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CURRENT DEVELOPMENTS/ ACTIVITIES ON THE SAFETY OF MANUFACTURED NANOMATERIALS/ NANOTECHNOLOGIES

Tour de Table at the 4th Meeting of the Working Party on Manufactured Nanomaterials

Paris, France, 11-13 June 2008

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Series on the Safety of Manufactured Nanomaterials

No. 7

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Environment Directorate
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT
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Also published in the Series of Safety of Manufactured Nanomaterials:

No. 1, *Report of the OECD Workshop on the Safety of Manufactured Nanomaterials: Building Co-operation, Co-ordination and Communication (2006)*

No. 2, *Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 1st Meeting of the Working Party on Manufactured Nanomaterials (2006)*

No. 3, *Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 2nd Meeting of the Working Party on Manufactured Nanomaterials (2007)*

No. 4, *Manufactured Nanomaterials: Programme of Work 2006-2008(2008)*

No. 5, *Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 3rd Meeting of the Working Party on Manufactured Nanomaterials*

No. 6, *List of Manufactured Nanomaterials and List of Endpoints for Phase One of the OECD Testing Programme*

About the OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 30 industrialised countries in North America, Europe and the Asia and Pacific region, as well as the European Commission, meet to co-ordinate and harmonise policies, discuss issues of mutual concern, and work together to respond to international problems. Most of the OECD's work is carried out by more than 200 specialised committees and working groups composed of member country delegates. Observers from several countries with special status at the OECD, and from interested international organisations, attend many of the OECD's workshops and other meetings. Committees and working groups are served by the OECD Secretariat, located in Paris, France, which is organised into directorates and divisions.

The Environment, Health and Safety Division publishes free-of-charge documents in ten different series: **Testing and Assessment**; **Good Laboratory Practice and Compliance Monitoring**; **Pesticides and Biocides**; **Risk Management**; **Harmonisation of Regulatory Oversight in Biotechnology**; **Safety of Novel Foods and Feeds; Chemical Accidents; Pollutant Release and Transfer Registers; Emission Scenario Documents; and the Safety of Manufactured Nanomaterials.** More information about the Environment, Health and Safety Programme and EHS publications is available on the OECD's World Wide Web site (http://www.oecd.org/ehs/).

This publication was developed in the IOMC context. The contents do not necessarily reflect the views or stated policies of individual IOMC Participating Organizations.

The Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) was established in 1995 following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. The participating organisations are FAO, ILO, OECD, UNEP, UNIDO, UNITAR and WHO. The World Bank and UNDP are observers. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organisations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

FOREWORD

The OECD Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology (the Joint Meeting) held a Special Session (June 2005) on the Potential Implications of Manufactured Nanomaterials for Human Health and Environmental Safety. This was the first opportunity for OECD member countries, together with observers and invited experts, to begin to identify human health and environmental safety related aspects of manufactured nanomaterials. The scope of this session was intended to address the chemicals sector.

As a follow-up, the Joint Meeting decided to hold a Workshop on the Safety of Manufactured Nanomaterials in December 2005, in Washington, D.C. The main objective was to determine the "state of the art" for the safety assessment of manufactured nanomaterials with a particular focus on identifying future needs for risk assessment within a regulatory context.

Based on the conclusions and recommendations of the Workshop [ENV/JM/MONO(2006)19] it was recognised as essential to ensure the efficient assessment of manufactured nanomaterials so as to avoid adverse effects from the use of these materials in the short, medium and longer term. With this in mind, the OECD Council established the OECD Working Party on Manufactured Nanomaterials (WPMN) as a subsidiary body of the OECD Chemicals Committee in September 2006. This programme concentrates on human health and environmental safety implications of manufactured nanomaterials (limited mainly to the chemicals sector), and aims to ensure that the approach to hazard, exposure and risk assessment is of a high, science-based, and internationally harmonised standard. This programme promotes international co-operation on the human health and environmental safety of manufactured nanomaterials, and involves the safety testing and risk assessment of manufactured nanomaterials.

