umwelt und Naturschutz Deutschland eV (BUND)
Friends of the Earth Germany
Kaiserin-Augusta-Allee 5
D - 10553 Berlin, Germany, +49 030 275 86 40
bund.net