International Standards Supporting Nanotechnology Development

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On behalf of ISO TC229 (Nanotechnologies)

What are Standards

- Different types of standards
- Focus on documentary standards for this discussion
- ISO/IEC definition *(emphasis added)*: document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context

NOTE Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits.

[ISO/IEC Guide 2:2004, definition 3.2]

Standards Matter

Courtesy: www.treehugger.com

Standards Matter

- Common language for communication
- Enable protection of health, safety and environment
- Reflect state of technology
- Foundation for technological innovation
- Enable economies of scale

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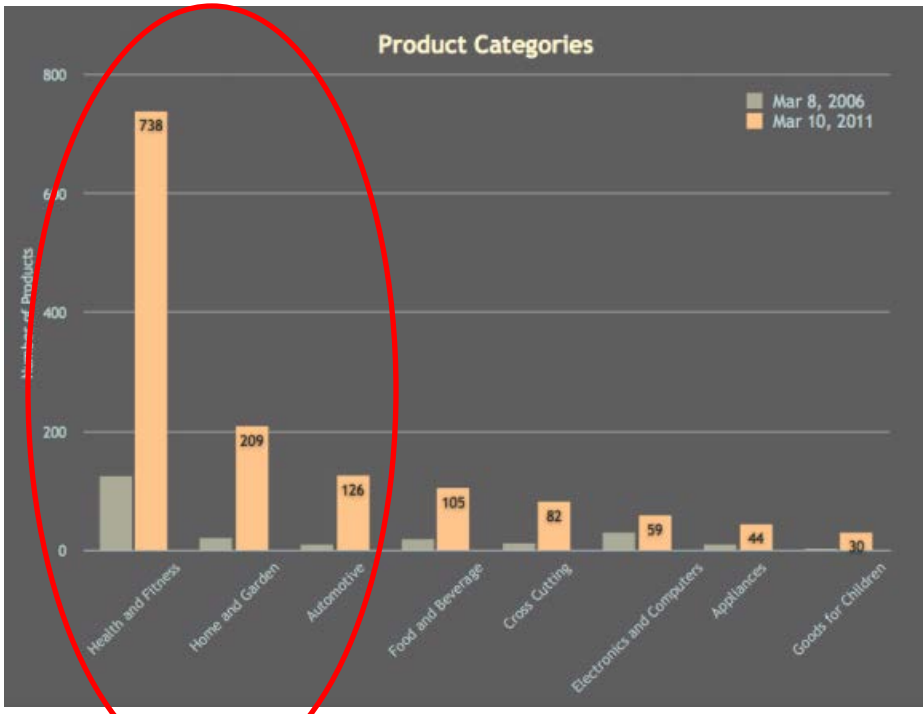
Courtesy: www.axeleration.com

Courtesy: www.boeingcapital.com

Growing ubiquity

- According to The Project on Emerging Nanotechnologies **(http://www.nanotechproject.org/inventories/consumer/analysis_draft/):**
  - 1300+ nano- based/containing products (as of March, 2011)
  - Categories:
  - 738 in Health and Fitness
  - 209 in Home and Garden
  - 126 in Automotive
  - 105 in Food and Beverages
  - 82 in cross-cutting applications
  - 59 in Electronics and Computers
  - 44 in Appliances
  - 30 in Goods for Children



Nanotechnology and Standards

Benefits:

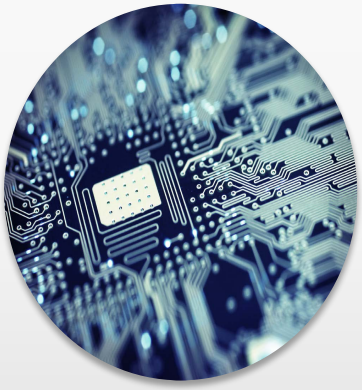
- Address important questions – e.g., is it safe, what to measure, how to measure?
- B-2-B efficiencies
- Supports technology development
- Enables product innovation
- Help with regulatory compliance

Challenges:

- Right time to standardize?
- Prioritization
- Competing user demand
- Availability of robust underlying data
- Availability of skill and expertise