In each meeting of the WPMN, the delegations have an opportunity to provide their developments on the safety of manufactured nanomaterials, so called "Tour de Table". An earlier version of this document was originally provided to the 4th meeting held 11-13 June 2008 in Paris, France. This document compiles information provided by member countries and other delegations on current developments on the safety of manufactured nanomaterials (section I) in their countries or organizations. There are also written reports on current activities related to nanotechnologies/ nanomaterials in other International Organisations including the International Organisation for Standardisation (ISO) and the Intergovernmental Forum on Chemical Safety (IFCS) (section II). In addition, Section III includes the report from the OECD Secretariat.

This document is published on the responsibility of the Chemicals Committee. This is intended to provide delegations and other stakeholders with a "snapshot" of information on activities related to manufactured nanomaterials, as well as other activities on nanotechnologies, at the national and international level.

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SECTION I
RECENT AND PLANNED NATIONAL ACTIVITIES IN CHEMICALS REGULATORY AREA ON HEALTH AND ENVIRONMENTAL SAFETY ASPECTS OF MANUFACTURED NANOMATERIALS

Background

1. The purpose of the agenda item, the Tour de Table, at the 4th meeting of the WPMN was to give each delegation the opportunity to describe recent or planned national initiatives and/or events related to the safety of nanomaterials. This will facilitate the implementation of the eight projects of the WPMN by allowing delegations to share their experiences and preoccupations with respect to safety, and will identify opportunities for future co-operation and co-ordination.

2. At the previous meetings of the WPMN, delegations provided written submissions in advance of the meeting and highlighted (in their interventions) points that were not already included in their written submissions. The WPMN agreed that these reports were informative and recommended that they be made available publicly. These reports have been declassified by the Chemicals Committee and are publicly available as publications in the series on *the Safety of Manufactured Nanomaterials*.

Headings for the Tour de Table

3. In considering the Tour de Table, the information from each delegation is organised, where possible, under the headings identified below, while recognising that not all delegations would be able to supply information under each heading. It is to be expected that there is considerable variation amongst delegations as to the issues they wish to address, so there is some flexibility in the way the information is provided. In addition, delegations added a short bulleted list of highlights at the top of their submissions. The highlights are to give readers a general idea of key events since the 3rd meeting of the Working Party.

Firstly, please provide a list of the latest developments in your country and organisation since the 3rd meeting of the WPMN (November 2007) as highlights to appear at the top of your document (see recommended format below). Then identify work completed, underway or planned in your country or organisation, which relates to activities on health and environmental safety aspects of manufactured nanomaterials (focusing on the chemicals sector):

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;
2. Developments related to voluntary or stewardship schemes;
3. Information on any risk assessment decisions;
4. Information on any developments related to good practice documents;
5. Research programmes or strategies designed to address human health and/ or environmental safety aspects of nanomaterials;
6. Information on any public/ stakeholder consultation.

Additional Information

Delegations may wish to provide any additional related information, e.g., any consideration of the benefits of nanotechnologies and consideration of ethical implications.

RESPONSES FROM DELEGATIONS

AUSTRALIA

Highlight of developments since the 3rd meeting of the WPMN (November 2007)

- Progression of the National Nanotechnology Strategy (NNS), including consideration of the Report on Possible Impacts of Nanotechnology on Australia's Regulatory Frameworks, and on-going cross-government consultation through the Health, Safety and Environment Working Group (HSE WG).
- Work has commenced under the Nanotechnology Occupational Health and Safety (OHS) Research and Development (R&D) Program of the Australian Government Department of Education, Employment and Workplace Relations (DEEWR) (**Attachment A**).
- Convening of the National Industrial Chemical Notification and Assessment Scheme (NICNAS) Nanotechnology Advisory Group (NAG).
- Commencement of technical reviews of literature pertaining to environmental fate of manufactured nanomaterials, and effectiveness of workplace exposure mitigation controls.

Work completed, underway or planned

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**

The Health, Safety and Environment Working Group (HSE WG), established under the National Nanotechnology Strategy (NNS) continues to maintain consultation across The Australian Government to build a uniform, whole of government approach to regulation of nanomaterials. Regular meetings and workshops support communication between departments, including a multi-agency workshop entitled *Regulators Risk Assessment Workshop on Nanotechnology,* which is planned for June 2008. The workshop will focus on issues relating to human risk assessment of nanotechnology, and regulation of nanoscale chemicals, materials and products.

