

Current Status of Efforts to Develop Governance Structure to Control Nanochemicals in Japan

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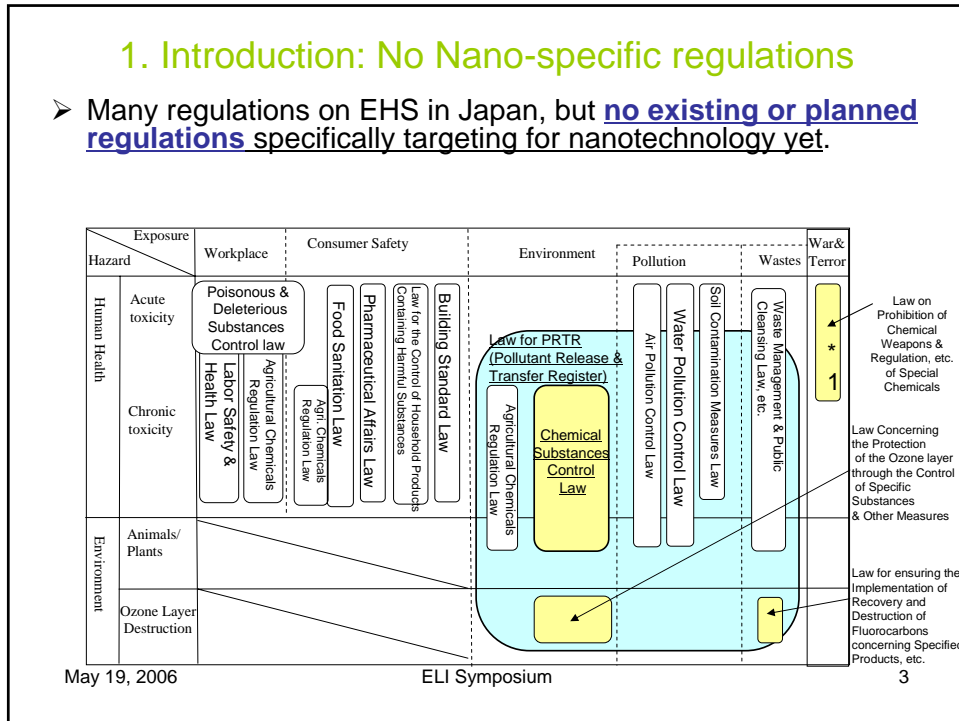
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Outline

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 - (2) Standardization
3. Regulation or a Voluntary Framework?
 - (1) Basic Viewpoints
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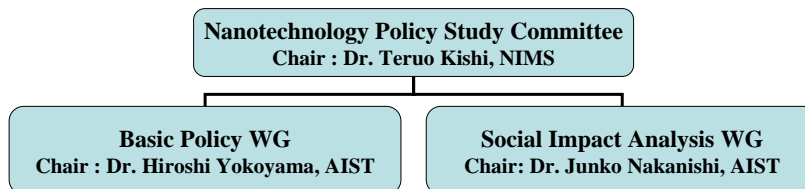
1. Introduction: No Nano-specific regulations

- Many regulations on EHS in Japan, but **no existing or planned regulations** specifically targeting for nanotechnology yet.



METI's Policy Report on Nanotechnology (March 2005)

- Extensive Discussions for three months
- 1 Main Committee and 2 Working Groups
- One WG specifically focused on Social Impact Issues
- Committee/WGs composed of Industry/Academia/Pub. Institute Experts



NIMS: National Institute for Materials Science, Japan

AIST: National Institute of Advanced Industrial Science and Technology

Conclusions of the Committee

- More research is needed before drafting nano-specific regulations
- Physical and chemical properties of nano-materials used in testing should be defined prior to toxicity tests
- Screening tests for nano-materials should be developed

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2. What we need first?

