

OECD WPMN SG7

The role of alternative methods in nanotoxicology

John Garrod

UK Department for Environment Food and
Rural Affairs (Defra)

www.defra.gov.uk

Feb. 26-28, 2008

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

Overview of Current Nanotech Standards Program (1)

- **Areas of standardisation** - Validation of *in vitro* testing methods and subsequent test guideline development through OECD
- **Drivers** - Reduction in use of animals in testing methods/ mode of action studies/ cost considerations in testing
- **Stakeholders** - Industry, regulators, NGOs and general public are stakeholders
- **Work completed** - OECD *in vitro* guidelines (428, 430, 470 series)
- Validated skin corrosion and irritation tests (ECVAM)

Overview of Current Nanotech Standards Program (2)

- **Work underway** - Many endpoints under development with *in vitro* systems listed in SG7 operational plan
- **Prioritisation efforts** - Role of SG 7 to prioritise tests for validation and TG development in due course
- **Collaborations** - Working with OECD member economies and EU
- **Immediate and medium term plans** - List available methods and review use with nanomaterials - production of guidance as addition to SG 3 document
- **Challenges** - Role of *in vitro* methods in nano-toxicology – validation against *in vivo* tests
- Screening use and concept of ‘shallow testing’

Documentary Standards

Needs/Gaps

- **Prioritisation challenges** - Establish suitability of methodology per se and adequacy of data to replace an animal test or to adapt standard testing regimes
- Criteria for validation of *in vitro* assays are laid down in OECD Guidance Document 34.
- Use of non-testing methods – QSARs – OECD Principles of validation of (Q)SAR models.
- **Measurement and characterization** are needed for materials used in *in vitro* tests (similar to *in vivo*?)

Documentary Standards Needs/Gaps

- Supporting reference materials will be needed
- A number of *in vitro* methods at the research stage
- Market need for alternative approaches to testing – integrated testing strategies
- Policy issues - Animal welfare (3Rs) important policy driver for alternative methods - for example in REACH regulation