

**Overview of Current Development in Manufactured Nanomaterials
(Japan)**

Date	Major Development	Participants of WPMN meeting
July 2010	(N/A)	
Oct 2009	<p>Three reports and one revised notification on safety of manufactured nanomaterials hereunder were published by the Japanese government in March 2009.</p> <ul style="list-style-type: none"> • Report: The Expert Meeting on Safety Measures for Nanomaterial Manufactures etc. (Ministry of Economy, Trade and Industry) • Guidelines for preventing the environmental impact of manufactured nanomaterials: Expert committee on the environmental impact of manufactured nanomaterials (Ministry of the Environment) • Report: The Committee on Safety Measure for Nanomaterials (Ministry of Health, Labour and Welfare) • Revised notification for exposure prevention in the workplace (Ministry of Health, Labour and Welfare) 	Mr. Shuji TAMURA etc. (total 13)
March 2009	<ul style="list-style-type: none"> • The Ministry of Health, Labour and Welfare (MHLW) issued a notification for exposure prevention in the workplace in February, 2008. According to the report of a committee, which was established to discuss safety of nanomaterials in occupational settings, MHLW revised the notification in March, 2009. MHLW also established another committee on safety of manufactured nanomaterials in consumer products, and the committee is issuing a report shortly. • In November 2008, Ministry of Economy, Trade and Industry (METI) organised an expert meeting focusing on the voluntary safety measures for handling nanomaterials by manufactures. A study report was published in March 2009. • In June of 2008, the Ministry of the Environment (MOE) established an expert committee on potential risk of manufactured nanomaterials to health and environment through exposure in the ambient environment. The committee discussed the possibility of the environmental exposure of manufactured nanomaterials and the control methods for them, and published the guideline on the environmental sound management of manufactured nanomaterials in March 2009. 	Mr. Shuji TAMURA etc. (total 14)
June 2008	<ul style="list-style-type: none"> • MHLW issued the notification for the exposure prevention in the workplace handling nanomaterials in February, 2008. • AIST together with the OECD and NEDO organised an international symposium on the “Risk Assessment of Manufactured Nanomaterials” 	Mr. Shuji TAMURA etc. (total 9)

	<p>in April 2008, which attracted more than 500 attendees. It was held back-to-back with the OECD Tokyo Workshop on the Sponsorship Programme for the Testing of Manufactured Nanomaterials.</p> <ul style="list-style-type: none"> • NIES is in the middle of a 5-year NanoTox program. Some in vitro studies on toxicity of nano-carbons and nanotubes have been completed. NIES is now moving on to an in vivo toxicological study on nanotubes and nano-metals. • MHLW established two committees on the safety of manufactured nanomaterials. Those committees will discuss the safety of nanomaterials at occupational settings and in consumer products, respectively. It is expected that each committee will publish a report in 2008. • In June of 2008, Ministry of the Environment (MOE) established an expert committee on potential risk of manufactured nanomaterials to health and environment by the exposure in the ambient environment. The committee aims to discuss the possibility of the environmental exposure of manufactured nanomaterials and the control methods for them, and is expected to organise interim advices on the environmental sound management of manufactured nanomaterials as a guideline, respectively. 	
Nov 2007	<ul style="list-style-type: none"> • The National Institute of Occupational Safety and Health Japan (JNIOSH) has started a three-year project study on possible health issues related to exposure to manufactured nanomaterials in the workplace since April 2007. • The National Institute for Environmental Studies (NIES) has installed a nose-exposure chamber to investigate in vivo effects of nanomaterials in a doubly-shielded room. NIES will soon start an inhalation study for in vivo toxicity test for nanomaterials using rats or mice. 	Mr. Takashi FUKUSHIMA etc. (total 7)
April 2007	<ul style="list-style-type: none"> • The National Institution of Occupational Safety and Health, Japan (JNIOSH) will start a new research on possible health issues in April 2007, due to exposure to nanomaterials in the workplace. This research on nano-related industries includes measurement methods in the workplace, and toxicology of nanoparticles. • The Cabinet Office has decided to establish a committee that coordinates research and development policy on nanotechnology. Dr. Junko Nakanishi will participate in this committee as a coordinator. One of its targets is to establish the information infrastructure to accelerate innovation, by facilitating research and development of nanotechnology and research for public acceptance of nanotechnology in a focused and strategic manner. • METI has conducted a preliminary survey on safe handling of nanomaterials at manufacturing sites and research laboratories in fiscal year 2006. Through the survey, METI has reviewed existing good practices both from domestic and overseas and has drafted basic guidelines. These draft guidelines are to be reviewed by industry 	Mr. Takashi FUKUSHIMA etc. (total 3)