(1) Research

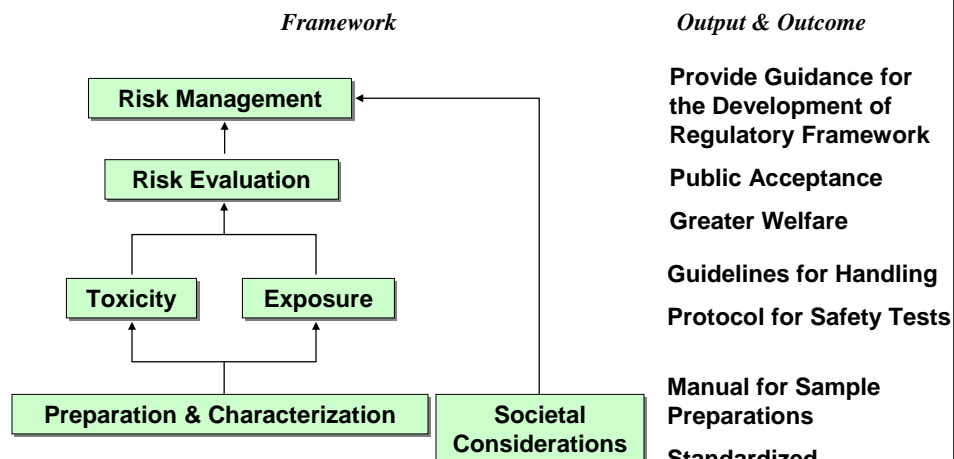
- Japan's "3rd Science & Technology Basic Plan" (for FY 2006-2010, issued by the Council for Science and Technology Policy (CSTP) in March 2006) refers to the importance of:
 - ✓ Research on social impact of nanotechnology
 - ✓ Scientific fact-based risk assessment
 - ✓ Dialogue b/w science community and the public
- CSTP's "Field Specific Promotion Strategy" (March 2006) stresses:
 - ✓ Responsible R&D on nanotechnology
 - ✓ Research on public acceptance of nanotechnology

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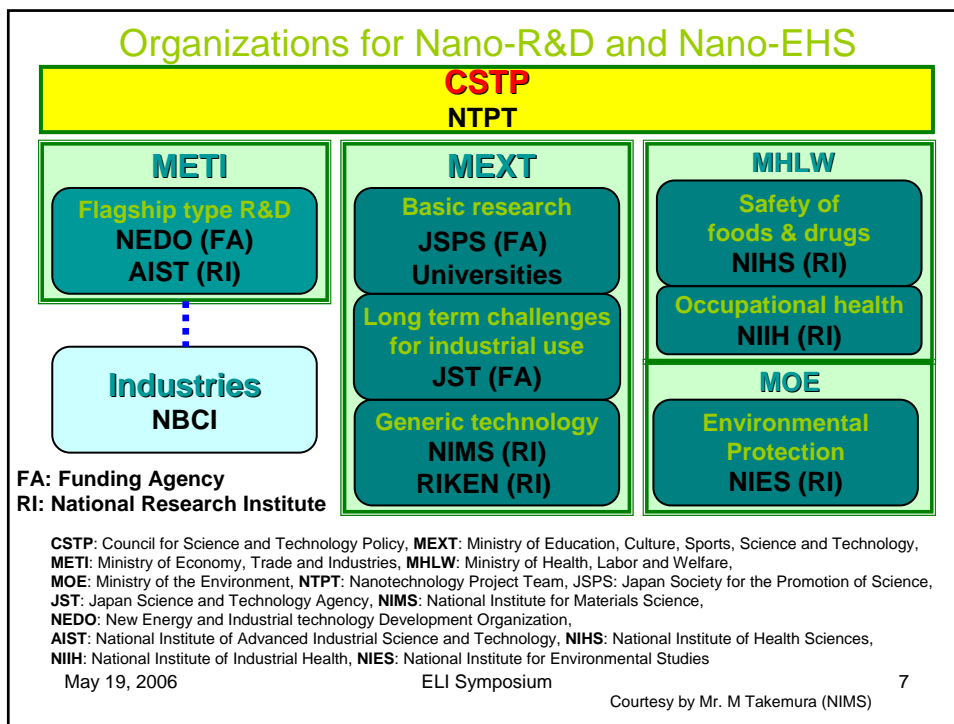
Major Components of Research Projects



