The Expert Meeting on Safety Measures for Nanomaterial Manufactures etc.

Report

(tentative translation)

March 2009

Ministry of Economy, Trade and Industry (METI)

JAPAN

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I. Introduction (Outline and Objectives)

Nanotechnology is expected to yield benefits in a wide range of sectors such as information and communications, environment, energy, etc., as industrial basic technology for the next generation. In particular, it is anticipated for nanomaterials, which are materials that use nanotechnology, to express new functions that do not exist in conventional materials.

On the other hand, it has been indicated that nanomaterials have impacts on the health of humans due to their small particle size, etc., and also since they possesses characteristics and configurations that are different from those of conventional materials. However, the effects of nanomaterials on the environment and human health is not sufficiently clear at the present moment, and it has been pointed out that thorough approaches cannot be made through conventional toxicity assessment methods. In addition, the behavior of nanomaterials in the human body and in the environment has also not been made sufficiently clear under the present circumstances.

If such an unclear state is to be left as is, it is possible that social concerns regarding nanotechnology would expand, and the benefits of nanotechnology may not be fully applied due to refrained production, use, etc. At the same time, unless proper handling is implemented based on the fact that safety has not been sufficiently confirmed, there is the risk of impacts on health and the environment arising.

Accordingly, the purpose of this expert meeting is to organize the points to keep in mind regarding nanomaterials as based on present scientific findings, and to review a broad range of safety measures that are not limited to measures for preventing exposure at workplaces, but that also include voluntary safety surveys by business operators and the sharing of information in the supply chain, etc.

II. Definition of "Nanomaterials" that Are Reviewed

"Nanomaterials" is defined by international organisations (OECD, ISO), etc. as "materials in a solid state, which are manufactured using elements or other raw materials, and which are either nano-objects, or nanostructured materials (including objects that have nano-scale structures inside, as well as aggregations of nano-objects), with at least one of the three dimensions smaller than 100 nanometers"[1].

The reasons for defining nanomaterials separately from conventional materials is that in addition to the physicochemical and biological effects that atoms and molecules themselves possess, there are also cases where the unique properties attributed to nanosize, such as mechanical and optical properties, are expressed.

In this expert meeting, to review these properties that are attributed to nanosize, nanomaterials where the primary particle size, etc. is deliberately controlled to nanosize so that unique functions are expressed are targeted for review, and nanomaterials that are generated by natural means or unintentionally generated in the

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1 With regard to carbon nanotubes, although there are some carbon nanofibers with a fiber diameter greater than 100 nm, such carbon nanotubes are considered as being applicable to reviews here.

manufacturing process, and nanomaterials that are found in very little amounts in fine particles are not subject to reviews.

Since reviews regarding the definition of “nanomaterials” are continuously being implemented by international organisations, etc., focus will be placed on the status of future approaches related to the definition of terminology, such as “nanomaterials,” that will be carried out both within and outside of Japan, and the latest findings will be applied.

Although there is information indicating that nanomaterials based on various substances exist, in this expert meeting, to give priority to approaches for major nanomaterials, reviews were conducted on the six substances of carbon nanotubes, carbon black, titanium dioxide, fullerenes, zinc oxide, and silicon dioxide, which are nanomaterials with production volumes exceeding a certain level, or that may be produced in increased amounts in the future. Overviews of the six substances subject to reviews are shown in Chart 1, and their corresponding production volume and particle size are shown in Diagram 1.

Chart 1 Domestic production volume and major purposes of substances subject to reviews

Substance name	Production volume in Japan[2]	Major purposes
Carbon nanotubes	120 to 140 t	Electronic materials, etc.
Carbon black	800,000 t	Tires, automotive parts, etc.
Titanium dioxide	1,450 t	Cosmetics, photocatalysts, etc.
Fullerenes	2 t	Sporting goods, etc.
Zinc oxide	480 t	Cosmetics, etc.
Silicon dioxide	90,000 t	Ink, synthetic rubber, tires, etc.

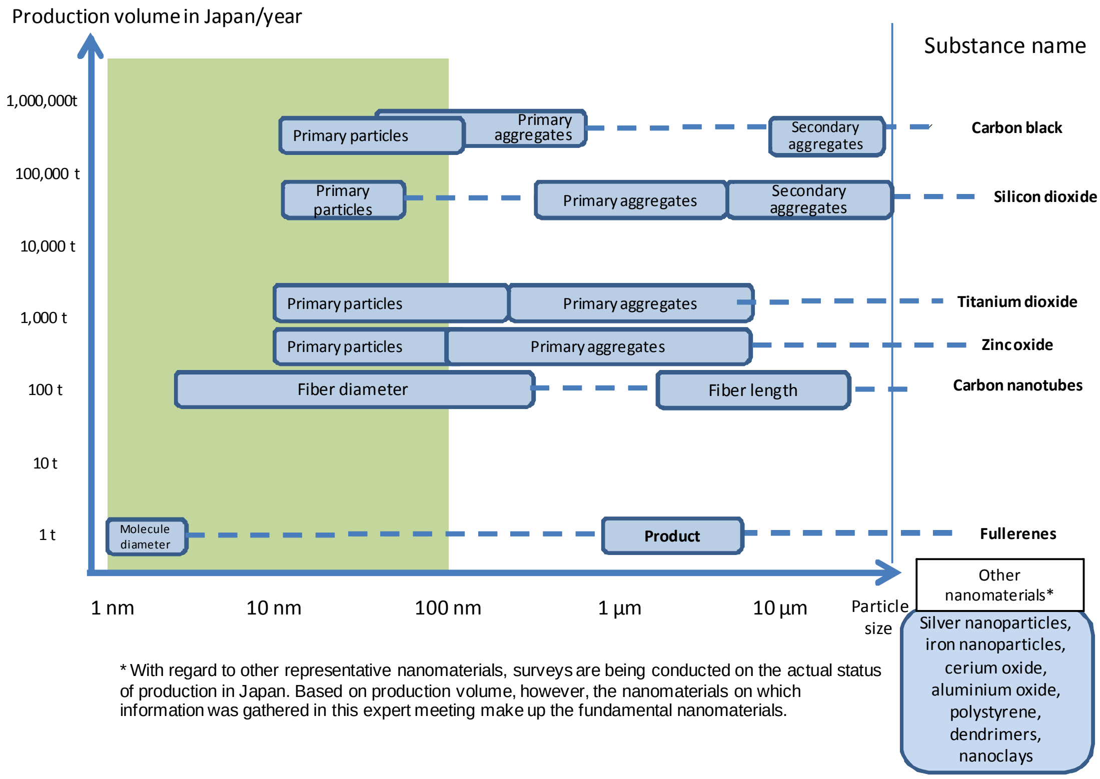


Diagram 1 Production volume and particle size of the nanomaterials on which information was gathered in this expert meeting[2]

As of the present point in time, the abovementioned six substances account for over 99%[3] of the production volume of nanomaterials produced in Japan.

III. Major Nanomaterials

In reviewing measures regarding nanomaterials, it is necessary to obtain an overview of the general conditions of nanomaterials in Japan and the status of common approaches. For the six substances that were targeted for reviews, since an industrial organization existed for each substance, this expert meeting was used as an opportunity for information provision by the representatives from each of the industrial organizations, for the purpose of comprehending the characteristics and status of approaches for each substance.

