Japanese Perspective on Nanotechnology Standardization

Submitted by: Japan
Background of Nanotechnology Standardization

- Japan is one of the leading economies in nanotechnology R&D.

- Japanese industries have already been widely and deeply involved with nanotechnologies, especially material and instrumentation industries.

- Application industries of emerging nanomaterials, i.e. carbon nanotubes and fullerene, are not yet mature and expected to grow faster.

- Application industries of emerging nanomaterials are becoming more interested in well-characterized, reproducible, and safety-endorsed nanomaterials.

- Environment, health and safety issues affect dissemination of emerging nanomaterials to the market.

- Standardization of emerging technologies is Japan’s national technology policies.
Priority Areas in Nanotechnology Standardization

1. New Nanomaterials
   - **Carbon nanotubes**
     Standardization for carbon nanotubes, both of single and multi walls, are of highest priority because of their high potential. R&D progress in national institutes and universities. Commercialization is under way in companies.
   - **Fullerenes**
     Fullerene is commercialized by a Japanese company. However, standardization is not of high priority because of limited suppliers.

2. Measurement and Characterization of Nanomaterials
   Standardization of test methods for carbon nanotubes is of high priority because well-characterized nanomaterials are inevitable for industrial applications and risk assessments of carbon nanotubes.

3. Test Materials for Toxicity Assessments
   Well-characterized samples of nanomaterial are of high priority because reliable and comparable results are required in toxicity tests and product applications associated with engineered nanomaterials.

4. Risk Assessment of Nanomaterials
   Methodologies of hazard and exposure assessments has been developed for manufactured nanomaterials.

   Occupational exposure limits were set for carbon nanotubes, fullerenes and titanium dioxides through toxicity tests.
RESponsible Development of Nanotechnologies for Societal Acceptance

1. Measurement Standards and Reference Materials
2. Characterization of Nanomaterials and Test Materials
3. Tests on Health, Safety & Environment
4. Risk Assessments
5. Regulators & Consumers

Stage 1: Metrology
Stage 2: Characterization
Stage 3: Tests
Stage 4: Assessment

Societal Acceptance

NANOTECHNOLOGY DEVELOPMENT

SCIENCE BASED

METROLOGY FOR NANO-MATERIALS

TOXICITY ASSESSMENTS

SATFETY MANAGEMENT

BENEFIT ANALYSIS

SOCIAL ACCEPTANCE
Risk Assessment of Manufactured Nanomaterials

Development of exposure assessment methods

Development of hazard assessment methods

Development of characterization method

Policy: to prepare test samples with secondary particles in the nanoscale and well characterized.

Results were published as Sample Preparation Manuals

Further information: http://www.aist-riss.jp/projects/nedo-nanorisk/index_e.html

Occupational Exposure Limit (Period Limited)

OELs were set that assume a subchronic exposure period of 15 years or so on the condition that a reevaluation be conducted within the next ten years or so using future scientific findings.

<table>
<thead>
<tr>
<th>Material</th>
<th>OEL (PL)</th>
<th>Remarks</th>
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<tbody>
<tr>
<td>Carbon Nanotubes (CNT)</td>
<td>0.03 mg/m³</td>
<td>Value was derived for SWCNT with specific surface area of approx. 1000 m²/g.</td>
</tr>
<tr>
<td>Fullerene (C₆₀)</td>
<td>0.39 mg/m³</td>
<td>For C₆₀ with a number-weighted geometric mean diameter of 96 nm (GSD = 2.0)</td>
</tr>
<tr>
<td>Titanium Dioxide (TiO₂)</td>
<td>0.6 mg/m³</td>
<td>Value was derived for Evonik Degussa P25, which is considered to have a relatively high toxicity among TiO₂ nanomaterials.</td>
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</tbody>
</table>

Gamo 2011

Endpoint: pulmonary inflammation
Japanese Contribution to ISO/TC229 as Project Leaders

(Terminology)

(Characterization and Measurement)
ISO/PRF TS 10797 Nanotechnologies -- Characterization of SWCNT using TEM
ISO/TS 10868:2011 Nanotechnologies -- Characterization of SWCNT using UV-Vis-NIR absorption spectroscopy
ISO/TS 11251:2010 Nanotechnologies -- Characterization of volatile components in SWCNT samples using EG/GC-MS
ISO/PRF TR 10929 Nanotechnologies -- Characterization of MWCNT samples
ISO/AWI TS 16195 Nanotechnologies -- Guidance for developing test materials (TM) consisting of nano-objects in dry powder form (Well-characterized materials)

(Material Specification)
ISO/NP TS 17200 Nanotechnology -- Nanoparticles in powder form -- Characteristics and measurements (Generic Specification to determine whether it is nanomaterial)

SUMMARY OF JAPANESE PERSPECTIVE

1. New Nanomaterials
   SWCNT and MWCNT, and fullerenes

2. Measurement and Characterization
   Characterization of SWCNT and MWCNT

3. Test Materials
   Development of well-characterized nanomaterials
   Reliability & comparability in toxicity tests and product applications

4. Risk Assessment of Nanomaterials
   Test methods for hazard and exposure assessments
   Occupational exposure limits
THANK YOU
FOR YOUR ATTENTION!