Courtesy by Dr. Junko Nakanishi
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Ongoing and Planned Research Projects on Risk Assessment of Nanomaterials in Japan

Area	Start / End (FY)	Funding Organization	Supervisor. Members
Public Acceptance of Nanotechnology	2005	MEXT: \$ 0.3 M	M. Ata. MHLW, MEXT, ME, AIST
	2006	MEXT: \$ 0.2 M	TBD: NIMS, NIHS, NIES
Preliminary Inhalation Test	2005	NEDO.METI.: \$ 0.3 M	K. Okuyama & I. Tanaka :universities
Toxicity (Screening Level)	2005.2007	METI: \$ 1 M	H. Kawasaki. AIST, universities
Risk Assessment	2005.2007	AIST: \$ 1 M.for 2005.	J. Nakanishi. AIST, universities
Risk Assessment & Management	2006. 2010(planned)	NEDO.METI. approx. \$ 20 M	

NEDO= New Energy and Industrial Technology Development Organization, **MEXT=**Ministry of Education, Culture, Sports, Science and Technology, **MHLW=**Ministry of Health, Labour and Welfare, **ME=** Ministry of the Environment, **METI=**Ministry of Economy, Trade and Industry **NIMS=**National Institute for Material Science, **NIHS=**National Institute of Health and Sciences, **NIES=**National Institute for Environmental Studies, \$1, 100 Yen

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Key Recommendations by the “Public Acceptance of Nanotechnology” Project Report FY2005

In order to encourage responsible R&D, to foster public trust, and to contribute to the prospective future in nanotechnology:

Public research institutes should...

recognize their social responsibilities,
 establish risk assessment methodologies,
 develop publicly accessible database and information, etc.

Nanotechnology companies...

proactively participate in “soft” area activities (such as outreach activities to fill the gap b/w companies and the public),
 conduct voluntary risk assessment of nanomaterials,
 actively cooperate with public research institutes, etc.

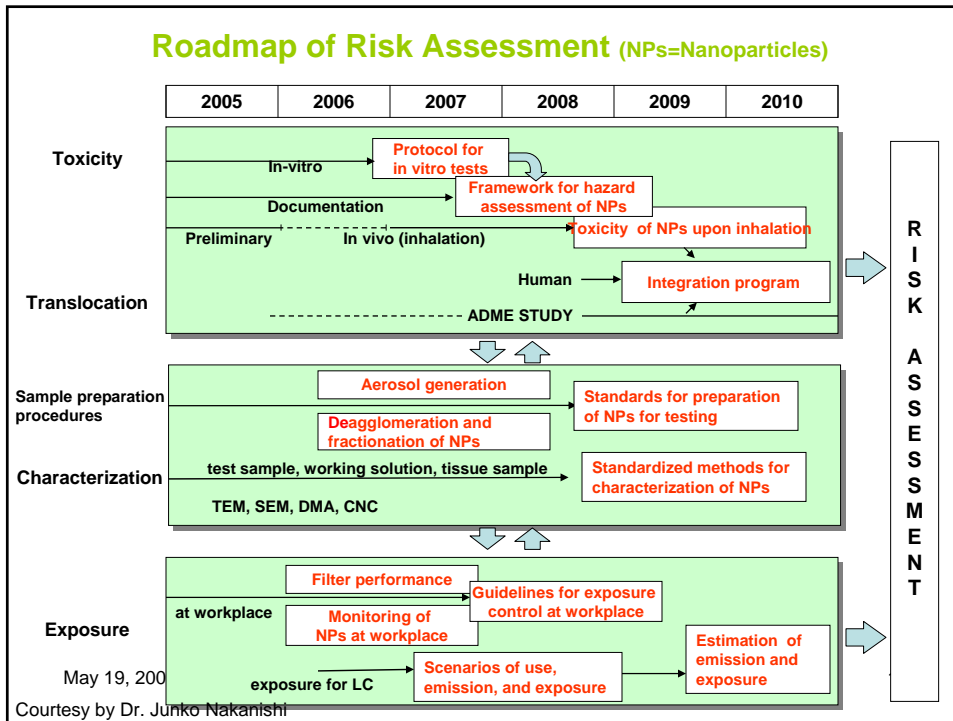
The Government should...

have a clear vision of the future on nanotechnology and share it with the public,
 actively promote research on the societal implication of nanotechnology,
 establish common fora and facilitate collaboration among stakeholders,
 develop necessary roadmaps,
 contribute to international harmonization,
 develop database and information sharing system, etc.

