

**OECD Workshop on the
Safety of Manufactured Nanomaterials**

BUILDING COOPERATION, COORDINATION AND COMMUNICATION

December 7-9, 2005

Washington DC, USA

**Japan's Approaches to
Risk Assessment of Manufactured Nanomaterials**

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CRM: Research Center for Chemical Risk Management

AIST: National Institute of Advanced Industrial Science and Technology

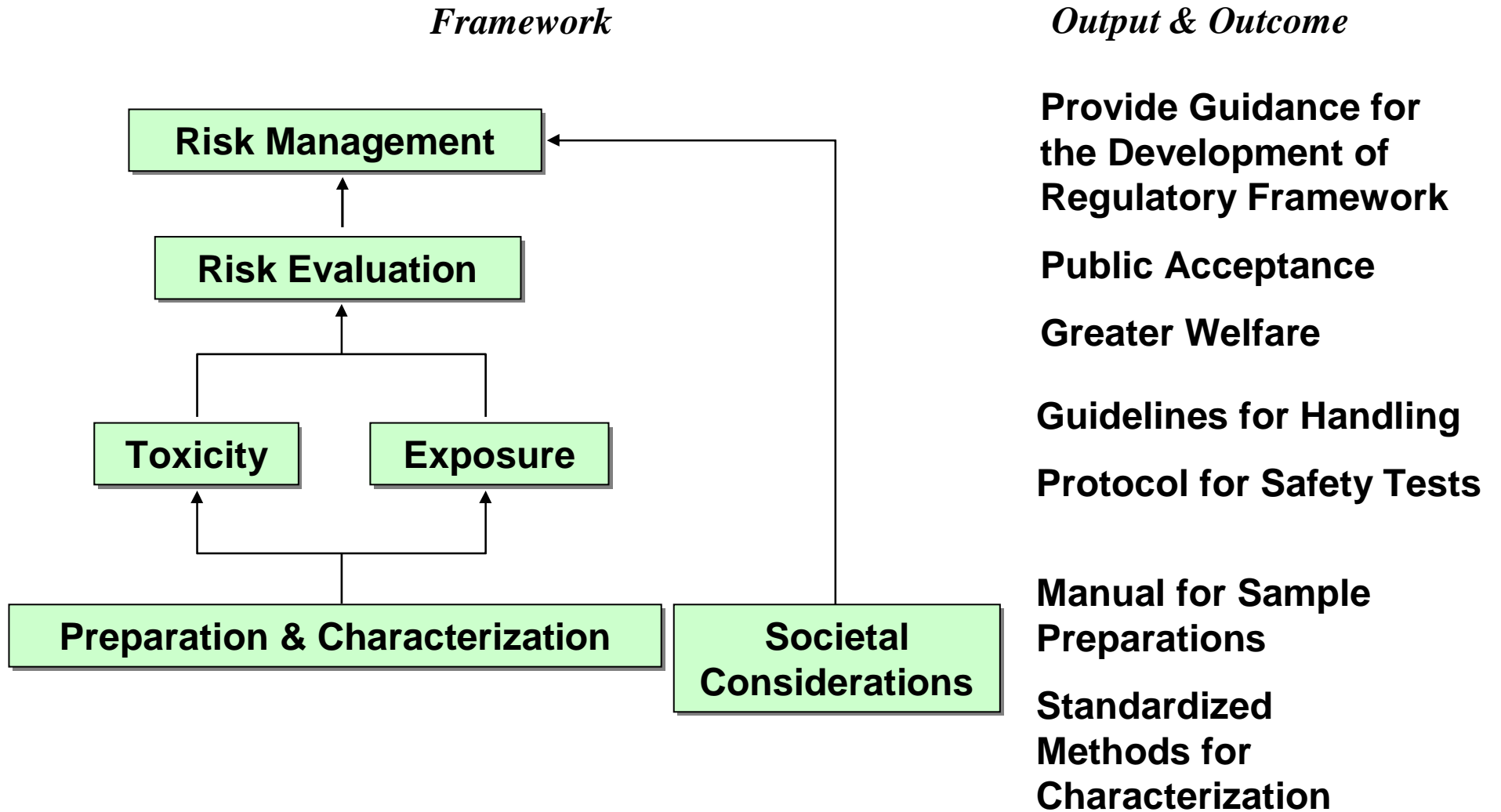
Ongoing and Planned Research Projects on Risk Assessment of Nanomaterials in Japan