It should be noted that the status of approaches that were clarified by conducting reviews represents the general status of approaches by each industrial organization. Furthermore, with regard to measures for preventing exposure and emission, etc. of nanomaterials, general dust prevention measures and methods for waste disposal are specified in relevant laws such as the Industrial Safety and Health Act and the Waste Disposal Act. Additionally, with regard to measures for preventing exposure of nanomaterials, the "Notification

[2] Created by the secretariat based on the contents announced by this research group. Indicates the production volume of nanosized materials.
[3] Estimated by the secretariat based on the results, etc. of Toray Corporate Business Research, Inc.

on Present Preventive Measures for the Prevention of Exposure at Workplaces Manufacturing and Handling Nanomaterials" was issued in February 2008 by the Director of the Labour Standards Bureau, Ministry of Health, Labour and Welfare (MHLW).

1. Carbon nanotubes (Nanotechnology Business Creation Initiative)

1) Characteristics, production volume, etc. of nanomaterials

Carbon nanotubes have a fiber diameter ranging from a few nm to 150 nm, and a length ranging from approximately a few µm to tens of µm. The production volume of single-walled carbon nanotubes is approximately 100 kg/year, while the production volume of multi-walled carbon nanotubes (fiber diameter of 10 to 70 nm) is approximately 60 to 70 t/year, and that of carbon nanofibers (maximum fiber diameter of approximately 150 nm) is approximately 60 to 70 t/year (based on research by the Toray Research Center, Inc.). Carbon nanotubes are generally aggregatory, and are extracted from the manufacturing process in the form of aggregates, but since they have low dispersibility in such a state, it is a technical issue as to how to industrially disperse carbon nanotubes. An example of a scanning electron micrograph of a carbon nanotube in an aggregational state is shown below. Single-walled carbon nanotubes are being developed for use in transistors, fuel cells, functional materials, etc., while multi-walled carbon nanotubes are used in semiconductor trays, etc., and carbon nanofibers are used in lithium-ion secondary batteries, etc. In the future, it is possible that carbon nanotubes will be applied toward usage that corresponds with environmental objectives, such as in vehicle batteries, storage of wind-generated power, as well as high-strength and lightweight material, etc. that can be substituted for metal by serving as various composite materials.

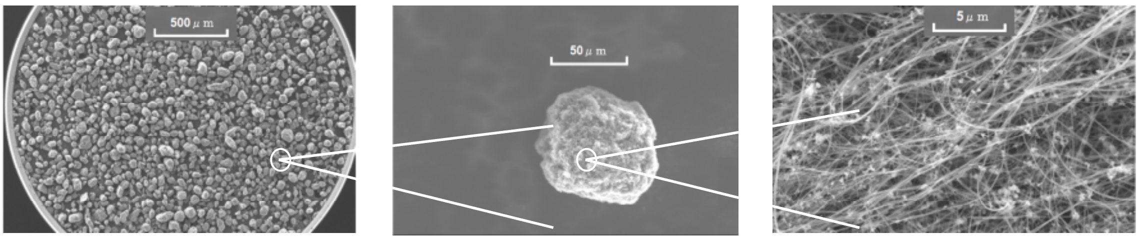


Photo 1 Example of a scanning electron micrograph of a carbon nanotube (aggregational state)

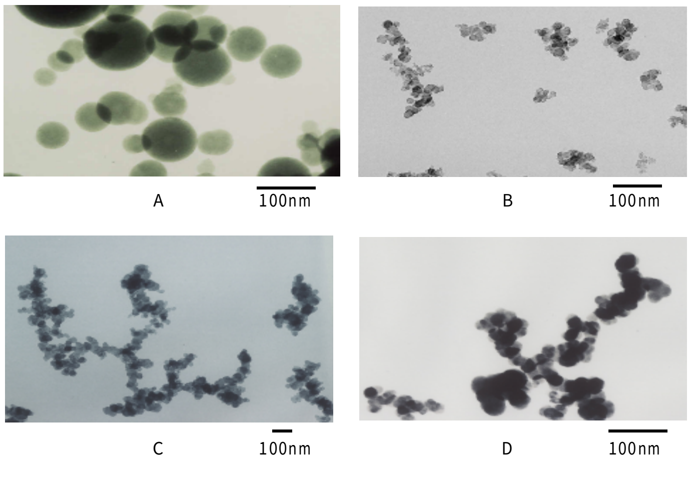
2) Exposure and emission prevention measures, etc.

As examples of safety management, in addition to making the manufacturing process a fundamentally closed system, the operating staff are required to wear protective gear. In addition, environmental measurements are taken in manufacturing facilities. With regard to emission prevention measures, emissions are prevented by using pre-filters, HEPA filters, etc., and as for water discharge, there is almost no mixing of nanomaterials into the water drainage as coolant water is mostly used. Inside manufactured products such as semiconductor trays, it is unlikely that carbon nanotubes become kneaded into the resin and scatter easily. In the case of lithium-ion secondary batteries as well, it is difficult to consider that carbon nanotubes are emitted from the battery during use, as they are secured to electrodes and the battery itself is enclosed in packaging. Wastes are processed in accordance with the Waste Disposal Act, and a large portion of wastes is incinerated as industrial waste. In addition, Material Data Safety Sheets (MSDS) are also distributed to shipment destinations and promotion of awareness regarding handling is carried out.

2. Carbon black (Carbon Black Association)

1) Characteristics, production volume, etc. of nanomaterials

Carbon black is defined as soot-like material produced under controlled conditions (black lead with turbostratic structure). It has extremely high electric and thermal conductivity, is not soluble in water or oil, and has very high corrosion resistance. Carbon black is formed in a process where primary particles referred to as domains (approximately 10 to 500 nm) are fused by heat in the generation process, after which hydrocarbons become bonded and carbonized, and primary aggregates known as aggregates[4] (approximately tens of nm to hundreds of nm) that is extremely resistant against breaking is formed. The aggregates then aggregate to form secondary aggregates known as agglomerates[5] (several µm to hundreds of µm). During shipment, it is often the case that carbon black is shipped in units of beads (particle size of approximately 1 mm). Carbon black is thought to exist in the form of an agglomerate state, rather than an aggregational state, both inside manufactured products and in air. The production volume of carbon black in Japan is approximately 800,000 t/year, and the import volume is approximately 200,000 t/year (based on research by the Carbon Black Association). The amount of carbon black produced in the world is 9,530,000 t/year, and carbon black is used in strengthening agents for rubber, black colorants, conductivity-imparting agents, etc. (specifically, tires, automotive parts, electric parts, printed matter, semiconductor parts, semiconductor trays, etc.).



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[4] Aggregate: Particle comprising strongly bonded or fused particles where the resulting external surface area may be significantly smaller than the sum of calculated surface areas of the individual components. (The forces holding an aggregate together are strong forces, for example covalent bonds, or those resulting from sintering or complex physical entanglement.)

[5] Agglomerate: Collection of weakly bound particles or aggregates or mixtures of the two where the resulting external surface area is similar to the sum of the surface areas of the individual components. (The forces holding an agglomerate together are weak forces, for example van der Waals forces, or simple physical entanglement.)

Photo 2 Electron micrograph of carbon black (aggregates)

2) Exposure and emission prevention measures, etc.

With regard to exposure prevention measures, in addition to an enclosed structure, in principle, generation of dust is controlled through methods such as installing a dust suction apparatus in chutes and outlets used for shipping, where dust easily arises, to prevent leakage outside of the system. In addition, measures are also being taken based on the Industrial Safety and Health Act (Ordinance on Prevention of Hazards Due to Dust), such as through the use of appropriate protective gear. As a measure to prevent emission, carbon black is collected by processing emissions using bag filters. Wastes are also reused as much as possible, and those that cannot be reused are incinerated in accordance with the Waste Disposal Act. Furthermore, safety guidelines and MSDS are distributed to users and transport operators, and safety measures are being taken thoroughly.