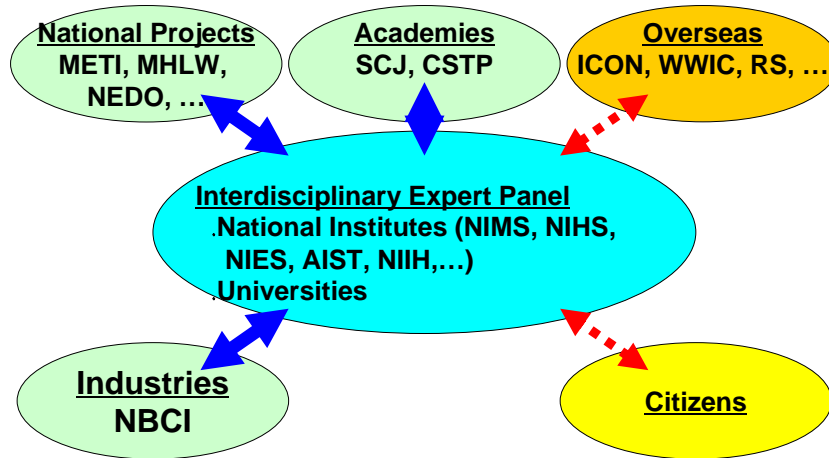
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Communication - Interdisciplinary Expert Panel on Nano-EHS & ELSI



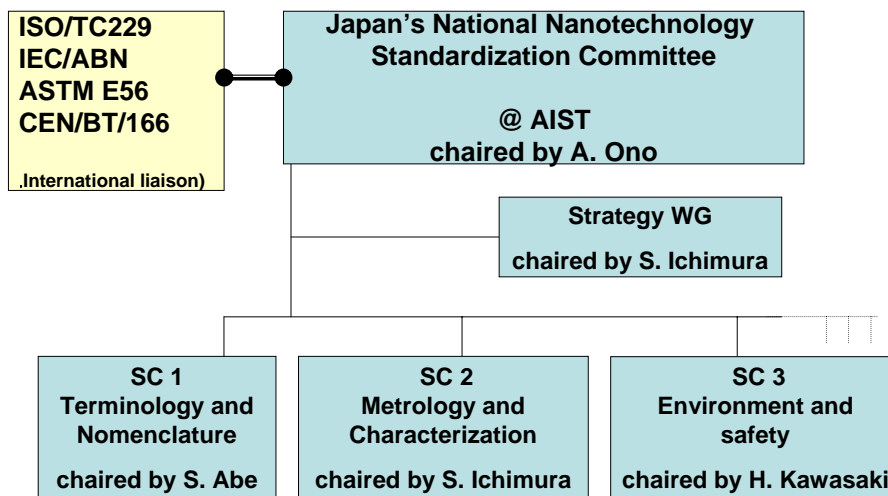
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Courtesy by Mr. Masahiro Takemura (NIMS)

(2) International Standardization

In order to discuss potential risks of nanomaterials, common terminology and characterization methods are indispensable.



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Courtesy by Dr. H. Murayama

3. Regulation or a Voluntary Framework? (1) Basic Viewpoints

- Even before the serious risk of nanomaterial is proven scientifically, a voluntary risk management framework in the private sector should be explored.
- If the serious nano-specific risk is proven scientifically, it would be managed within an appropriate framework – though there has been no consensus yet on whether such framework should be voluntary or mandatory.