Area	Start / End (FY)	Funding Organization	Supervisor: Member
Public Acceptance of Nanotechnology	2005	MEXT, \$ 0.3 M	M. Ata(*) : MHLW、MEXT, ME, AIST
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(**)	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 Economics, Trade and Industry

(*)= AIST Researcher, (**) = planned , \$1 ≙ 100 Yen

Major Components of Research Projects



Basic Standpoints of Projects

<Toxicity>

- To identify size-dependent adverse effects of NPs
- To apply a tiered approach to toxicity tests that include in vitro and in vivo tests
- To carry out toxicity tests of NPs that are well characterized

<Exposure>

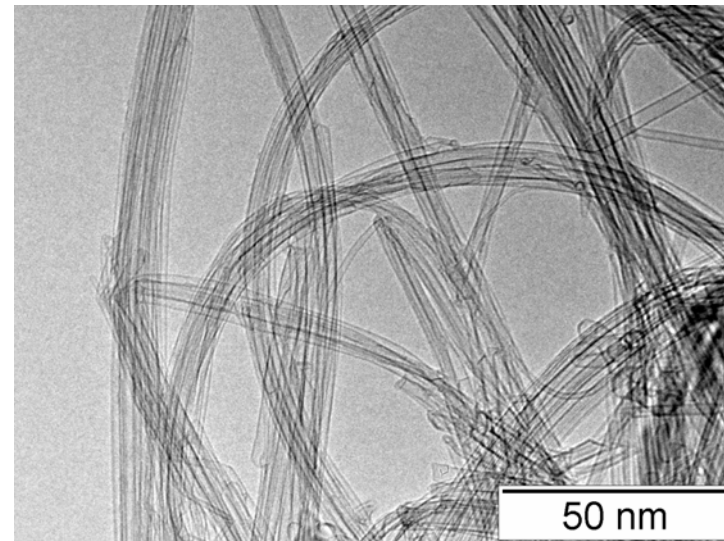
- To carry out exposure analysis for NPs' entire life cycle

<Characterization & deagglomeration>

- To establish standardized methods for characterization and deagglomeration

<Testing NPs>

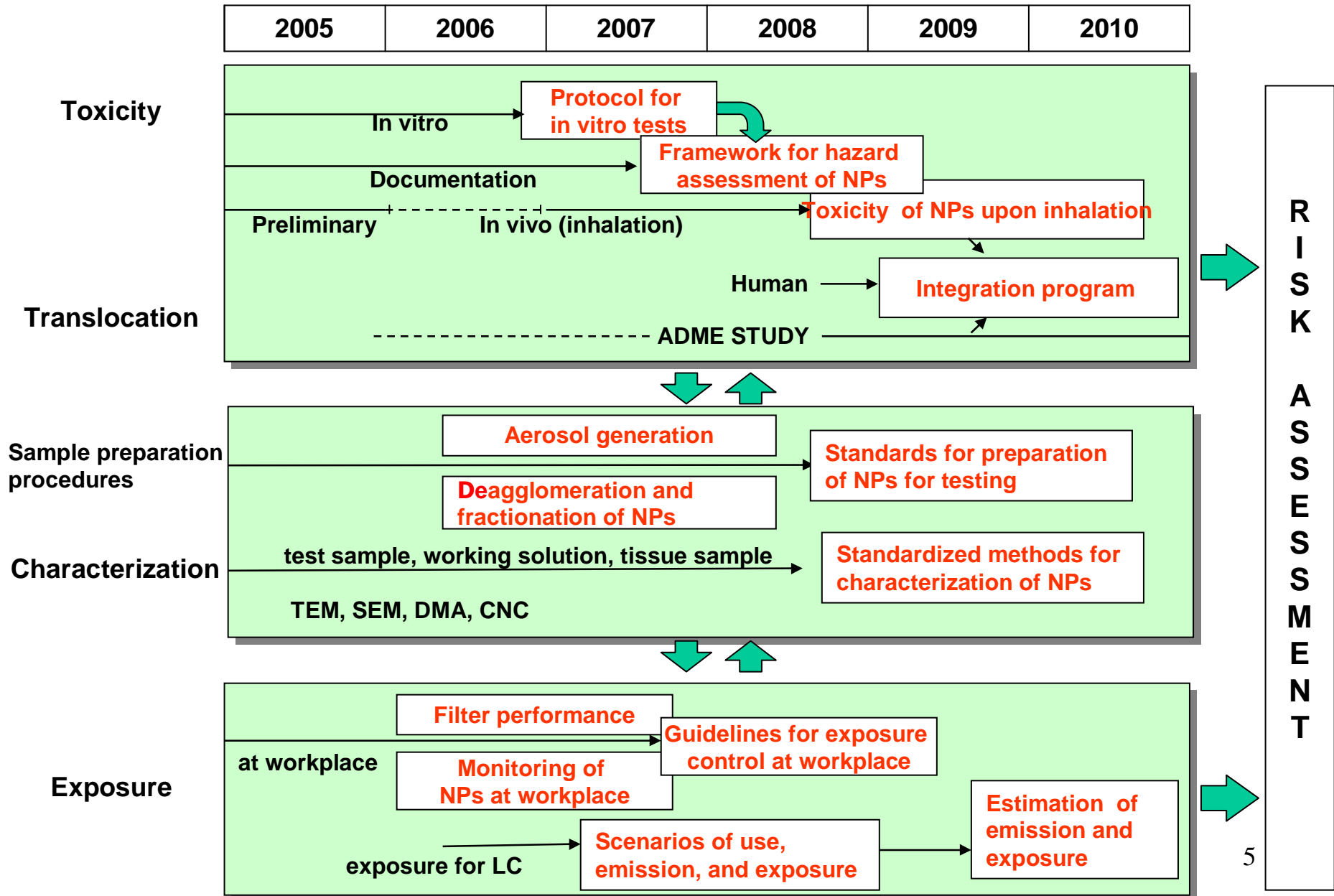
- TiO₂, C₆₀, CNT, ..