The report commissioned by the HSE WG, to investigate impacts of nanotechnology on regulatory frameworks, is complete and is under consideration by the relevant Australian Government Departments. In respect to the National Industrial Chemical Notification and Assessment Scheme (NICNAS), current frameworks adequately regulate industrial nanomaterials, however, some future adaptations may be needed. NICNAS, in consultation with key industry and community groups, has developed a strategy to address possible gaps identified in the report. The strategy includes: use of a working definition of nanomaterials, and increasing awareness of this definition amongst industry and the general public; consideration of applicability of current risk assessment and management protocols to nanomaterials; on-going and increased stakeholder engagement.

The Department of Education, Employment and Workplace Relations (DEEWR) considers engineered nanomaterials used in occupational settings to be regulated under existing regulatory frameworks for workplace chemicals. DEEWR has identified OHS regulatory issues associated with nanotechnology (e.g. relating to classification and measurement of engineered nanomaterials) and has commenced work under the Nanotechnology OHS R&D Program to address potential nanotechnology related OHS regulatory issues.

The Australian Pesticide and Veterinary Medicines Agency (APVMA) is reviewing the existing APVMA regulatory framework for nanoscale pesticides/biocides, and amending APVMA Registration Application Forms to "flag" inclusion of nanoscale pesticides/biocides.

2. Developments related to voluntary or stewardship schemes

The national industrial chemical regulator, NICNAS, has convened a Nanotechnology Advisory Group (NAG), with members from industry, community and academia, to advise on strategies to address regulatory and safety impacts of nanomaterials. The NAG has suggested rapid progression of a voluntary information gathering program, targeting research and development groups as well as industry. In contrast to voluntary schemes in the UK and USA, this scheme will have a short, six month, time frame for response. NICNAS is currently developing this information gathering program, which is expected to run initially from July to September 2008. Similar to the UK and USA voluntary schemes, the information requested will include volume in use/production, availability of physico-chemical and toxicity data, life cycle data, as well as workplace risk mitigation procedures.

In December 2007, The Australian Nano Business Forum (a non-government organisation) launched a voluntary *Responsible Nanotechnology Code* (http://www.anbf.com.au/PDF/Responsible%20NanoCode_Australia_Proposed%20Draft%20Code.pdf). The code has seven principles designed to aid responsible development of nanotechnologies, in business of all sizes across all industries.

3. Information on any risk assessment decisions

No developments since the 3rd meeting of the WPMN.

4. Information on any developments related to good practice documents

No developments since the 3rd meeting of the WPMN.

5. Research programmes or strategies designed to address human health and/ or environmental safety aspects of nanomaterials

Australia has responded to the OECD Sponsorship Program for Safety Testing of a Representative Set of Manufactured Nanomaterials, by agreeing to contribute data and consideration of co-sponsorship of certain, identified nanomaterials.

Various Australian Government departments and agencies are currently establishing strategies and research programs:

- The Department of the Environment, Water, Heritage and the Arts (DEHWA) has commissioned a technical review on the environmental fate of manufactured nanomaterials to inform its risk assessment methodologies and provide scientific advice to regulatory agencies.

- DEEWR has developed a Nanotechnology OHS R&D Program (**Attachment A**), to support the implementation of the NNS. This Program will be implemented over the period 2007-09. The Program includes:

  - Research to review the toxicology of engineered nanomaterials. Particular focus will be placed on examining research findings over the period 2006-2008, so that stakeholders are informed on the most up-to-date understanding of potential health concerns associated with these materials.

  - Research to review the evidence for the effectiveness of workplace controls in preventing exposure to engineered nanomaterials. The review findings will be used to inform guidance for organisations and good practice document development, and to inform research priorities relating to control methodologies.

  - Establishing an expert group to help development of Australian measurement capability of workplace exposures to engineered nanomaterials.