3. Titanium dioxide (Japan Titanium Dioxide Industry Association)

1) Characteristics, production volume, etc. of nanomaterials

Titanium dioxide is chemically stable, and occurs in two types of crystal forms—rutile and anatase (anatase converts to rutile at temperatures of approximately 1,000 degrees). Nanosized titanium dioxide (pigment-grade titanium dioxide and large-particle titanium dioxide, which have a larger primary particle size as compared to nanosized titanium dioxide, are also being produced) have strong performance in blocking ultraviolet rays. Nanosized titanium dioxide is formed based on primary particles of less than 100 nm aggregating to form aggregates of approximately 200 nm, which further aggregate to form agglomerates. Although its form of existence in final product sand in the atmosphere has yet to be confirmed, it is perceived that nanosized titanium dioxide exists in the form of agglomerates. Although tests have been conducted on the conditions of the powder in air, nanosized particles were not able to be observed. The production volume of nanosized titanium dioxide in Japan is estimated to be 950 t/year, and 1,450 t/year overseas (based on research by the Fuji Chimera Research Institute, Inc.). As for its uses, the rutile form is used in cosmetics, paint, external additive for toner, etc., and the anatase form is used for photocatalysts, etc.

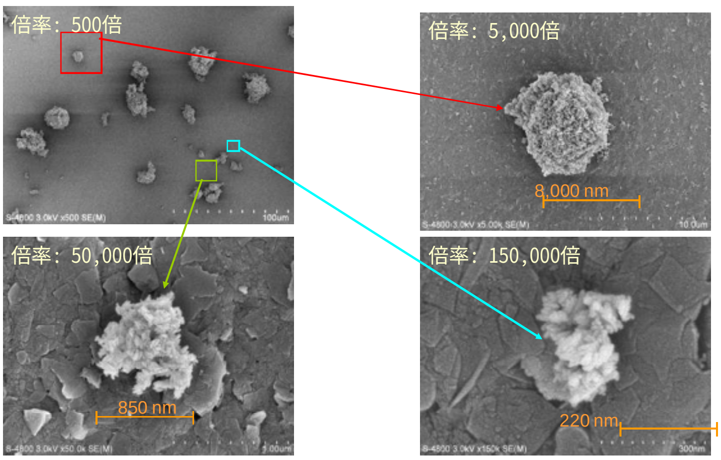

Photo 3 Electron micrograph of titanium dioxide

2) Exposure and emission prevention measures, etc.

With regard to exposure prevention measures, in the packaging process during which there is the possibility that workers may come in direct contact with the powder, local ventilation equipment is installed, and the workers are required to wear masks in accordance with the Industrial Safety and Health Act (Ordinance on Prevention of Hazards Due to Dust). With regard to emission prevention measures, titanium dioxide is collected and removed from emissions using bag filters, and wastes are landfilled as sludge in accordance with the Waste Disposal Act. In addition, MSDS are distributed to shipment destinations.

4. Fullerenes (Nanotechnology Business Creation Initiative)

1) Characteristics, production volume, etc. of nanomaterials

Fullerene is a generic name for carbon molecules that comprise a cage-shaped network. Fullerenes are insulators, and are soluble in nonpolar solvents such as toluene, xylene, chlorobenzene, etc. The diameter of a molecule is 1 nm, but it is difficult for a molecule to exist independently and thus form primary aggregates based on special molecular crystallization, after which these primary aggregates aggregate to form secondary or tertiary aggregates. As fullerenes have strong aggregability, only aggregates of approximately 1 µm can be detected using laser diffraction particle size distribution equipment and particle size distribution equipment using the dynamic light scattering method.

The production volume is thought to be approximately 2 t/year in Japan (based on research by the Toray Research Center, Inc.) and approximately 3 t/year worldwide (based on research by the Nanotechnology Business Creation Initiative), but these are not accurate statistical data. Fullerenes are used in sporting equipment (for golf and tennis), electronic materials (organic EL, etc.), cosmetics, etc.

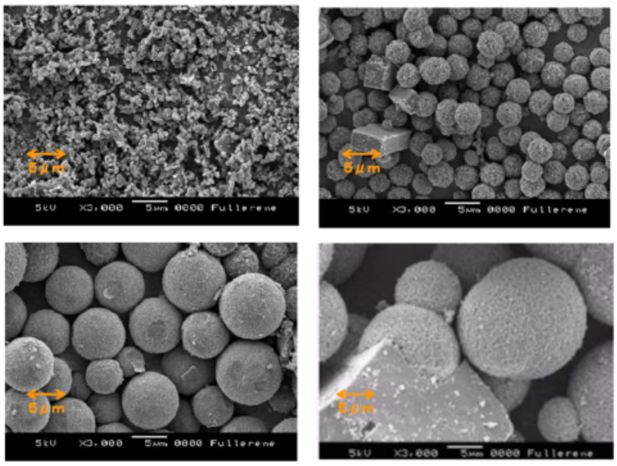

Photo 4 Electron micrograph of fullerenes

2) Exposure and emission prevention measures, etc.

With regard to exposure prevention measures, local ventilation is carried out in the manufacturing process, and workers are required to wear dust-protective masks, special coats, and goggles as protective gear. Results from working environment measurements show that even during work when fullerenes are being handled, there was found to be a smaller amount of fullerene nanoparticles than naturally-derived nanoparticles, which are detected in the background, and that it is difficult to distinguish between the two. With regard to emission prevention measures, the particles inside emissions are collected using filters, and the solvents are reused after undergoing distillation and refining. Wastes are disposed of in accordance with the Waste Disposal Act, and are incinerated, including containers, protective gear, etc. In addition, various safety tests have been implemented, and the results of such tests are described in MSDS and distributed to shipment destinations.

5. Zinc oxide (Japan Inorganic Chemical Industry Association)

1) Characteristics, production volume, etc. of nanomaterials

Since zinc oxide dissolves in acids and alkalis, it is used after coating its surface. Nanosized zinc oxide has strong performance in blocking ultraviolet rays, and does not disperse easily since its primary particles are bonded extremely strongly and form aggregates. These aggregates further aggregate and form agglomerates. Even if a dispersant, etc. is used to disperse the final product, since the size of most of the particles is greater than 100 nm, it is perceived that zinc oxide exists as agglomerates in the final product. In addition, upon measuring the particle size of the powder that is stirred up during packaging of the final product, the particle size was found to be several µm (even small particles were approximately 0.1 µm). The production volume of nanosized zinc oxide is approximately 480 t/year (based on research by Toray Corporate Business Research, Inc.), and it is mostly used in cosmetics.

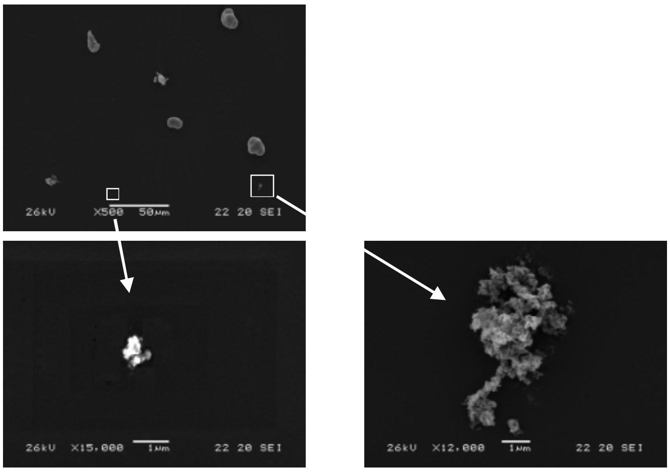

Photo 5 Electron micrograph of zinc oxide

2) Exposure and emission prevention measures, etc.