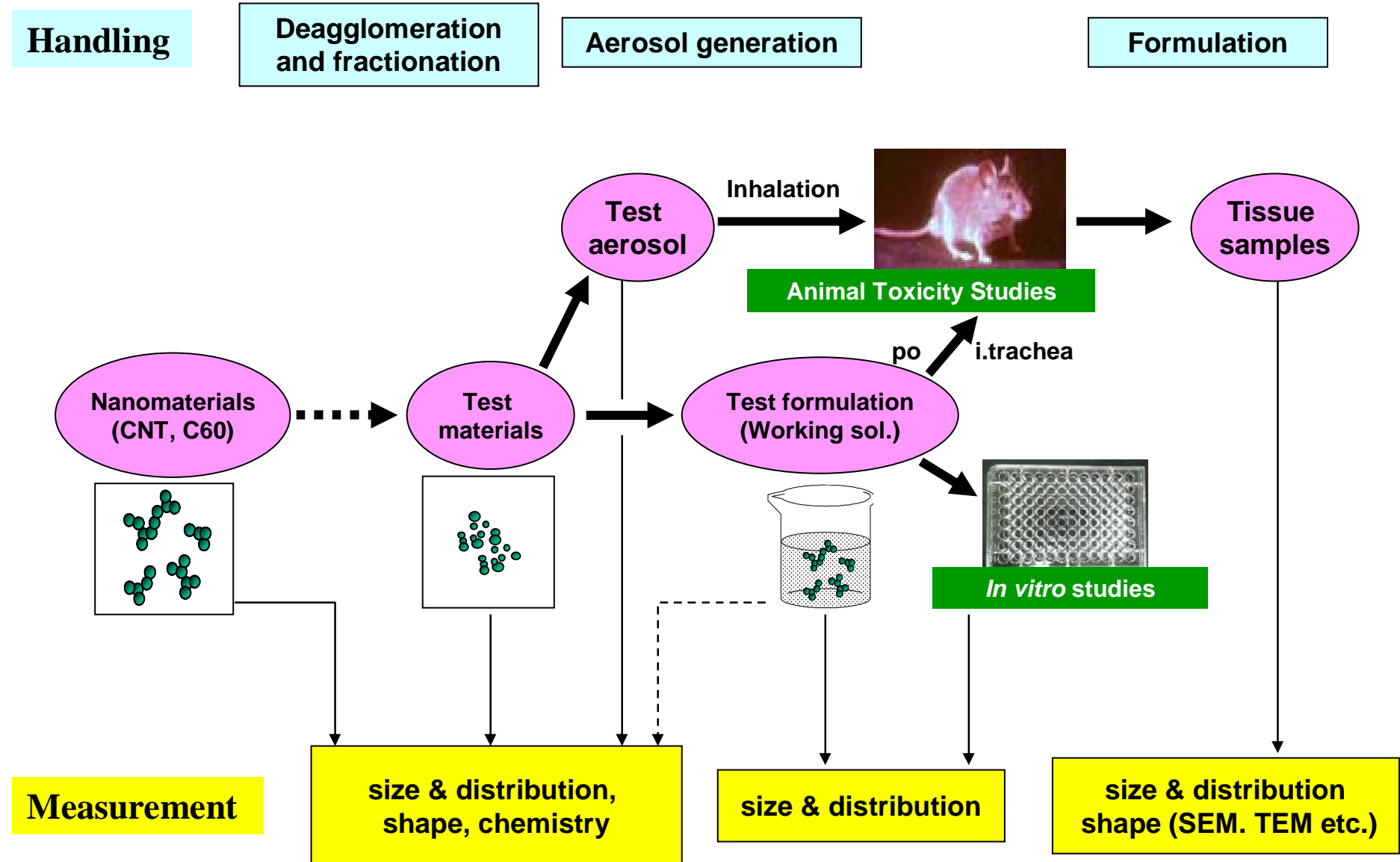
TEM image of a SWCNT (as-grown)
K. Mizuno and K. Hata (AIST, 2005)