Australia's national medical research funding agency, The National Health and Medical Research Council (NHMRC), is investigating options for collaborating with other government agencies, especially regulatory bodies, to identify gaps in research and knowledge in regard to health and safety issues associated with nanomaterials. Any research supported by the NHMRC to increase the knowledge base on health hazards and risk assessment, as well as exposure and monitoring tools, will be complementary to, and may inform, regulatory regimes.

6. Information on any public/ stakeholder consultation

NICNAS continues to actively consult with industry, community and research scientists in regards to industrial nanomaterials. NICNAS' Community Engagement Forum (CEF) and the NAG are involved with development of information products on nanomaterials.

DEEWR has established a Nanotechnology OHS Reference Group to consult on OHS aspects of nanotechnology. Members of the Group include the Australian Council of Trade Unions (ACTU), Australian Chamber of Commerce and Industry (ACCI), Australian OHS regulators, NICNAS and the Australian Office of Nanotechnology (AON).

The APVMA will publish a Call for Information notice in an upcoming issue of the APVMA Gazette, with the objective of obtaining information from industry on importation, manufacture or formulation of nanoscale pesticides/biocides. The APVMA is developing a Position Paper on nanotechnology, for posting on the APVMA website, and a Fact Sheet on nanotechnology.

ATTACHMENT A

DEPARTMENT OF EMPLOYMENT & WORKPLACE RELATIONS
OFFICE OF THE AUSTRALIAN SAFETY & COMPENSATION COUNCIL

NANOTECHNOLOGY OHS RESEARCH & DEVELOPMENT PROGRAM TO SUPPORT THE NATIONAL NANOTECHNOLOGY STRATEGY

1. In support of the National Nanotechnology Strategy, a Nanotechnology OHS Research & Development program has been developed. Specific projects will be developed over the life of the workplan to reflect national priorities.

2. The program is Australia-focussed, and will also contribute to global efforts on nanotechnology OHS.

3. The program has federal government funding, and will be managed by the Department of Education, Employment & Workplace Relations, Office of the Australian Safety and Compensation Council (ASCC).

4. A plan for the program has been defined, covering:

- OHS support for Australian nanotechnology businesses and research organisations
- Research Coordination - covering Australian research projects and international collaborations
- Evaluation and Development of Workplace Controls
- Considering the OHS Regulatory Framework in relation to Nanotechnology – includes identifying the specific information and knowledge requirements to ensure the framework operates effectively

NANOTECHNOLOGY OHS RESEARCH & DEVELOPMENT PROGRAM TO SUPPORT THE NATIONAL NANOTECHNOLOGY STRATEGY

1. Business Support

PROGRAM 1.1

Work by an interdisciplinary field team to partner with employers and others in conducting field studies, to observe and assess OHS practices in facilities where nanotechnology processes and applications are used.

This initiative will help protect the health & safety of employees in the nanotechnology industry and nanotechnology research in the short, intermediate and long term, and will facilitate the development of guidance material and dissemination of best practices across the industry and research.

Assuming suitable measurement equipment is available, it will also enable increased understanding of the actual levels of workplace exposures.

PROGRAM 1.2

Development of guidance material for the management of nanoparticles to minimise health risks, and rollout of the information.

PROGRAM 1.3

Development of guidance material for the safe management of nanoparticles, and rollout of the information.

Support companies to evaluate potential unique safety risks (e.g. explosivity, flammability and catalytic properties) associated with engineered nanoparticles.

2. OHS Regulatory Framework in relation to Nanotechnology

PROGRAM 2.1

Considering the Australian OHS Regulatory Framework in relation to Nanotechnology.

Evaluating the ability of the OHS regulatory framework to deal with nanotechnology hazards.

Includes identifying the specific information and knowledge requirements to ensure the framework operates effectively.

3. Research Coordination

PROGRAM 3.1

This program aims to establish and participate in international collaborative research and development to optimise Australian nanotechnology OHS management.

It will not be possible for all research and development programs to be undertaken with rigour in Australia. Hence, Australian programs should be (a) Australia-focused, and (b) coherent with and complementary to work

that is occurring globally.

It is necessary for Australia to be fully informed of international activities and to be involved in key international collaborative work, and to present our initiatives in key forums.

This work will be undertaken in close liaison with relevant Australian agencies.

