Standards for nanotechnologies

Dr Peter Hatto,
Chairman ISO TC 229, CEN TC 352 and BSI NTI/1
Nanotechnologies standardization committees
Director of Research, IonBond Ltd

Standards and standardization as a tool for the dissemination and implementation of research results
DG Research, Brussels
14th December 2010
Major challenges for nanotechnologies standardization

- Diversity of disciplines contributing to and impacted by nanotechnologies
- Global impact of nanotech developments
- Rapid speed of development and of commercialisation (over 1000 consumer products on the market – see Woodrow Wilson International Center for Scholars inventory: http://www.nanotechproject.org/inventories/consumer/
- Concern about potential negative health and environmental impacts of exposure to some nanomaterials (nanoparticles and nanofibres)

- Critical areas are ‘horizontal’, anticipatory standards:
  - Guidance and protocols to ensure health and environmental safety (EHS)
  - Terminology and nomenclature
  - Measurement and characterization
  - Materials specifications
  - Coordination and harmonization across standards developers and stakeholders
‘International’ standards bodies for nano

**ISO TC 229 Nanotechnologies**
- **Established June 2005**
- **Currently 36 ‘P’ members and 8 ‘O’ members** (see [http://www.iso.org/iso/standards_development/technical_committees/list_of_iso_technical_committees/iso_technical_committee_participation.htm?commid=381983](http://www.iso.org/iso/standards_development/technical_committees/list_of_iso_technical_committees/iso_technical_committee_participation.htm?commid=381983))
- **Liaisons with 26 other ISO/IEC/CEN TCs and SCs and 9 external bodies** – ANF, BIPM, EC JRC, ECOS, IRMM, IUPAC, OECD, VAMAS and ETUI

**CEN TC 352 Nanotechnologies**
- **Established November 2005**
- **All 30 members of CEN are notionally members** – around 12 active (see [http://www.cen.eu/cen/Sectors/TechnicalCommitteesWorkshops/CENTechnicalCommittees/Pages/default.aspx?param=508478&title=CEN/TC%20352](http://www.cen.eu/cen/Sectors/TechnicalCommitteesWorkshops/CENTechnicalCommittees/Pages/default.aspx?param=508478&title=CEN/TC%20352))
- **Liaisons with 10 CEN/ISO TCs and 9 external bodies** – ECOS, ENTA, NORMAPNE, NIA, EC DGs Enterprise and Industry, Environment, Health and Consumer Protection, JRC & Research
TC 229 - Nanotechnologies – Structure/working areas

Terminology and Nomenclature (JWG 1)
“what you call it” – Convened by Canada

Measurement and Characterization (JWG 2)
“How you measure/test it” – Convened by Japan

Material Specifications (WG 4)
(Convened by China)

Health, Safety and Environment (WG 3)
“what effect it might have on health and the environment” – Convened by USA

Support for “REGULATION” and voluntary governance structures
**Nano-object terms**

- Nano-object
- Nanoparticle
- Nanofibre
- Nanoplate
- Nanoplate
- Nanotube
- Nanorod
- Nanowire
- Particle
- Ultrafine particle
- Quantum dot
- Agglomerate
- Aggregate
- Equivalent diameter
- Specific surface area
- Mean diameter

- Nanomeasurement
- Nanoproduction
- Nanomaterials
- Nanotechnology
- Nanoscience
- Nanomaterial
- Nano-object
- Nanoparticle
- Nanofibre
- Nanoplate
- Nanotube
- Nanorod
- Nanowire
- Particle
- Ultrafine particle
- Quantum dot
- Agglomerate
- Aggregate
- Equivalent diameter
- Specific surface area
- Mean diameter

- Nanobio interface
- Nanoscale measurement and instrumentation
- Published/approved documents and current work
- Nano-devices and applications
- Vocabulary - Part 1: Core Terms
- Vocabulary - Part 3: Carbon nano-objects – published as TS 80004-3 May 2010
- Vocabulary - Part 4: Nanostructured materials
- Vocabulary - Part 5: Nano-bio interface
- Vocabulary - Part 6: Nanoscale measurement and instrumentation
- Vocabulary - Part 7: Healthcare – Therapeutics and Diagnostics
- Vocabulary - Part 8: Nanomanufacturing processes

**Seminar on Standards and Standardization, DG Research, Brussels, 14th December 2010 slide 6**
ISO/TC 229 JWG2: Published/Approved documents and current work