NPs= Nanoparticles, SWCNT=single-walled carbon nanotube

Roadmap of Risk Assessment (NPs=Nanoparticles)

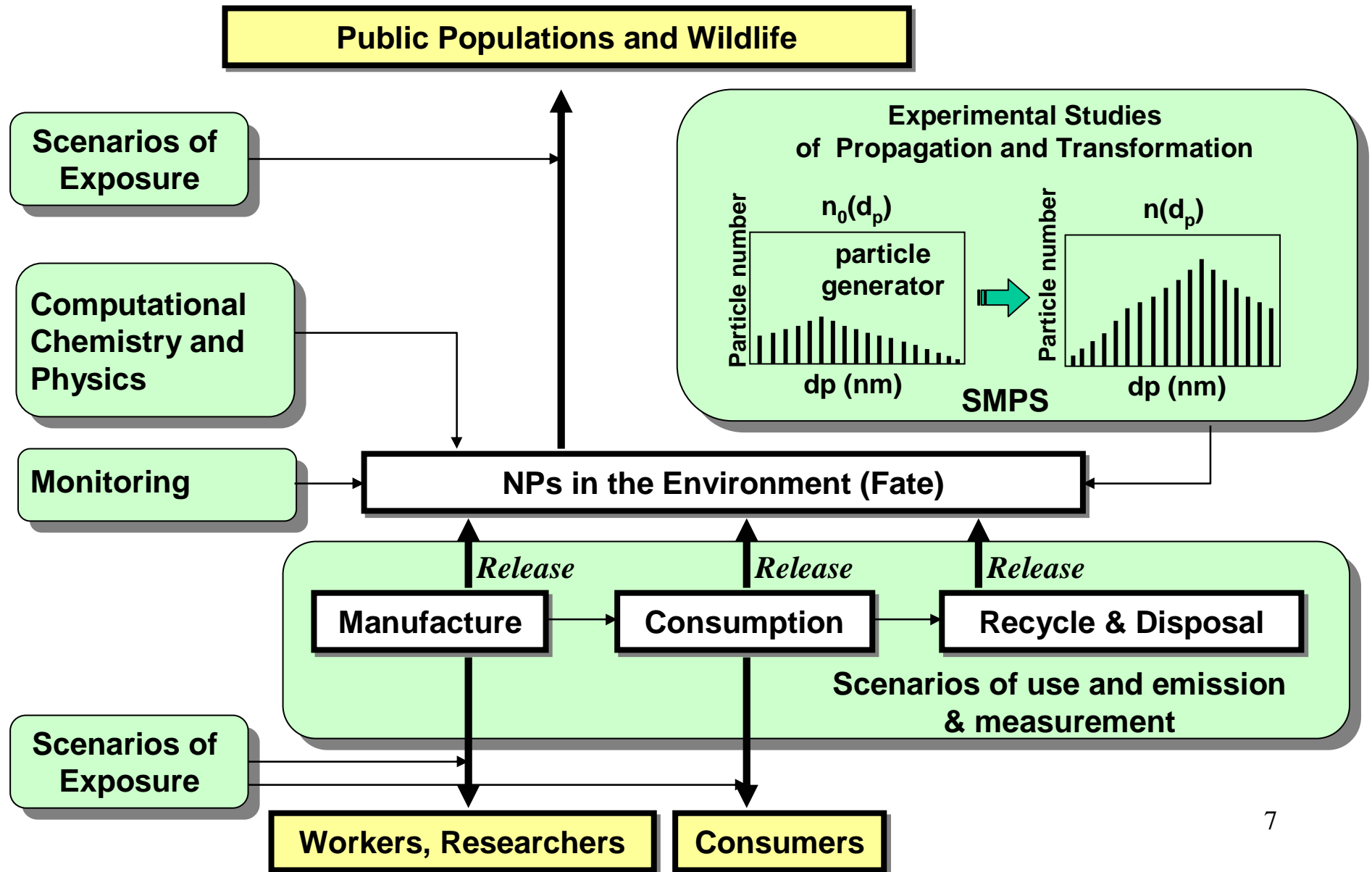


Handling & Measurement- essential for Toxicity Tests



Exposure Analysis for NPs' Entire Life Cycle

NPs Release and Behavior in Various Environments



Intermediate Goals

To present various guidelines and protocols

Goals of Projects by FY 2010

To present proposals for controlling risks associated with the use of NPs and to provide scientific evidence in the following terms:

- ◆ for the academic community - how to fill the data gaps,
- ◆ for manufacturers - how to handle NPs at workplace, how to apply nanotechnologies,
- ◆ for the government - how to apply and/or adapt existing rules or how to make new regulatory frameworks,
- ◆ for consumers - how to choose and use consumer goods containing NPs

Thank you !

Reference Materials 1: **Research Project on
“Facilitation of Public Acceptance of Nanotechnology”**

FY'05, MEXT

**Special Coordination Funds for Promoting Science and Technology,
Supervisor; Masafumi ATA**

I. Research and surveys on risk assessment of nanomaterials
by AIST (Research Center for Chemical Risk Management)

II. Research and surveys on health issues of nanomaterials
by National Institute of Health Science

III. Research and surveys on environmental issues of nanomaterials
by National Institute for Environmental Studies, Universities

IV. Research and surveys on ethics and societal issues of nanotechnology
by National Institute of Materials Science, Universities

*V. Research and surveys on technology assessment for promoting
public acceptance of nanotechnology and socioeconomic effects*