	stakeholders for implementation.	
Oct 2006	<p>1. Any national regulatory developments on human health and environmental safety including recommendations or discussions related to adapting existing regulatory systems or the drafting of laws/ regulations/ guidance materials;</p> <p>In the existing regulatory system, the Chemical Substance Control Law obliges manufacturers to notify the government about nanomaterials if they are new chemicals subject to the law, and some notifications concerning fullerene derivatives have been submitted under the small quantities exemption of the new chemical notification.</p> <p>The Ministry of Economy, Trade and Industry (METI) has just had a preliminary discussion on the health and environmental safety issues of manufactured nanomaterials as one of the emerging issues to be addressed in the near future within the framework of chemical management in METI's Policy Council on Chemical Issues. However, no proposal regarding concrete measures restricting manufactured nanomaterials has been put on the table yet.</p> <p>2. Developments related to voluntary or stewardship schemes;</p> <p>The Japanese Government does not have any voluntary reporting scheme on health and environmental safety issues of manufactured nanomaterials at this stage. However, METI has just started a preliminary survey on safe handling of nanomaterials at manufacturing sites and research laboratories.</p> <p>3. Information on any risk assessment decisions;</p> <p>The Japanese Government does not have any risk assessment decisions regarding manufactured nanomaterials.</p> <p>4. Information on any developments related to good practice documents;</p> <p>The Japanese Government has just started a programme on safety nanomaterial project "Evaluation of the Potential Risks of Manufactured Nanomaterials based on Toxicity Tests with Precise Characterization" that is mentioned hereinafter. It could lead to develop guidance documents relating to good practices for appropriate handling methods of manufactured nanomaterials in the workplace, such as at research institutes and at sites of production fields.</p> <p>5. Research programmes or strategies designed to address human health and/ or environmental safety aspects of nanomaterials;</p> <p>The Japanese Government does not have any strategies designed to address human health and/ or environmental safety aspects of nanomaterial.</p> <p>However, in the fiscal year 2005, four national institutes, namely The National Institute of Advanced Industrial Science and Technology (AIST), the National Institute of Health Science (NIHS), the National Institute for Environmental Studies (NIES), the National Institute of Materials Science (NIMS), and some universities have jointly conducted research and surveys to facilitate public acceptance of nanotechnology. They focused</p>	Mr. Takashi FUKUSHIMA etc. (total 5)

on 1) risk assessments of nanomaterials, 2) health issues of nanomaterials, 3) environmental issues of nanomaterials, 4) ethical and societal issues of nanotechnology, and 5) technology assessment for promoting the public acceptance of nanotechnology and its economic effects by the funding of the Ministry of Education, Culture, Sports, Science and Technology (MEXT). The survey team has issued a report which contains a series of recommendations to public institutes, the private sector and the government. These survey results may possibly be used as a guide for future national measures by the government. In the fiscal year 2006, by the MEXT funding, the project named “The multidisciplinary experts panel for nanotechnology implication” has started. The project is composed of the above institutes and the university researchers, and focuses on “what are preferential tasks with reference to clarifying the nanotechnology implication for health, environment and social acceptance.” The additional objective is the establishment of the researchers’ network on nanotechnology implication.

METI has launched a five-year project named “Evaluation of the Potential Risks of Manufactured Nanomaterials based on Toxicity Tests with Precise Characterization.” The project focuses on toxicity test protocols (mainly an inhalation test) and a risk assessment methodology of manufactured nanomaterials, based on developing:

- characterization methods/apparatuses and sample preparation protocols for nanomaterials themselves and for organs or cells etc. which contains nanomaterials;
- inhalation test apparatus for nanomaterials;
- non-invasive in vivo imaging protocols and apparatus to measure biological reductive ability;
- biological reaction profiles of in vitro tests;
- methods of evaluation of protective equipment (*e.g.* mask), and also based on surveillance of amounts and types of nanomaterials released from/inside facilities.

Fullerene and carbon nanotubes are given priority in this project. Literature research of nanomaterials toxicity, together with social and legal scientific studies is also implemented.

Also, MHLW conducted a preliminary project in 2005, and has launched a subsequent three-year project named “Research on the hazard characterization and toxico-kinetic analysis of manufactured nanomaterials for the establishment of health risk assessment methodology” led by NIHS from 2006. The project has been focusing on detecting methodology of nanomaterials in the biological samples, ADME analysis, long-term health implication using experimental animals, and development of transpulmonary experiment system.

The National Institute of Occupational Safety and Health, Japan (JNIOSH) is planning to start a research program in order to assess exposure to nano-materials and study the effective management of their risks, especially concerning health issues at workplaces, from fiscal year 2007.

The National Institute for Environmental Studies (NIES) has started both in vitro and in vivo toxicology research to evaluate health effect potencies of nanomaterials including nanostructured fibers. Besides, NIES has been investigating effects of atmospheric nanoparticles on respiratory and circulation systems for the last 2 years using chronic inhalation chambers for small rodents.

6. Information on any public/ stakeholder consultation.

The Japanese Government has not implemented public or stakeholder consultation focusing on safety issues of manufactured nanomaterials. However, in the above mentioned survey, a series of workshops in 3 which public and members of NGOs actively participated were conducted by national institutes and recommendations have been developed based on the outcomes of these workshops. Furthermore, METI's Policy Council on Chemical Issues is open to the public, and representatives of environmental NGOs and other stakeholder organizations participate in the conference.