**ISO/TC 229 JWG2: Published/Approved documents and current work**

- **DSM + EDXA**
- **SEM + EDXA**
- **TEM**
- **NIR-PL Spectroscopy**
- **Raman**
- **EGA-GCMS**

SWCNT characterization

**IS: General Framework for Determining Nanoparticle Content in Nanomaterials by Generation of Aerosol**
**TS: Artificial gratings used in nanotechnology: description and measurement of dimensional quality parameters**
**TS: Generic requirements for reference materials for development of methods for characteristic testing, performance testing and safety testing of nano-particle and nano-fiber powders**

MWCNT characterization

**Joint developments with CEN (CEN lead):**
**TR: Guide to methods for nano-tribology measurements**
Controlling Occupational Exposures to Nanomaterials

- TR: Nanomaterial risk evaluation framework
- TS: Guidance on safe handling and disposal of manufactured nanomaterials
- TS: Guidelines for occupational risk management of nanomaterials based on “control banding”
- TR: Preparation of Material Safety Data Sheet (MSDS) for nanomaterials

Determining Relative Hazard Potential of Nanomaterials

- TR: Guidance on physico-chemical characterization of nanomaterials for toxicology testing
- IS: Endotoxin test on nanomaterial samples for in vitro systems
- IS: Generation of Metal Nanoparticles for inhalation toxicity testing
- IS: Characterization of nanoparticles for inhalation toxicity testing

Toxicological Screening of Nanomaterials
- cooperation with OECD WPMN

- TS: Surface characterization of gold nanoparticles for nanomaterial specific toxicity screening - FT-IR method
- TR: Guidance on toxicological screening methods for manufactured nanomaterials
- TR: Guidance on sample preparation methods and dosimetry considerations for manufactured nanomaterials (for toxicology screening)
- TS: Determination of Muramic Acid as a biomarker for silver nanoparticles activity
TC 229 Work programme – Materials specifications (WG4)

• *TS: Materials specification for nano-titanium dioxide – Part 1 General requirements*

• *TS: Materials specification for nano-titanium dioxide – Part 2 Requirements for specific applications*

• *TS: Materials specification for nano-calcium carbonate – Part 1 General requirements*

• *TS: Materials specification for nano-calcium carbonate – Part 2 Requirements for specific applications*

• *TS: Guidance on specifying manufactured nano-materials*

**Other Projects**

*Joint development with CEN (CEN lead):*

• *Guidance on labelling of products containing manufactured nanoparticles – under preparation for ballot in both committees*
CEN/TC 352

- Work mostly done in collaboration with ISO/TC 229 using the ‘Vienna Agreement’, with ISO lead
- Responsible for coordinating development of standards to satisfy EC MANDATE ADDRESSED TO CEN, CENELEC AND ETSI FOR STANDARDIZATION ACTIVITIES REGARDING NANOTECHNOLOGIES AND NANOMATERIALS (M/461):
  - Validated methods for determination of physicochemical properties relevant to hazard characterisation of nanomaterials
  - Sampling and measurement of workplace, consumer and environment exposure
  - Methods to simulate exposures to nanomaterials
  - H, S & E
  - Further work on terminology and nomenclature
    - many items within the scope of other CEN or ISO technical committees hence need for coordination
What standards are still needed for commerce and regulation

Support for the commercial perspective

“if you can’t measure it you can’t make it”

- Validated characterization techniques for manufactured nano-objects:
  - Basic character set - composition, geometrical properties, sampling methods
  - Advanced character set – e.g. elemental structure, chemical functionality, electrical, magnetic, mechanical, optical properties
- Validated characterization techniques for coatings and nanostructured materials
  - Basic character set: geometrical properties, composition, density
  - Advanced character set – e.g. electrical, magnetic, mechanical, optical, thermal….. properties
- Materials specifications – generic and specific
- H, S and E, including life cycle evaluation and end of life treatment
- Terminology and nomenclature relevant to specific nanomaterial classes
- Application standards will be done by sector committees

Support for the regulatory perspective:

“if you can’t define it and you can’t measure it then you can’t regulate it” - European Commission Mandate M/469 and OECD WPMN
Issues for standardization

- Effective participation of ‘all parties concerned’, i.e. all stakeholders at the national level – issue of ‘pay to play’ in some countries
- Identification and active participation of experts
- Training of experts and project leaders
- Informed and complete response to ballots by national member bodies
- Vigilance of all national members
Thank you