by AIST (Technology Information Department, the Nanotechnology
Research Institute, Metrology Institute of Japan),
Nanotechnology Business Creation Initiative, Universities, NGO, Journalists

Reference Materials 2:

In Vitro Studies

Endpoints	Measurements
Oxidative stress	8-OH-dG production lipid peroxide formation
Mitochondrial structure	Observation by SEM & TEM
Proinflammatory cytokine production	TNF, IL-6, IL-8, MCP-1, etc.

TNF: Tumor Necrosis Factor, IL-6: Interleukin-6,

IL-8: Interleukin-8, MCP-1: Monocyte chemotactic protein-1

Reference Materials 3:

Measured Items

	Test samples	Administered samples	Tissue samples
Size Distribution	SEM, TEM, DLS, DMA, FFF(SCE)-MALS(DLS), SMPS(DMA-CNC)		SEM, TEM
Morphology	SEM, TEM		
Agglomeration State			
Surface Area	BET		
Chemical Composition	Elemental analysis (spectroscopies)		
Impurities			
Surface Chemistry	Spectroscopies		
Surface Charge		Zeta potential	
Concentration	Elemental analysis by spectroscopies		11

Reference Materials 4:

Acronyms of Measurement Apparatus

- Liquid sample FFF(SCE)-MALS(DLS)
 - FFF: Field Flow Fractionation
 - SEC: Size Exclusion Chromatography
 - DLS: Dynamic Light Scattering
 - MALS: Multiangle Laser Light Scattering
- Aerosol samples
 - SMPS: Scanning Mobility Particle Sizer (DAM-CNC)
 - DMA: Differential Mobility Analysis
 - CNC: Condensation Nucleus Counters
- Spectroscopies
 - UV-VIS: Ultraviolet - Visible Light Spectrometry
 - XPS: X-ray Photon Spectroscopy
 - AES: Auger Spectroscopy
 - XRD: X-Ray Diffraction
- Elemental analysis
 - ICP-MS: Inductively Coupled Plasma - Mass Spectrometry
 - AA: Atomic Absorption Spectrometry
- TEM: Transmission Electron Microscope; SEM: Scanning Electron Microscope