Impact of Nanotechnology Standardization

Trade



Technology

Innovation

Competition

http://www.technologyed.com/courses/c160/index.ph
http://econintersect.com/wordpress/?p=17696
http://www.guzer.com/pictures/sumo_mismatch.php

Drivers for Nanotechnology Standardization

Ubiquity of nanotechnology and nanotechnology enabled products

- Are they safe
- Consumer confidence
- Regulations – use of standards can ease implementation and compliance

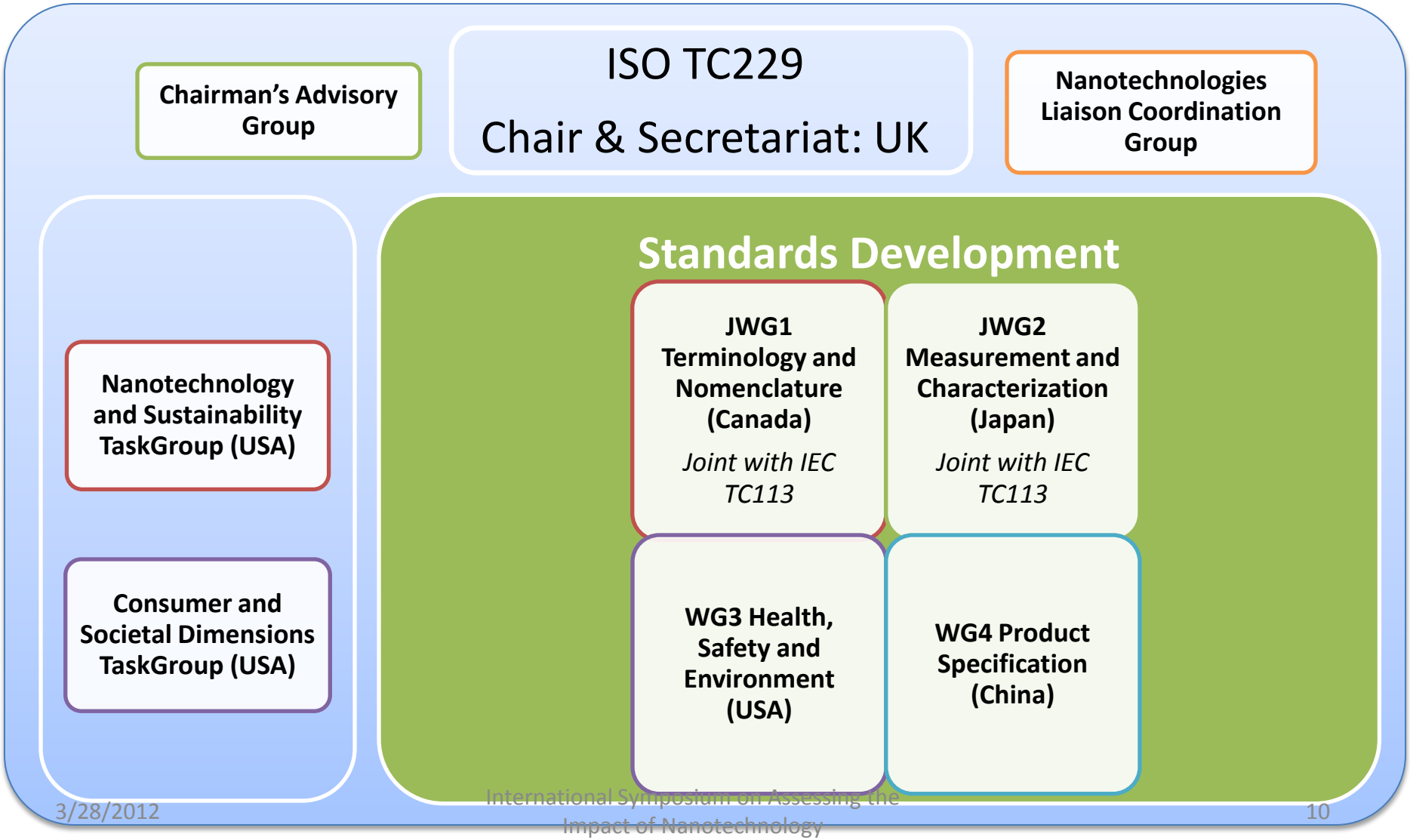
Trade: projections of 100s of millions - billions of dollars of global trade in nanotechnology