With regard to exposure prevention measures, the manufacturing process is made a closed system to the maximum extent possible, and for areas that are not closed, approaches are made through installing local ventilation equipment. In addition, workers are required to wear appropriate protective gear. With regard to emission prevention measures, the powder in emissions is collected using bag filters. Wastes are reused as much as possible, and those that cannot be used are landfilled at waste disposal sites as sludge, in accordance with the Waste Disposal Act. Clothing and packaging materials onto which nanosized zinc oxide had adhered are incinerated. In addition, MSDS are distributed beforehand to shipment destinations.

6. Silicon dioxide (Japan Inorganic Chemical Industry Association)

1) Characteristics, production volume, etc. of nanomaterials

Forms of silicon dioxide include crystalline quartz and crystal, and amorphous diatomaceous earth. As a synthetic, silicon dioxide is manufactured as synthetic crystalline quartz, etc., but it is synthetic amorphous silica of the dry type and the wet type (hereinafter referred to simply as "silica") that are handled as nanomaterials. For silica, primary particles form aggregates through fusion and intermolecular forces, and aggregates represent the smallest building block. Aggregates further aggregate physically to form agglomerates (tens of µm to hundreds of µm).

The production volume is 90,000 t/year in Japan (60,000 t/year of wet silica and 30,000 t/year of dry silica), and 1,590,000 t/year worldwide (1,430,000 t/year of wet silica and 150,000 t/year of dry silica) (based on research by the Japan Inorganic Chemical Industry Association). Silica is used in additives for ink, synthetic rubber, fillers for tires, silicon sealants, delustering agents, toners for printers, etc.

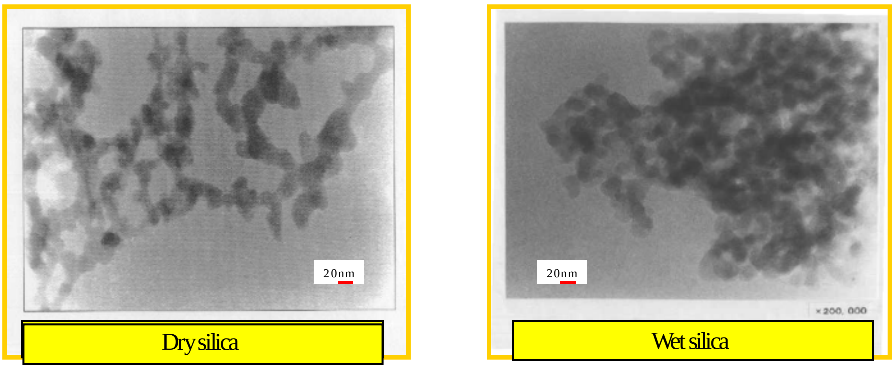

Photo 6 Electron micrograph of silicon dioxide

2) Exposure and emission prevention measures, etc.

With regard to exposure prevention measures, the manufacturing process is fundamentally a closed process, and local ventilation equipment is installed in locations for the packaging process, etc. that are not closed. In addition, workers are required to wear protective gear such as dust-protective masks, and environmental measurements for dust are being implemented voluntarily in some areas. With regard to emission prevention measures, emissions are processed using dust collectors such as bag filters. Wastes are landfilled in accordance with the Waste Disposal Act, and are processed as cement raw materials, etc. In addition, since silica is a notifiable substance under the Industrial Safety and Health Act, MSDS are distributed to shipment destinations.

7. Conclusion

According to the disclosed details for each nanomaterial, the nanomaterials do not exist in products and in air as primary particles of approximately 1 nm to 100 nm, but rather, the majority of nanomaterials exist as larger agglomerates. In addition, since it has not been proven that nanosized particle sizes do not exist in products and in air, it is necessary to continue gathering knowledge.

In addition, it is often the case that nanomaterials are transformed into powdery products, and since it has been recognized since the past that such powdery products disperse and drift in the air as powder, measures that are based on relevant laws such as the Industrial Safety and Health Act and the Waste Disposal Act, etc., are already being carried out by nanomaterial manufacturers, etc., and some of these measures are considered as being effective for nanomaterials as well. However, these measures are taken as general measures against dust, and it is possible that further measures are necessary for nanomaterials. Based on the MHLW notification issued in February 2008, implementation of measures regarding manufacturing facilities and work management, etc. has been initiated as preventive approaches for preventing exposure of nanomaterials.

IV. Major Approaches Within and Outside of Japan Pertaining to Safety Measures for Nanomaterials

1. Approaches within Japan

1) Ministry of Economy, Trade and Industry (METI)

(1) "Investigative Research concerning Appropriate Management at Nanotechnology Research and Manufacturing Sites" (a tentative translation)

In "Investigative Research concerning Appropriate Management at Nanotechnology Research and Manufacturing Sites," (a tentative translation) which is part of commissioned survey operations for FY2006, METI surveyed the current conditions of sites at which research and manufacturing related to nanotechnology are being carried out, investigated examples of management abroad, and reviewed optimal methods for managing nanomaterials in Japan.

(2) "Research and Development of Nanoparticle Characterization Methods" (FY2006 to FY2010)

To implement appropriate assessments regarding nanoparticles based on science, (1) the establishment of measurement technology (characterization) of nanoparticles, (2) the development of methods for assessing biological effects, (3) the development of methods for assessing exposure, and (4) the establishment of methods for risk assessment and management of nanoparticles are being promoted. (Implemented by the National Institute of Advanced Industrial Science and Technology (AIST), the University of Occupational and Environmental Health, etc. as a NEDO project.) In April 2008, the NEDO-AIST-OECD International Symposium on the Risk Assessment of Manufactured Nanomaterials was held.

2) Ministry of Health, Labour and Welfare (MHLW)

(1) Labour Standards Bureau

In February 2008, present preventive approaches for exposure prevention of nanomaterials were coordinated, and requests were broadly made to relevant organizations to provide information to their members and other related workplaces. In addition, to give instructions to directors of prefectural labor bureaus for thoroughly raising awareness at relevant workplaces, the Director of the Labour Bureau issued the "Notification on Present Preventive Measures for the Prevention of Exposure at Workplaces Manufacturing and Handling Nanomaterials."

Furthermore, since it is necessary to indicate concrete management methods that are based on actual conditions at worksites, and to review the current state of and issues regarding exposure prevention measures in order to increase the effectiveness of nanomaterial measures at workplaces, the "Study Group on Preventive Measures for Workers' Exposure to Chemical Substances of which the Hazardousness on Humans Is Unclear" (a tentative translation) convened 9 times between March and October 2008, and organized a report.

(2) Pharmaceutical and Food Safety Bureau

Since FY2004, the factors that affect the onset of toxicity have been systematically comprehended, and progress is being made with research, etc. that contributes to the development of utilizable methods for evaluating toxicity resulting from exposure of nanomaterials, based on the MHLW's Grants-in-Aid for Scientific Research on "Research Project on Risks of Chemical Substances," (a tentative translation) etc.

While application of nanomaterials is expanding, since the effects of nanomaterials on human health is not yet clear, the "Investigative Commission on Reviews on Safety Measures for Nanomaterials" (a tentative translation) has also been convening from March 2008 to conduct reviews on the ideals for safety measures and methods for safety assessment.

