

**5th Workshop Event**  
***National Science Foundation, Arlington***

## Purpose of the workshop

- **Further promote and deepen the US-EU collaboration on nanosafety research**
- **Understand progress toward the goals and objectives of the Communities of Research (COR)**
- **Take stock of last years' activities**
- **Identify areas of cross-Community collaboration**
- **Clarify and communicate future common plans**
- **Share best practices**

# Need for collaboration and harmonisation

- **Common Standards/Harmonised Approaches**
  - **Definition**
  - **Guidelines for measurements**
  - **Guidelines for safety assessment**
  - **Reference materials**
  - **Reference methods**
- **Collaboration is crucial**
  - **Method validation**
  - **Production of reference materials**
  - **Reproducibility of results - comparability**

# Specific Needs related to the safety of nanomaterials

- **Test guidelines suitable for nanomaterials – in all fields**
- **Even better co-ordination between research and regulatory needs**
- **Reference nanomaterials – not only for size**
- **Considering the whole life cycle in NM safety assessments**
- **Methods to analyse NMs in products and the environment**
- **Quantification of exposure to NMs**
- **Better accessibility to quality data**

# OECD – Working party for manufactured nano-materials and the Test Guidelines Programme

- **Test guidelines** – assessment for their applicability to NMs, also through a hazard testing programme, which includes dispersion protocols
- **Test guidelines** – adaptation to nanospecific characteristics  
(e.g. solubility, Ames test, inhalation toxicity)
- **New test guidelines to be developed**  
(e.g. Nanomaterial Removal from Wastewater)

# OECD – Working party for manufactured nanomaterials and the Test Guidelines Programme – 2

- **Grouping and read-across for hazard assessment of nanomaterials**
  - In principle possible, but nanomaterial-specific guidance needed
  - to avoid testing of a huge variety of nanomaterials one by one

## Information needs: More accessible quality information

- **Variety of databases exist, difficult to compare information**  
e.g. Contents, data format, data quality, relevance
- **Mapping of datasets across databases (e.g. European Project eNanomapper)**
- **Criteria for data quality and completeness**  
(e.g. article *How should the completeness and quality of curated nanomaterial data be evaluated?* Nanoscale, in press) – EU-US effort
- **Research activities ongoing, but a real breakthrough still to be expected**



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## How should the completeness and quality of curated nanomaterial data be evaluated? †

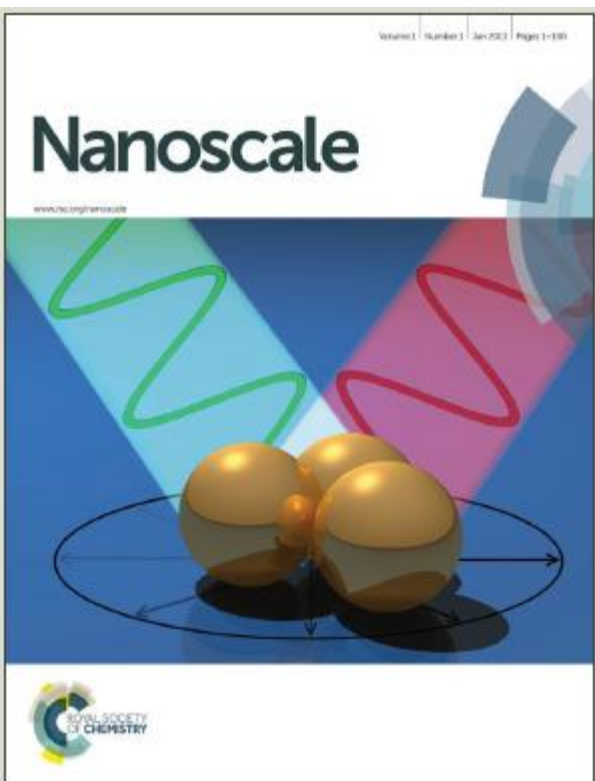
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Nanotechnology is of increasing significance. Curation of nanomaterial data into electronic databases offers opportunities to better understand and predict nanomaterials' behaviour. This supports innovation in, and regulation of, nanotechnology. It is commonly understood that curated data need to be sufficiently complete and of sufficient quality to serve their intended purpose. However, assessing data completeness and quality is non-trivial in general and is arguably especially difficult in the nanoscience area, given its highly multidisciplinary nature. The current article, part of the Nanomaterial Data Curation Initiative series, addresses how to assess the completeness and quality of (curated) nanomaterial data. In order to address this key challenge, a variety of related issues are discussed: the meaning and importance of data completeness and quality, existing approaches to their assessment and the key challenges associated with evaluating the completeness and quality of curated nanomaterial data. Considerations which are specific to the nanoscience area and lessons which can be learned from other relevant scientific disciplines are considered. Hence, the scope of this discussion ranges from physicochemical characterisation requirements for nanomaterials and interference of nanomaterials with nanotoxicology assays to broader issues such as minimum information checklists, toxicology data quality schemes and computational approaches that facilitate evaluation of the completeness and quality of (curated) data. This discussion is informed by a literature review and a survey of key nanomaterial data curation stakeholders. Finally, drawing upon this discussion, recommendations are presented concerning the central question: how should the completeness and quality of curated nanomaterial data be evaluated?