PROGRAM 3.2

Watching Brief on current knowledge of OHS risks from nanotechnology – identified, actual OHS risks.

PROGRAM 3.3

Provide input and advice to help establish & manage research to understand the health effects associated with exposure to engineered nanoparticles.

This research should be applicable across health-related portfolios and agencies.

It is anticipated that this will be a cross-agency program.

4. Evaluation and Development of Workplace Controls

PROGRAM 4.1

Assisting the development of cost-effective and robust ambient air monitoring systems for nanotubes, nanopowders, quantum dots and similar materials in workplace environments, that can provide accurate information on worker exposures.

Link in with work at the National Measurement Institute (NMI).

Dependent on international advances in measurement.

PROGRAM 4.2

Examining the effectiveness of control equipment, e.g. filters, respiratory protective equipment, gloves, and engineering controls.

PROGRAM 4.3

Research on preventing work-related injury and illness, by using engineered nanomaterials to produce, for example, sensing and communication nanodevices, and nanomachinery.

AUSTRIA

Highlight of developments since the 3rd meeting of the WPMN

- A **platform ("Österreichische Nanotechnologie-Plattform")** of relevant ministries, agencies, NGOs, occupational health organisations, the Austrian Chamber of Commerce (WKO) and research institutions lead-managed by the Federal Ministry of Agriculture, Forestry, Environment and Water Management (BMLFUW) was established in autumn 2007. Its main purpose is the exchange of information as well as the discussion and planning of possible activities with a focus on risk assessment and risk management of nanomatierials as well as information for th pubic. In order to address these topics in a more fundamental way the Austrian Umweltbundesamt compiled the report "Statusbericht Nanotechnologie" (in German with an English summary) on the current status of developments in the European Union and the OECD. The report also includes recommendations for further actions for Austria. The report will be made publically available on the internet in the near future.

- **EURO-NanoTOX** is an open virtual center and national platform which is co-ordinated by the BioNanoNet Forschungsgesellschaft mbH and co-funded by the Federal Ministry of Science and Research (BMWF). It will elaborate strategies to conduct standardised toxicological in-vitro as well as in-vivo methods on nanostructered material. The main focus is human nanotoxicology and human risk assessment. Comparative studies will be organised.

- The project **NanoTrust,** funded by the Austrian Federal Ministry for Transport, Innovation and Technology (BMVIT), is a research project to continually survey, analyse and summarise the state of knowledge regarding potential health and environmental risks of nanotechnology. Research gaps will be identified and differing assessments will be made transparent. A database on consumer products containing nanomaterials/nanostructures – mainly cosmetic and food products available in Austria - will be established. Additionally dossiers on specific nanorelated topics will be released.

- Currently NanoTrust is also working on an encompassing, annotated **bibliographic database (NanoLit)** on potential environmental and health risks as well as on risk governance, which will be made publicly available via the internet. Partners in this project are BioNanoNet Forschungsgesellschaft mbH and the Austrian Umweltbundesamt. Furthermore NanoTrust works as an information platform and takes part in the research on nanotechnology with own contributions from a technology assessment perspective.

- The Austrian Umweltbundesamt in co-operation with the quality radio station Radio Österreich 1 launched the "Initiative **Risiko:dialog".** The aim is to open dialogues on risk topics – with potential effects on human health, environment and society – with stakeholders and the public in an early stage. One of the started dialogue processes concerns nanotechnology and potential risks. Several open events talks and expert discussions were held to support an open dialogue about potential risks, regulation topics and risk communication with civil society, economy, science, media and stakeholders from politics and administration. These activities are supplemented by the Homepage: http://www.risikodialog.at/nanotechnologie/nanotechnologie-dialog/. Partners of the dialogue process on nanotechnology are the Federal Ministry of Agriculture, Forestry, Environment and Water Management., the Federal Ministry for Health, Family and Youth, the Federal Ministry for Transport, Innovation and Technology, the Institute of Technology Assessment, the Austrian Agency for Health and Food Safety (AGES), the Austrian Research Centers GmbH, and Joanneum Research/NANONET Styria/BioNanoNet

GmbH. Currently the build up of a focal point to answer nanosafety questions from media and public are discussed with the partners of the dialogue process on nanotechnology.