3) Ministry of the Environment

To gather and organize knowledge regarding the possibility of nanomaterials being emitted into the environment as well as management methods in a manner that takes the actual state of use of nanomaterials into consideration, the "Investigative Commission on Fundamental Surveys on the Environmental Impact of Nanomaterials" (a tentative translation) was established in June 2008 and has been conducting reviews. In March 2009, this investigative commission created and published "Guidelines for Preventing Environmental Impacts Related to Manufactured Nanomaterials." (a tentative translation)

2. Major approaches by public agencies abroad

1) Australia

The Australian Department of Health and Aging started calling for provision of information regarding nanomaterials in 20006, and published the results in January 2007 (contents include the names of chemical substances, product names, chemical formulas, production volumes, etc.). In January 2008, the Department started calling for provision of information a second time (provision of information that includes physiochemical data, toxicity data, use information, and life cycle information related to manufactured nanomaterials (over 100 kg per year)).

2) United Kingdom

The UK Department for Environment, Food and Rural Affairs (Defra) implemented the "Voluntary Reporting Scheme (VRS) for Manufactured Nanomaterials" as a voluntary reporting system over a two-year pilot period extending from September 2006 to September 2008. There were 13 reports submitted.

Presently, Defra is conducting a questionnaire survey on the industrial and academic worlds regarding ideas related to the VRS. As the pilot period has ended, future approaches are planned on being reviewed in the "Ministerial Group on Nanotechnologies."

3) United States

(1) "Nanoscale Materials Stewardship Program"

The US Environmental Protection Agency (EPA) initiated the "Nanoscale Materials Stewardship Program NMSP) (hereinafter referred to as "stewardship program")," which is a program for corporations that handle nanomaterials to voluntary provide information, on January 29, 2008.

The stewardship program promotes the gathering of information by encouraging corporations, etc. that handle nanomaterials to voluntarily provide data based on the Toxic Substances Control Act (TSCA), to enable for deeper understanding of safe handling of nanomaterials, to narrow down the rights and wrongs of regulations in the future and the necessary target of regulations, and to promote safe development of nanomaterials. The contents for which information is expected to be provided consist of information such as physiochemical characteristics of nanomaterials, toxicity information, exposure information, and risk management measures.

The stewardship program is comprised of the Basic Program and the In-Depth Program. The Basic Program is a program in which only information that is readily available is provided, and the In-Depth Program is a program for acquiring new data at a cost (such as for implementing animal testing, etc.) while consulting with the EPA. An interim report was presented in January 2009, and a final report is planned on being presented two years later. At the time of this final report, a decision will be made on the future orientation of the program (including reviews on the use of regulatory authority as based on the TSCA) (in some cases, it is possible that the publication of the report and the formulation of regulations may be implemented at an earlier time). In the Basic Program, information was provided by 29 business operators regarding 123 different types of nanomaterials as of December 2008.

(2) Handling of carbon nanotubes by the EPA and in the TSCA (October 31, 2008)

The EPA confirmed that many carbon nanotubes are new chemical substances that are specified in Article 5 of the TSCA, since the TSCA can be applied to carbon nanotubes, and carbon nanotubes are chemical substances that can be distinguished from graphite and other carbon allotropes in the inventory for the TSCA. Business operators that manufacture and import carbon nanotubes for commercial use are required to submit a notification regarding the manufacture and import of the carbon nanotubes 90 days in advance.

* With regard to whether manufactured nanomaterials are "new chemical substances" or "existing chemical substances," the EPA has created a paper entitled "TSCA Inventory Status of Nanoscale Substances – General Approach," and declared that the same judgment standards as those in the past (where molecular identity serves as the standard, and physical properties such as size are not taken into consideration) will be applied on a case-by-case basis. Concretely, multi-walled carbon nanotubes, single-walled carbon nanotubes, fullerenes, etc., which are carbon allotropes, will be considered as being "new" chemical substances, but nanosized titanium dioxide and silver nanoparticles, etc. will be considered as being "existing" chemical substances.

(3) Measures at the regional level

In the United States, approaches such as a compulsory reporting system and calling for provision of information, etc. are being implemented or are under review in the city of Berkeley, the city of Cambridge, and the state of California.

3. Major approaches by international organisations

1) OECD

(1) In September 2006, the Working Party on Manufactured Nanomaterials was established as a subsidiary body under the OECD's Chemical Committee. In order to promote the development of strict safety assessments regarding nanomaterials, progress is being made in international cooperation on aspects related to safety of manufactured nanomaterials on human health and the environment, with the OECD as the base. The framework for activities is as follows.

SG1: Development of a Database on Human Health and Environmental Safety Research
SG2: Research Strategies on Manufactured Nanomaterials
SG3: Safety Testing of a Representative Set of Manufactured Nanomaterials
SG4: Manufactured Nanomaterials and Test Guidelines
SG5: Co-operation on Voluntary Schemes and Regulatory Programmes
SG6: Co-operation on Risk Assessment
SG7: The Role of Alternative Methods in Nanotoxicology
SG8: Exposure Measurement and Exposure Mitigation

(2) As part of the approaches for SG3, a Sponsorship Programme has been launched in November 2007. This program consists of conducting tests or gathering safety information regarding endpoints that have been agreed upon relating to representative nanomaterials (14 substances; refer to Chart 2) that were selected from the perspective of production volume, etc. Each country voluntarily becomes a sponsor of a specified nanomaterial, and formulates a testing plan.

Presently, Japan has expressed becoming a sponsor together with the United States of fullerenes, single-walled carbon nanotubes, and multi-walled carbon nanotubes, and relevant ministries such as METI and agencies such as the AIST, etc. have started gathering information and implementing tests.

In addition, information is being exchanged on trends in regulations, etc., of OECD member countries and on approaches, etc. by relevant organisations, etc. (ISO, UN, and some non-member countries such as Russia, China, Thailand, and Brazil).

Chart 2 Representative nanomaterials in the OECD Sponsorship Programme (14 substances)[6]

	Lead Sponsor	Co-sponsor	Contributors
Fullerenes	Japan, US		Denmark, China
Single-walled carbon nanotubes	Japan, US		Canada, France, Germany, EC, China, BIAC
Multi-walled carbon nanotubes	Japan, US	Korea, BIAC[7]	Canada, France, Germany, EC, China, BIAC
Silver nanoparticles	Korea, US	Australia, Canada, Germany, Nordic Council of Ministers	France, EC, China
Iron nanoparticles	China	BIAC	Canada, US, Nordic Council of Ministers
Titanium dioxide	France, Germany	Australia, Canada, Korea, Spain, US, BIAC	Denmark, China
Carbon black			Denmark, Germany, US
Zinc oxide	UK/BIAC	Australia, US, BIAC	Canada
Silicon dioxide	France , EC	Belgium, Korea, BIAC	Belgium, Denmark
Cerium oxide	US, UK/BIAC	Netherlands	Australia, Germany, Switzerland, EC
Aluminium oxide			Germany, US
Polystyrene			Korea
Dendrimers		Spain	US
Nanoclays			Denmark, US

(3) Background behind approaches related to nanomaterials by the OECD

June 2005 — At the 38th Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology, a Special Session on the Potential Implications of Manufactured Nanomaterials for Human Health and Environmental Safety was held

December 2005 — In Washington D.C., a Workshop on the Safety of Manufactured Nanomaterials was held

September 2006 — The Working Party on Manufactured Nanomaterials (WPMN) under the Chemicals Committee was established

October 2006 — 1st meeting of the WPMN (agreement on Programme of Work 2006-2008, and on 6 projects)

April 2007 — 2nd meeting of the WPMN (agreement on the operational plans for the 6 projects)

November 2007 — 3rd meeting of the WPMN (agreement on the Sponsorship Programme for the Testing of Manufactured Nanomaterials; agreement on the role of alternative testing for nanotoxicology, and on the establishment of a working group related to exposure

6 As of December 2008.
7 Business and Industry Advisory Committee

	measurement and exposure mitigation)
April 2008	Sponsorship Programme Workshop (discussions on the formulation of a guidance manual, etc.)
June 2008	4th meeting of the WPMN (determination of sponsors for 7 substances)
November 2008	Sponsorship Programme Workshop (reports on the progress of creation of Dossier Development Plans (DDPs))

2) ISO

In May 2005, a technical committee for nanotechnologies (TC229) was established in the ISO. Three working groups on "Terminology and nomenclature (JWG1)," "Measurement and characterization (JWG2)," and "Health, Safety and Environmental Aspects of Nanotechnologies (WG3)" were also established at the same time. It was decided that the conveners (chairmen) of WG1, WG2, and WG3 would be Canada, Japan, and the United States, respectively.