Innovation: new products/applications requiring new measurement techniques

Nanotechnology Standardization Activities within ISO TC229

- International Organization for Standardization (ISO) Technical Committee 229 – locus for nanotech focused standards development within ISO.
- 34 participating countries, 10 observing countries
- Broad scope reflected in liaisons with 23 other ISO TCs, IEC TC 113, and 9 external organizations, including OECD

Nanotechnology Standardization In ISO TC229



Nanotechnology Standardization Focus

Terminology	• "What do you call it"
Measurement	• "How you measure it"
EHS	• "What effect it may have on health and environment"
Specification	• "What needs to be measured"

Impact of ISO TC229 Standardization

Enable Collaboration

- Industrial interests
- Across nations
- Unique partnerships with the international scientific community

Support for regulatory aspects

- Dialog with regulators to identify their needs and respond
- Partnership with OECD-WPMN

NIST-ANSI Workshop on Increased Nanotechnology Standards Use

Dec. 13 and 14, 2011

Goal: Better understanding of issues impacting broader use and update of nanotechnology standards

Objectives:

- Nanotechnology standards and needs?
- Factors inhibiting broader use of nanotech standards?
- Solutions to address impediments to broader use of nanotech standards

NIST-ANSI Workshop on Increased Nanotechnology Standards Use

Standards developer perspectives:

- Variety of standards developers involved
- Active and robust processes for nanotech standards development
- Multiple mechanisms for seeking input
- Various drivers – industry, government mandates, etc.
- Very high level of awareness about importance and need

NIST-ANSI Workshop on Increased Nanotechnology Standards Use

Challenges:

- Early stage of technology development
  - Absence of established and validated measurement and characterization equipment and protocols
  - Knowledge gaps about EHS impacts of exposure to nanomaterials
  - Participants limited knowledge of standards development processes
- Cross-cutting nature of technology
- Limited participation by manufacturers
- Communication and alignment due to involvement of multiple SDOs
- Availability of expertise

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Industry perspectives on standards use

- Consistency in communication and reduce misunderstanding
- Facilitates communications between scientific disciplines
- Improved comparability and validation of data
- Support and safeguard EHS aspects

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Standards needs and challenges

- More measurement standards – broader range of nanomaterials
- Essential property information using economical methods and instruments
- Lack of broader industrial participation
- Increased regulator participation in standards development
- Availability of expertise

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Gov. and Regulator perspectives

- Standards important role in meeting mission
- Existing and evolving policy frameworks
- Synergies between different priorities
- Participation in standards development
- Standards use depends upon specificity, broadly applicable standards often not useful or feasible for regulatory purposes

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Needs and challenges

- Greater specificity (specific to individual types of nanomaterials) in standards is desired
- Larger matrix of data
- Development and validation of risk assessment approaches to estimate potential health effects
- Gaps in developing test methods and standards
- Information and awareness

NIST-ANSI Workshop on Increased Nanotechnology Standards Use

Participant perspectives:

- Pressing need for underlying R&D and validated methods
- Higher prioritization of societal and regulatory needs
- Greater funding to support standardization activities
- Increased outreach to ensure industry and government is aware of standardization activities

Conclusions

- Important role of standards in spurring nanotechnology development and innovation
- Great progress in standards development work, but important questions and issues remain
- Opportunities for improving understanding of role of standards and standardization
- Need greater community involvement in nanotech standards development and use

Additional Information

ISO TC229 (www.iso.org)

http://bit.ly/QTNcd

- Chairman of ISO TC229: Simon Holland (UK) simon.j.holland@gsk.com
- Secretary of ISO TC229: David Hyde (UK) david.hyde@bsi-global.com

NIST-ANSI workshop

http://gsi.nist.gov/global/index.cfm/L1-8/L2-33/A-598

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