Work completed, underway or planned

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

Austria takes part in **EU working groups** (also) dealing with nanomaterials: e.g. **REACH Competent Authorities subgroup on Nanomaterials** by the Federal Ministry of Agriculture, Forestry, Environment and Water Management (BMLFUW) or the Novel Food Working Group by the Federal Ministry of Health, Family and Youth (BMGFJ).

Bilateral exchange was intensified by participation at the 1st International Authorities Dialogue between Switzerland, Austria, Germany and Liechtenstein. Voluntary measures in risk management of nanotechnology and the creation of a network were discussed.

2. Developments related to voluntary or stewardship schemes

Currently, discussions with industry representatives are carried out regarding voluntary measures.

3. Information on any risk assessment decisions

No information provided

4. Information on any developments related to good practice documents

No information provided

5. Research programmes or strategies designed to address human health and/ or environmental safety aspects of nanomaterials

The project **NanoRate** carries out a lifecycle analysis of nanoproducts including an assessment of risks and benefits. Partners in this project are IFZ - Inter-University Research Centre for Technology, Work and Culture, "die umweltberatung", Österreichisches Ökologie Institut and Joanneum Research (contact: Manfred Klade, IFZ). It is funded by the Jubiläumsfonds of the Austrian Nationalbank and the Federal Ministry of Agriculture, Forestry, Environment and Water Management (BMLFUW).

A **Workshop on Aquatic Nanoscience & Nanotechnology** - bridging environmental nanosciences and nanotoxicology was organised in December 2007 by the working group "Nanoscience and Nanotechnology" of the German Waterchemical Society and the Department for Environmental Geosciences at Vienna University (contact person: Frank van der Kammer; Department for Environmental Geosciences, Vienna University).

Together with the Department Of Freshwater Ecology, the Department for Environmental Geosciences University Vienna conducted a research project dealing with the behaviour, fate and effects of different TiO2 nanoparticles in the aquatic environment.

EU-projects with Austrian participation within FP6:

DIPNA: Development of an integrated platform for nanoparticle analysis to verify their possible toxicity and eco-toxicity, project leader: Antonietta M. Gatti, University of Modena, Italy; Austrian partner: University of Salzburg, department for molecular biology (Albert Duschl).

NANOCAP: Nanotechnology capacity building NGOs,
Leadership: Drs. Jacques Cornelis van Broekhuizen, IVAM UvA BV, Amsterdam, Niederlande;
Austrian partner: ppm Forschung und Beratung, Linz (Günther Kittel).

NanoBioPharmaceutics: Nanoscale Functionalities for Targeted Delivery of Biopharmaceutics (including toxicological aspects): Austrian participants in the Consortium are the Medical University of Graz, University of Innsbruck, Joanneum Research GmbH and Thiomatrix GmbH.

POLYSOA: Polymers in Secondary Organic Aerosols (NEST Insight activity):
Austrian partner: Technical University of Vienna, Hans Puxbaum; already finished.

The Austrian Research Center GmbH- ARC, the Austrian Worker´s Compensation Board (AUVA) and the Österreichische Staub- und Silikosebekämpfungsstelle, Leoben, worked on a project "Toxicological Investigation of Nanoparticles - Effects On Human Cells": The aim was the establishment of an in-vitro test system to reveal the potential risk to human health of **nanoparticles at the workplace**.

The Austrian **NANO Initiative** is a multi-annual funding programme for Nanoscale Sciences and Nanotechnologies (NANO for short) in Austria which is supported by several ministries, federal provinces and funding institutions, under the overall control of the Federal Ministry for Transport, Innovation and Technology (BMVIT). The programme is managed by the Austrian Research Promotion Agency FFG on behalf of the BMVIT. The programme is also open for projects targeting health and environment risks (e.g. in the project "Nano-Health: Nano-structured Materials for Drug Targeting, Release and Imaging" toxicological studies related to the nanostructured materials used are conducted. Project coordinator is Frank Sinner, Joanneum Research und BioNanoNet Forschungsgesellschaft mbH).