In addition to the three WGs of TC229, a fourth working group on "Material specifications (WG4)" was newly established in February 2008, and it was decided that China would be the convener.

November 2005	1st meeting (London, United Kingdom)
June 2006	2nd meeting (Tokyo, Japan)
November 2006	3rd meeting (Seoul, Korea)
June 2007	4th meeting (Berlin, Germany)
December 2007	5th meeting (Singapore)
May 2008	6th meeting (Bordeaux, France)
November 2008	7th meeting (Shanghai, China)

4. Major approaches by overseas business operators[8]

1) Voluntary formulation of codes of conduct and technical guidelines

In Europe, various entities such as business operators, industry organizations, joint bodies formed based on cooperation between business operators/industrial organizations and NGOs, etc., are formulating Codes of Conduct and voluntary guidelines. For example, as a business operator aimed toward responsible development of nanomaterials, BASF in Germany has formulated a Code of Conduct for prescribing principles and is practicing communication and risk assessment/management of individual nanomaterials based on this Code of Conduct. In addition, business operators such as BASF and Bayer, and several industrial organizations have

[8] Created based on the results from FY2008 "Survey and Research concerning Handling of CNT by the Industries Overseas" (a tentative translation) (Japan Machinery Foundation).

also voluntarily formulated safety handling guidelines for workplaces that manufacture and handle nanomaterials, as well as safety handling guidelines that are to be distributed to customers together with MSDS.

DuPont in the United States has developed a “Nano Response Framework (NRF),” which is a technical guideline related to risk assessment and management of nanomaterials, and is applying NRF to all of the nanomaterials manufactured and used within the company. Assessments of individual nanomaterials including titanium dioxide have already been conducted using NRF. By implementing these operations in collaboration with the Environmental Defense Fund (EDF), which is an environmental NGO, consideration is also being made to making an appeal for neutrality.

2) Voluntary implementation of safety and exposure assessments

Large-scale business operators such as BASF, Bayer, and DuPont that are capable of collecting safety information, etc. on their own have established the different kinds of tests that are necessary for safety assessments of nanomaterials such as carbon nanotubes, carbon black, titanium dioxide, zinc oxide, etc., that they have manufactured, and are voluntarily collecting safety data based on these tests (dermal toxicity tests, inhalation tests, genotoxicity tests, and aquatic toxicity tests). In addition, there are also examples of business operators that, like BASF, have proposed methods for safety assessment of nanomaterials to various national governments and international organisations. There are also examples of even venture corporations and small- and medium-sized enterprises, which have difficulties conducting their own safety assessment, actively gathering safety data by commissioning toxicity testing in the form of joint research with business partners and external testing agencies such as universities, as demonstrated by Nanocyl in Belgium. DuPont has voluntarily specified the permissible exposure limit of the nanoscale titanium dioxide that it manufactures, and is carrying out risk assessment by making comparisons with exposure concentration.

3) Active transmission of information related to safety

It is evident that business operators are trying to acquire credibility by using various opportunities to actively disclose information regarding the safety of products they have manufactured. One way of doing so is by actively cooperating in the voluntary information provision system operated by public agencies. DuPont took the initiative to submit data based on NRF to the US EPA’s stewardship program. In addition, there are also business operators and industrial organizations, such as BASF, that carry out dialogues with consumers and labor unions every year. Many of the approaches mentioned in 1) and 2) are published on company Web sites, at academic societies and symposiums, and in academic papers, etc. Such activities aim to ensure the transparency of corporate activities and build confidence from society, by actively disclosing the stance of approaches that are taken by business operators on a routine basis towards safety issues concerning nanomaterials. Furthermore, DuPont is also making approaches toward standardization, such as by registering

NRF as a technical report with the ISO (TC229).

5. Conclusion

In Japan, development of methods for risk assessment and management of nanomaterials is being implemented, and ideals for safety measures are also being reviewed by relevant ministries.

In foreign countries, a voluntary reporting system is being implemented in various countries, regulations have been initiated for some substances, and voluntary approaches by business operators, centering on large chemical companies, are being implemented prior to regulations.

International organisations are cooperating with each country to gather toxicity information and conduct safety tests, etc.

V. Philosophy of Approaches

1. Ideals for approaches

The toxicity and routes of exposure of nanomaterials have not yet been sufficiently clarified, but it has been pointed out that there is the possibility of new risks arising as result of the size of nanomaterials. With regard to the six types of nanomaterials on which information was gathered in this expert meeting, certain approaches are being implemented based on relevant laws and regulations with regard to the major routes of exposure that have been made clear as of this present moment—work environments, emissions into the environment, and wastes. However, there is also the possibility that unique routes of exposure and toxicity that can be attributed to the size of the nanomaterials exist. At the same time, voluntary reporting systems and the development of methods for risk assessment and management for gathering scientific knowledge are being implemented throughout the world. Based on the major uses of nanomaterials (such as usage after being kneaded into resin, etc.), the amount of nanomaterials being emitted into the environment is not thought to be very large under the current conditions, but it is necessary to pay particular attention to the state of emissions, etc. in the future.

Taking the above comprehensively into consideration, the philosophy of approaches in this expert meeting is as follows.

1) Since nanomaterials exhibit various physiochemical properties and functions associated with such properties, it is also perceivable that their behavior in the environment and the effects that they may have on health and the environment are also diverse, and it is necessary for each business operator to make detailed approaches that take various conditions into consideration. In preventing impacts on health and the environment that are caused by improper handling of nanomaterials, at the present point in time, it is desired for business operators to manufacture, use, and dispose of nanomaterials while establishing safety measures through voluntary management, so that flexible approaches can be possible. (Refer to Charts 4 and 5 for examples and

characteristics of voluntary management.)

2) In the future, to increase transparency and effectiveness of voluntary management, business operators and the national government should actively gather, provide, and transmit information on production volumes and intended uses, etc. of nanomaterials, as well as scientific knowledge relating to the safety and the effects of nanomaterials on health and the environment.

2. Targets for review

1) Business operators applicable to reviews

Since knowledge on the toxicity of nanomaterials is insufficient, and as there are also future expectations for expansions in their uses that make use of their characteristics, it is desirable to exhaustively comprehend the actual state of usage, etc. of nanomaterials. However, since it is perceivable that business operators that use nanomaterials do not possess enough knowledge relating to their safety, etc. as of the present moment, the business operators that will be applicable to reviews will first be manufacturers, importers, and industrial organizations that possess a great deal of knowledge on nanomaterials (hereinafter referred to as “manufacturers, etc.”). Business operators that use nanomaterials will make progress in sharing knowledge based in the provision of information from nanomaterial manufacturers, etc.

