

OECD WPMN SG 4:

Nanomaterials and Test Guidelines

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Feb. 26-28, 2008

***International Workshop on Documentary Standards for
Measurement and Characterization in Nanotechnologies***

Overview of Current Nanotech Standards Program (1)

- **Areas:**
- Methods for Physical-Chemical Characterization of NM.
- Metrology and Dosimetry of NM (horizontal).
- Methods for (Eco)Toxicological Hazard and RA.
- Methods for Fate and Behaviour in the Environment.
- **Drivers:** concern that current OECD Test Guidelines may not be adequate to appropriately address NM characterisation and assessment of their (eco)toxicological properties.
- **General Objectives:** 1) Review existing OECD TGs and other standards, 2) Identify need for development of new or revision of existing TGs, 3) work plan/proposal(s) for revising or develop, validate and gain acceptance, including ITS.
- **Players/Customers:** Regulators, Industry and NGOs are stakeholders
- **Pertinent work completed** – a) Operational Work Plan; b) Information sources compilation; c) Considerations Document; d) Preliminary priority properties and end-points with SG3; e) Work plans for 4 sub-groups; f) Preliminary assessment of Phys-Chem standards; g) Preliminary assessment of HH standards and proposal for Guidance Documents.

Overview of Current Nanotech Standards Program (2)

- **Work underway:** a) Review/evaluate OECD TGs in five areas b) Review used or under development non-OECD methods/protocols and decide whether and how to evolve them into TGs, guidance documents or add-ons to TGs.
- A **prioritization** effort clearly needed. (1st target PhysChem, metrology and dosimetry).
- **Collaborations:** All stakeholders included in one or several sub-groups (ISO as well).

Overview of Current Nanotech Standards Program (3)

- **Immediate and medium term plans:** Draft Reports on PhysChem, Ecotoxicity and Env Fate and behaviour to WPMN June 2008, final in November 2008.
Preliminary Report for human toxicity (June 2008). Final 2009.

GDocs on a) preparation and administration of dosing material; b) absorption and distribution/translocation ; c) use of *in vitro* studies (lead SG 7); d) instillation vs inhalation studies. 2009.

Revision in view of other groups results, prioritisation & planning: longer term.

- **Challenges and obstacles:** Availability of test results, identity, variety & variability of materials, critical endpoints and characteristics, characterisation, dose-metrics, agglomeration-disagglomeration, aggregates, actual exposure vs experiment exposure, translocation, preparation and dosing (in vivo and in vitro; environment), ADME, transport, deposition, degradation, accumulation.

Documentary Standards

Needs/Gaps

- **Prioritization challenges.** See Work plan & considerations document.
- **Fundamental knowledge issues:** Establish suitability of methodology per se and adequacy of data. See considerations document.
- **Measurement and characterization needs:** Already mentioned. See also considerations Document.
- **Supporting reference materials** will be needed in relation to parallel work with e.g. SG 3 & SG 7.
- **Pre- and co-normative research needs:** A lot!!
- **Market need/demand:** Need to ensure and demonstrate safe use of NMs.
- **Technical or policy issues:** Nanomaterials safety needs to be assessed in the frame of REACH (e.i.f. June 2008) and other regulations. Demand appropriate methods and ITS for hazard and RA in order to adequately manage possible risks.

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