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Current regulatory framework: in case of Chemicals Substances Control Law (CSCL)

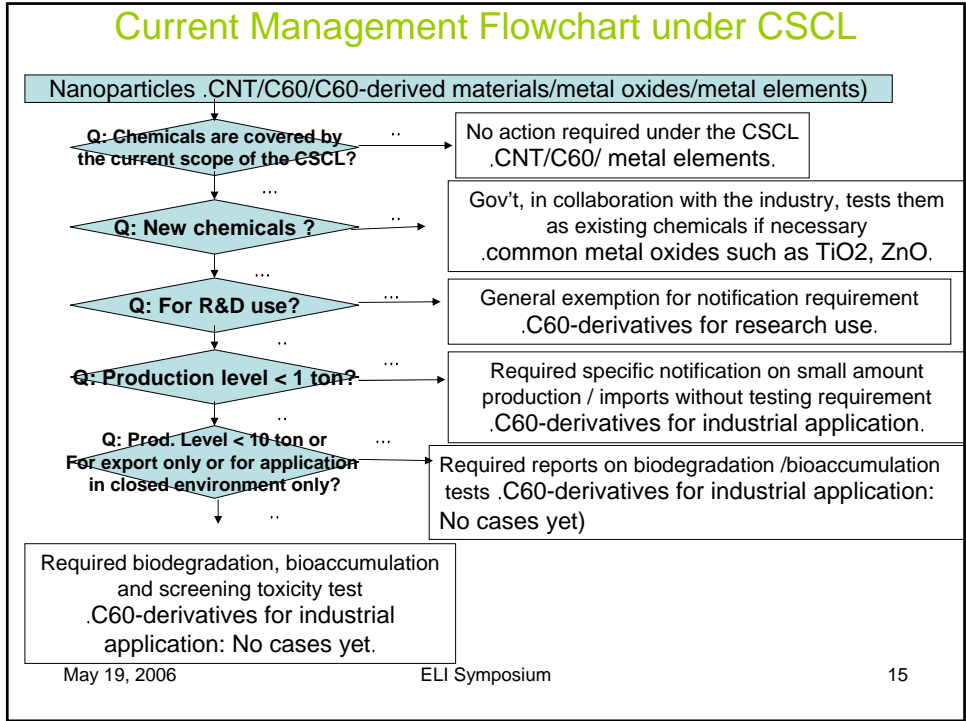
- Most currently produced nanoparticles (CNT, C60, metal elements) are not covered by CSCL.
- Most metal oxides (TiO₂, ZnO, etc.) could be addressed by CSCL, but many of these are “existing” substances which do not require additional testing. Moreover, they are not categorized by the size of the material or its structure of crystal.
- There are several notifications from companies to the government on the small amount production / import of C60 (fullerenes)-derived materials as new chemicals under CSCL, but the amounts produced / imported are less than 1 ton and thus such notifications are approved without any test report requirements.

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Current Management Flowchart under CSCL



(2) Approach by the Private Sector: NBCI

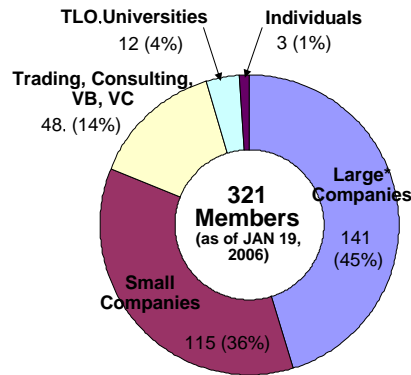
NBCI (Nanotechnology Business Creation Initiative)

Foundation: Oct. 15, 2003

- NBCI is a private organization run by annual-memberfee.
- Members consist of Big manufacturing cos, SME, VB, VC, Consulting cos, Trading cos, TLO, Academia etc in a variety of fields.
- NBCI's mission is to create and advance business utilizing nanotechnology and nanomaterials through inter-collaboration among industry, academia and government.

Members. 321(as of JAN 19,06)

- Chairman Mr.H.Sasaki (NEC Co., Ltd.)
- Vice-chairman Mr.M.Sasaki (Mitsubishi Corp.)
- Vice-chairman Mr.H.Shibano (OSAKA GAS CO.,LTD.)
- Vice-chairman Mr.M.Adachi (Cluster Technology Co., Ltd.)
- Vice-chairman Mr.T.Kikukawa (Olympus Corp.)
- Vice-chairman Mr.S.Kawachi (Sumitomo Chemical Co.,Ltd.)
- Vice-chairman Mr.F.Kawaguchi (Chubu Electric Power Co.,INC)
- Vice-chairman Dr.M.Nakamura (Hitachi, Ltd.)