2) Safety measures applicable to reviews

The safety measures to be reviewed in this expert meeting will be measures that respond to concerns related to toxicity unique to nanomaterials resulting from their nanosized particles, etc., as well as biological impacts and the physiochemical qualities that the chemical substances that comprise nanomaterials possess.

VI. Concrete Approaches

In voluntary management by nanomaterial manufacturers, etc., primarily, the role of business operators that carry out the voluntary management is important, but since some form of support is necessary to ensure transparency and effectiveness of the voluntary management, and prompt measures are required in the event that responses are difficult in voluntary management, active involvement by the national government is also necessary. Accordingly, the roles that business operators and the government should fulfill are organized below.

1. Approaches by nanomaterial manufacturers, etc.

1) Approaches related to risk assessment and management

In recent years, advances have been made in voluntary measures for preventing exposure and for preventing emissions of nanomaterials by business operators, both within and outside of Japan, and the circumstances have been changing rapidly, as demonstrated by the initiation of new approaches by governments and the acquisition of new knowledge relating to toxicity, etc.

As a result, there are expectations for nanomaterial manufacturers, etc. to gather information on and comprehend the progressive approaches made by domestic and foreign business operators as well as approaches made by both domestic and foreign governments regarding measures to prevent exposure in work environments and to prevent emissions into the ambient environment, to take this information into consideration, particularly in cases where notifications, guidelines, etc. concerning measures by relevant domestic ministries have been presented, and move forward with approaches related to risk assessment (surveys, etc. on the state of exposure in work environments through gathering and comprehending safety information and conducting environmental measurements, etc.) as well as approaches related to risk management (exposure prevention, etc. based on wearing protective gear, etc., and preventing emissions through establishing closed processes and local ventilation, etc.), based on their own actual state of manufacturing and use of nanomaterials.

2) Approaches related to communication

(1) Ideals for communication of information

Exposure to workers and emissions into the environment of nanomaterials may occur not only in relation to nanomaterial manufacturers, etc., but to business operators using nanomaterials as well. As a result, since it is necessary for nanomaterial users to carry out appropriate risk management, nanomaterial manufacturers, etc., should convey information on nanomaterials to business operators using nanomaterials, and carry out information sharing with such nanomaterial users. In addition, to appropriately manage nanomaterials during their entire life cycle, there are also expectations for information sharing to become developed, such as through nanomaterial users conveying how they are using nanomaterials to manufacturers, etc., rather than nanomaterial manufacturers, etc. providing information in a unilateral way.

As a result, what becomes necessary, concretely, is the promotion of communication between nanomaterial manufacturers, etc. and business operators that use nanomaterials, such as the sharing of safety information related to nanomaterials, points to remember when handling nanomaterials, use information, etc., while taking into consideration that such information may impair business operators' competitive positions.

For some nanomaterials, a MSDS is attached when transferring or providing the nanomaterial, either voluntarily by manufacturers, etc. or based on relevant laws and regulations. Such an MSDS describes the physical and chemical properties, toxicity information, exposure prevention measures, etc., but with the exception of some substances, many of the substances lack information that focuses on the substance being a nanomaterial. As a result, from among the items indicated in Chart 3, there are expectations for nanomaterial manufacturers, etc. to provide descriptions for items that they can provide information on, based on the characteristics and usage conditions of the nanomaterial, to business operators that use the nanomaterial. When doing so, it is desirable for manufacturers to take into consideration the fact that there is insufficient scientific knowledge on nanomaterials and communicate information within a range in which it is possible to obtain and disclose pertinent information as of the current point in time, focusing on the items that are important in assessing and managing the impacts on the environment as well as safety, rather than exhaustively providing information on all of the items in Chart 3, and also by taking heed of the properties intrinsic to each product and the chemical substances that comprise the nanomaterial. In addition, it is necessary for business operators that use the nanomaterial to be made aware when information is updated, taking into consideration that new knowledge will be accumulated in the future, both domestically and abroad.

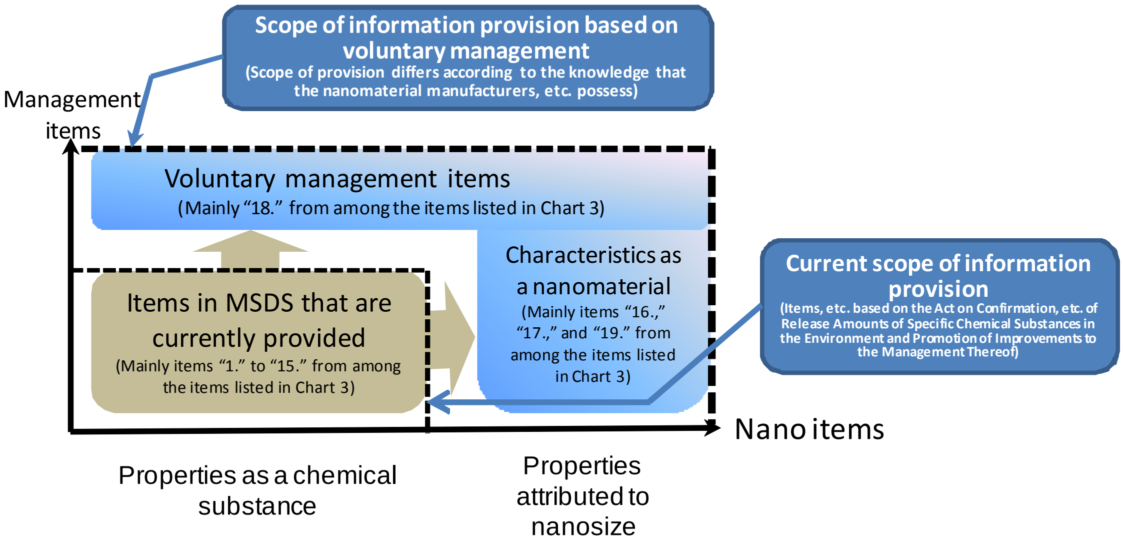

Diagram 2 Scope of communication of information

(2) Ideals for transmission of information

Since the approaches for voluntary management carried out by nanomaterial manufacturers, etc. are not based on laws and regulations, the manner in which transparency of this management is guaranteed is important. Accordingly, in order to broadly present their ideas related to safety, there are expectations for nanomaterial manufacturers, etc. to actively transmit the testing data that is in their possession and the approaches that they are taking for voluntary management, etc.

In transmitting such information, it is expected for business operators to coordinately closely with national governments, etc., such as by actively providing information, etc., in addition to actively disclosing the items from among those indicated in Chart 3 that the business operator can disclose via their own Web site, etc., based on the same concept as described in "(1) Ideals for communication of information."

2. Policy approaches

To enable for appropriate management of nanomaterials, it is necessary for nanomaterial manufacturers, etc. to take voluntary approaches, as well as for the national government to guarantee transparency of the voluntary management by business operators and take active approaches regarding the development of an infrastructure for safety measures, such as for technical development, etc.

To guarantee transparency of the voluntary management implemented by nanomaterial manufacturers, etc., the following three methods are possible.

(Method 1) The nanomaterial manufacturers, etc. voluntarily carry out transmission of information. (Concretely, transmission of information through the Web sites of the nanomaterial manufacturers, etc.)

(Method 2) The national government carries out transmission of information. (Concretely, a scenario where METI is provided information from nanomaterial manufacturers, etc. and carries out information transmission, etc.)