# **(Certified)Reference Materials (RM) and Representative Test Materials (RTM)**

- **(C)RMs and RTMs are essential for the characterization of NM properties in the safety assessment of NMs**
- **More nano (C)RMs are urgently needed not only for size but for all other tests on NMs**
- **Development of RMs takes time and is expensive**
- **RTMs support harmonisation of testing methods**
- **RTMs foster better comparability of NM-related studies**
- **JRC to expand production and supply of RMs and RTMs**

## JRC–NIST collaboration

- **NIST contributions to characterisation studies for JRC Reference Materials for nanoparticle sizing**
  - **ERM<sup>®</sup>-FD102 (bimodal colloidal silica, released 2014)**
  - **ERM<sup>®</sup>-FD101b (colloidal silica, to be released 2016)**
  - **ERM<sup>®</sup>-FD066/69 (corundum powder, ongoing)**
- **Collaboration in ISO Technical Committees**
  - **ISO/TC 229 'Nanotechnologies':**  
**Co-development of 'Metrology check-list' for the evaluation of proposed documentary standards on measurement issues**
  - **ISO/TC 24/SC4 'Particle characterisation':**  
**Joint workshop (Graz, AT, 2012) and feasibility study on a reference material for zeta potential measurements**

# JRC–NIST collaboration

- **Joint publications**

- *Interlaboratory Comparison of Size and Surface Charge Measurements on Nanoparticles prior to Biological Impact Assessment*, G. Roebben, **V. Hackley**, V. Kestens, et al., J. Nanoparticle Research (2011)
- *Nanoscale Reference Materials for Environmental, Health, and Safety Measurements: Needs, Gaps, and Opportunities*, **A. B. Stefaniak**, **V. A. Hackley**, G. Roebben, **M. T. Postek**, T. P. J. Linsinger, et al., Nanotoxicology (2013)
- *Reference nanomaterials to improve the reliability of nanoscale measurements*, G. Roebben, **V. Hackley**, H. Emons, book chapter to be published in 'Metrology and standardization of nanomaterials: protocols and industrial innovations' (2016)

- **Multilateral collaboration platforms**

- **VAMAS** (**V**ersailles project on **A**dvanced **M**aterials **A**nd **S**tandardisation)
  - Pre-normative organisation having MoUs with ISO, IEC and CIPM
  - Organises interlaboratory studies, e.g. for ISO/TC 229
  - NIST and JRC: members of steering committee for USA and EC

# Re-organisation of the European Commission's Joint Research Centre (JRC)

- **Will take effect from 1 July 2016**
- **Abolishment of Institutes, but merging activities into Clusters becoming Directorates**
- **Activities on life sciences will be carried out in JRC-Directorate.F in the JRC-Geel and JRC-Ispra site: Directorate for Health, Consumers & Reference Materials**
- **As a consequence, all activities related to nanomaterials will be grouped into Dir.F.**

Thank you for your attention!

**Measurements matter!**