* Listed in the first section of the stockmarket

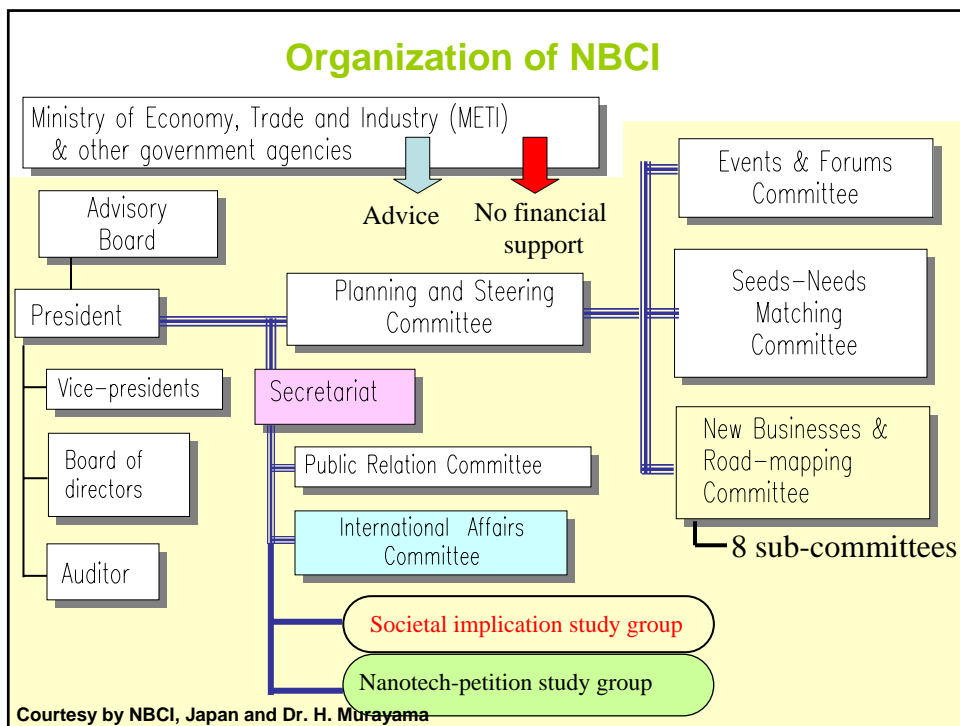
<http://www.nbcj.jp>

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Courtesy by NBCI, Japan and Dr. H. Murayama



NBCI's 8 Sub-committees

1. ELECTRONICS
2. BIOTECHNOLOGY, MEDICINE AND COSMETIC
3. FUEL CELLS AND ENERGY
4. ENVIRONMENT
5. NANO FABRICATION AND PROCESSING
6. CATALYST, COATING AND MATERIALS
7. AVIATION AND TRANSPORTATION VEHICLES
8. MEASUREMENT AND EVALUATION EQUIPMENTS

The 1st Version of "Nanotech Business Roadmaps" were presented in Y2005 .

http://www.nedo.go.jp/roadmap/data/nano_general.pdf (in Japanese)

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Courtesy by NBCI, Japan and Dr. H. Murayama

NBCI Study Group for Societal Impacts and Standardization of Nanocarbon Materials

- Scope**
- .Open Discussion and Sharing of Related Information among Nanocarbon Manufacturers, Users, and the Authorities Concerned.
 - .Proposal of Definition, Metrology, Toxicity Test Methods for Nanocarbon Materials as Integrated Opinions from Industry.