(Method 3) Together with Method 2, reviews are conducted by a third-party agency. (Concretely, a scenario where reviews are conducted by an agency in which a team of experts such as a council is established)

As described in "**V. Basic Orientation of Approaches**," in order to take appropriate approaches related to nanomaterials, business operators should voluntarily make approaches toward safety measures, and in addition, national governments should be responsible in reviewing ideals for approaches, taking into consideration the opinions of experts, etc. as well, and the approaches by business operators should be presented and evaluated by society as a whole. As a result, it is desirable for all of the three methods above to be implemented. Concretely, in addition to voluntary transmission of information by nanomaterial manufacturers, etc. that handle at least a certain amount of nanomaterials, such nanomaterial manufacturers, etc. should also provide as much information regarding the items presented in Chart 3 as possible to the national government, and the national government should coordinate with relevant administrative organs, etc. and actively disclose the information (for example, through METI's Web site). In addition, it is also desirable for a council, etc. made up of experts to review the provided information. When doing so, information provided by nanomaterial manufacturers, etc. that may impair their competitive positions should not be disclosed. When transmitting information, it is necessary to demonstrate an active stance on the transmission of information, such as by transmitting detailed information first, and allowing general citizens to be able to access detailed information, etc. At the same time, it is also necessary to organize information such as explanations of specialized terms, etc. that can be used by the press, and for international trends regarding safety to be transmitted in a concentrated manner.

In addition to transmission of information, continued coordination with relevant ministries should be made to promote the development of methods for risk assessment and management of nanomaterials (research and development, infrastructure development, and measurements), and international contributions should be actively made by providing the results of such developments to the OECD, etc.

Currently, there are not very many research institutes that can conduct safety assessments of nanomaterials, and in order for nanomaterial manufacturers, etc. to gather information related to safety, etc. the establishment of testing and assessment methods and the development of testing and research facilities that can carry out these methods are necessary. At the present stage, there are concerns relating to high costs and overlapping investments with regard to the development of respective testing and research facilities by each company. Consequently, it is also necessary to focus on enabling for testing to be implemented efficiently, such as through having the national government provide facilities for nano-testing and assessment and clarify testing methods, allowing nanomaterial manufacturers, etc. to make use of these facilities, and commissioning assessments using these methods to external testing agencies, etc.

Since preventive approaches relating to safety of nanomaterials are currently being implemented by relevant ministries, METI should also coordinate with the relevant ministries and make approaches when implementing the above measures.

VII. Issues for Review in the Future

The national government should appropriately gather information based on the scheme that was reviewed in this expert meeting, conduct regular reviews on the ideals for this scheme, and review the adequacy of safety measures based on voluntary management.

Reexaminations should be made on the information that is transmitted and provided by nanomaterial manufacturers, etc., taking into consideration the latest scientific knowledge relating to nanomaterials as well as domestic and international trends, etc. At the same time, with regard to providing information to the general public, information related to the collecting of information from nanomaterial manufacturers, etc. and to the detailed information directed toward experts should be transmitted, and reviews should be conducted on the preferable ways of doing so.

Although it can be considered that approaches have been made for a fixed portion of nanomaterials in Japan, through safety measures by the manufacturers, etc. handling the six substances that were subject to reviews here, reviews should continue to be conducted on safety measures by business operators that use the nanomaterials and on issues that were not reviewed at this time, taking into consideration the information provided by manufacturers, etc. regarding the state of approaches and the amount of handling of nanomaterials and the collection of new knowledge both domestically and abroad.

Chart 3 Items on which information provision and information transmission are carried out

1. Product & Company Information 2. Summary of Hazards and Toxicity 3. Composition and Constituent Information • Chemical name (generic name) • Product name • Molecular formula/molecular structure • CAS No. • Impurities, etc. 4. Emergency and First Aid Measures 5. Fire Fighting Measures 6. Accidental Release Measures 7. Precaution for Handling and Storage 8. Exposure Controls, Personal Protection 9. Physical and Chemical Properties • Physical state • Vapor pressure • Density • Solubility • Melting point, boiling point, and sublimation point • Dissociation constant • Octanol-water partition coefficient • pH • Combustion characteristics/explosive properties • Adsorption coefficient 10. Stability and Reactivity 11. Toxicological Information • Biodegradability/bioaccumulative potential • Health effects 12. Ecological Information • Environmental effects 13. Precaution for Disposal 14. Precaution for Transportation 15. Regulatory Information	16. Characteristics Unique to the Nanomaterial • Characteristics resulting from nanosize • Crystal structure • Aggregational state/dispersion state • Particle size distribution, configuration, mass • Surface area, charge, chemical composition • Porosity • Diffusion • Gravitational sedimentation • Sorption • Wet and dry movement • Effects from oxidation-reduction and photochemical reactions • Mobility in soil 17. Exposure Information (1) Information concerning manufacturing and transport • Manufacturing and transport amounts (for each fiscal year) (2) Exposure information • Use information, etc. • Manufacturing and processing facilities and processes • Exposure information (persons subject to exposure, exposure activities and time, etc.) • Amount of environmental emissions • Measurement techniques and measurement results 18. Status of measures for risk management • Discharge control measures • Education of workers • Roadmap for future measures, etc. 19. Comments by business operator relating to the properties, etc. of the nanomaterial 20. Other, etc.

* Items 1. to 15. correspond to the items provided on MSDS as shown in JIS Z 7250.

* The above items should serve solely as a reference when providing and transmitting information; it is not necessary to provide and transmit information on all of the items.

List of Attendees

Chairperson

Junko Nakanishi	Director, Research Institute of Science for Safety and Sustainability, National Institute of Advanced Industrial Science and Technology

Scholars

Atsuo Kishimoto	Research Institute of Science for Safety and Sustainability, National Institute of Advanced Industrial Science and Technology
Toru Takebayashi	Professor, School of Medicine, Keio University
Kazuya Nakayachi	Professor, Faculty of Psychology and Welfare, Tezukayama University
Ikufumi Niimi	Professor, Law School, Meiji University
Shoji Fukushima	Director, Japan Bioassay Research Center, Japan Industrial Safety & Health Association

Industrial world

Mineyuki Arikawa	Nanotechnology Business Creation Initiative
Jun Ogawa	Nanotechnology Business Creation Initiative
Takaaki Kanai	Carbon Black Association
Yoshimasa Kamata	Japan Titanium Dioxide Industry Association
Fumiaki Shono	Japan Chemical Industry Association
Kazuo Tatebe	Japan Inorganic Chemical Industry Association
Koh-ichiroh Magara	Japan Inorganic Chemical Industry Association
Takao Yamamoto	Nanotechnology Business Creation Initiative

Review Process

● 1st Session

Date and time	November 27, 2008 (Thursday) 14:00 to 16:00
Location	Central Government Building No. 7, 9F, Joint Conference Room 1
Agenda	1) About the convening of the Expert Meeting
	2) Current conditions, etc. related to nanomaterials
	(1) Trends within and outside of Japan related to safety of nanomaterials
	(2) Approaches by nanomaterial manufacturers, etc.
	3) How reviews will progress
	4) Other

● 2nd Session

Date and time	December 25, 2008 (Thursday) 10:00 to 12:30
Location	Ministry of Economy, Trade and Industry, Annex 10F, Conference Room 1020
Agenda	1) Current conditions, etc. related to nanomaterials
	(1) Voluntary approaches pertaining to manufactured nanomaterials
	(2) Approaches by nanomaterial manufacturers, etc.
	2) Provision of topics related to voluntary management
	3) Ideals for management of nanomaterials
	4) Other

● 3rd Session

Date and time	February 4, 2009 (Wednesday) 14:00 to 16:00
Location	Ministry of Economy, Trade and Industry, Annex 11F, Conference Room 1120
Agenda	1) "Present Measures for Nanomaterials"
	2) Other