

Lecture: nanotoxicology / nanobiotechnology

## Nanotoxicology and alternative testing methods – development, chances and needs on OECD and EU level

*Maria Purzner, Martin Paparella, Simone Mühlegger*

Umweltbundesamt (Vienna) (AT)

e-mail: maria.purzner@umweltbundesamt.at

Manufactured nanomaterials are intentionally produced to have specific properties or specific composition, a size range typically between 1nm and 100 nm and material which is either a nano-object or is nanostructured (OECD, 2008a). They are to a great extent products of the chemicals industry which by definition should be regulated by chemicals legislation. Chemicals legislation, however, was originally developed and designed to regulate macroscopic substances (Fischer and Hirmann, 2007). The current developments in nano-technology and insights in related hazard effects may cause the need for additional information on the substances in the future. The current state of development is not mature enough to include guidance on the identification of substances in the nanoform in the Technical Guidance Documents (TGD) for REACH (European Chemicals Agency, 2007). Toxic effects of nanomaterials tested to date show that they may be more toxic than micron sized particles of the same material (Hallock et al., 2008).

In order to address the specific properties, hazards and risks associated with nanomaterials, additional testing or information may be required. To determine specific hazards associated with nanomaterials, current test guidelines may need to be modified. Until specific test guidelines for nanomaterials exist, testing will have to be carried out according to already existing guidelines (SEC 2008 2036). Currently, testing of a set of 14 nanomaterials is being planned by the OECD in order to develop appropriate testing guidelines, taking into account the specific properties of nanomaterials. A steering group has been formed to work on alternative testing methods, evaluating *in vitro* and other methods, or validating them. It will identify additional endpoints that should be considered by the testing programme, and will give consideration to other alternative approaches and the broader issue of integrated testing strategies (OECD, 2008b).

This lecture will give an overview of the activities of the Working Party on Manufactured Nanomaterials (WPMN) of the OECD, as well as activities on EU level, and introduce the OECD Database on Safety Research and call for data entry. The role of the Umweltbundesamt will also be explained briefly.

### References

- European Chemicals Agency (2007). *Guidance for identification and naming of substances under REACH, Guidance for the implementation of REACH*. Helsinki: European Chemicals Agency.
- Fischer, A. and Hirmann, D. (2007). Chemikalienrecht und regulatorische Toxikologie – Prüfung auf Nanotauglichkeit. In A. Gazso, S. Greßler, F. Schiemer (eds.), *Nano – Chancen und Risiken aktueller Technologie* (115-129). Vienna, New York: Springer.
- Hallock, M. F., Greenley, P., DiBerardinis, L., Kallin, D. (2008). Potential risks of nanomaterials and how to safely handle materials of uncertain toxicity, *Journal of Chemical Health and Safety*, doi:10.1016/j.jchas.2008.04.001 (in press).
- OECD (2008a). Working Party on Manufactured Nanomaterials: *Report of Project One: OECD Database on Research into the safety of Manufactured Nanomaterials (Phase 1)*, ENV/CHEM/NANO(2008)3.
- OECD (2008b). Working Party on Manufactured Nanomaterials: *Draft Programme of Work 2009-2012*, ENV/CHEM/NANO(2008)13.
- SEC (2008) 2036. Communication from the Commission to the European Parliament, the Council and the European economic and social committee, regulatory aspects of nanomaterials. COM, 366.

*Keywords: manufactured nanomaterials, regulatory testing, specific properties, hazard assessment, OECD, EU, Umweltbundesamt*