Current Activities of the Study Group in NBCI

- . Preparation of a Classified List for CNT Manufacturing Methods
- . Preparation of a Flowchart for Classification of CNT Quality
- . Endeavor for Risk Assessment of CNT
- . Collaboration with Relevant Public Research Institutes
- . Study for *in vivo* Test Protocols

Kickoff Meeting on August 4, 2005

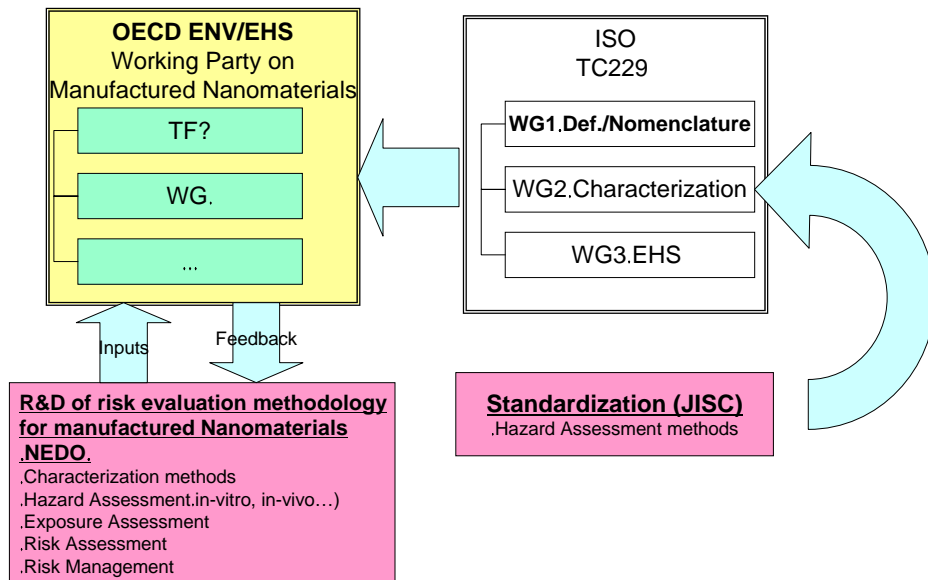
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4. International Coordination



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International Discussion in OECD Regulatory framework

Japan is in close coordination with OECD activities on safety of nanomaterials.

OECD (ENV/EHS)

Working Party on Manufactured Nanomaterials Main Activities.

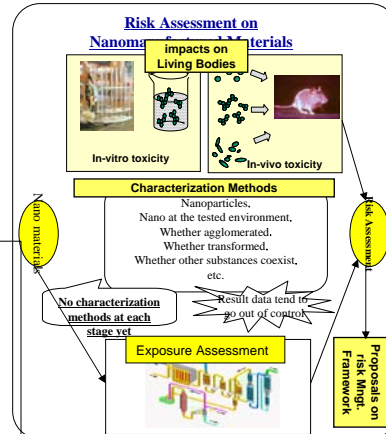
- ✓ Definition/Nomenclature/Characterization
- ✓ Environmental Fate/ Impact
- ✓ Exposure to Human and Impact on Health
- ✓ **Info Exchange on Regulations and Frameworks of Risk Control**

- Existing regulatory frameworks do not address chemical control by size.
- Japan plans to establish appropriate risk-management framework on nanomaterials through scientific assessment, and to propose them to OECD for consideration.
- OECD discussions will be taken into account in many countries' regulatory/ voluntary frameworks, including Japan's.

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R&D of risk evaluation methodology



NEDO R&D PJ 2006-2010, \$20 Million/201.

International Coordination - Future Events in Japan

- **ASTM E56 on Nanotechnology**
(22-24 May 2006 @Tsukuba, JAPAN)
- **ISO/TC229 on Nanotechnology**
(21-23 June 2006 @ Tokyo, JAPAN)
- **Second International Dialogue on Responsible Research and Development of Nanotechnology**
(26, 27, 28 June 2006 @ Tokyo, JAPAN)

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5. Conclusions

1. Currently no nanotechnology-specific regulations exist in Japan.
2. Too early for regulation. More studies & open discussion are needed.
3. Research on characterization / evaluation methods and standardization are important.
4. A voluntary framework in the private sector will be explored even before serious nano-specific risk of nanomaterials is proven scientifically.
5. If serious nano-specific risk of nanomaterials is proven scientifically, it would be managed within an appropriate framework.
6. International coordination is important; Japan is willing to actively participate in OECD and other international forums.