Participation in **EU-SKEP ERA-NET** (Scientific Knowledge for Environmental Protection) which is also dealing with nanotechnology and potential risks of Converging Technologies. The project aims to improve the co-ordination of environmental research in Europe.

The Austrian Agency for Health and Food Safety (AGES), in co-operation with the Institute of Technology Assessment (ITA) is planning the organisation of a **platform** with relevant ministries and consumer organisations to assess consumer products and distribute relevant information.

Participation in the FP7-project **NanoImpactNet**: The European Network on the Health and Environmental Impact of Nanomaterials (Coordinator: Michael Riediker, Institute for Work and Health, Lausanne, Switzerland) by Austrian participants.

6. Information on any public/ stakeholder consultation

CONANO: COmparative Challenge of NANOmaterials is a Stakeholder Dialogue Project, in which comparative risk-benefit-analyses of degradable and non-degradable nano-delivery-systems and conventional micro-delivery-systems in pharmaceutical and cosmetic uses are conducted. Partners are the Österreichisches Ökologie Institut, Wien, Novartis International AG, Ciba Spezialitätenchemie AG, Öko-Institut e.V., Freiburg and the Stiftung Risiko-Dialog, St. Gallen (leadership). A respective report was finalised in December 2007.

CANADA

Highlight of Developments since the 3rd Meeting of the WPMN

The following activities have taken place since the 3rd meeting of the OECD Working Party on Manufactured Nanomaterials in November 2007:

- Environment Canada and Health Canada issued the government response to the first multi-stakeholder workshop (September 2007). Major outcomes from the workshop include a decision to issue a mandatory information gathering survey under the authority of the *Canadian Environmental Protection Act, 1999*, and significant discussion on potential considerations and approaches for implementing an effective regulatory framework for nanomaterials.
- Environment Canada and Health Canada are targeting September 2008 for the launch of the information gathering survey under the authority of Section 71 of CEPA 1999. The objective of this survey is to gather use pattern information, including volumes and sectors of use, and any relevant toxicological data already available for nanomaterials already in or soon to enter commerce in Canada. In parallel to the mandatory survey, a voluntary initiative will be pursued to gather additional information such as stewardship practices and physical chemical property data. See Section 2.
- Environment Canada held discussions with departmental researchers (January 2008) to initiate the development of a research strategy on environmental and ecological issues of nanomaterials in support of legislative and regulatory mandates of the department. See Section 5.
- The Canadian Institute of Health Research, in conjunction with various federal government departments, held a workshop to examine the nano ethical, economic, environmental, legal, and social issues (January, 2008). See Section 5.
- In the area of scientific research, funding for two environmental effects projects have been approved and the research consortiums held two meetings (March and April 2008) to discuss the scope and research issues, as well as areas of collaboration and cooperation. See Section 5.
- In the area of policy research, the Council of Canadian Academies will issue in June 2008 an assessment of the current state of knowledge of potential human health and environmental risks of nanotechnology.

1. Regulatory Developments in Canada

Federal government actions

The first multi-stakeholder workshop was hosted by Environment Canada and Health Canada (September 2007) brought together representatives from government, industry, public interest groups, and academia to obtain feedback on a proposed regulatory approach for nanomaterials under the *Canadian Environmental Protection Act, 1999*. The government will soon issue a response to the workshop which includes a decision to issue a mandatory information gathering survey under the authority of the *Canadian Environmental Protection Act, 1999*; significant discussion on approaches for implementing an effective regulatory framework for nanomaterials; and considerations for improved engagement of and communication with stakeholders.

The proposed regulatory framework for nanomaterials under the *Canadian Environmental Protection Act, 1999* has been expanded to include both regulatory and research considerations. At this time, planned regulatory activities include:.

Phase 1 (started fall 2006):

1. Continue work with international partners to develop scientific and research capacities (OECD, ISO).
2. Inform potential notifiers of their regulatory responsibilities under the current framework.
3. Develop initiatives to gather information from industry on the uses, properties, and effects of nanomaterials.
4. Consider whether amendments to CEPA 1999 or the NSNR would be needed to facilitate the risk assessment and management of nanomaterials.

Phase 2 (2008 – 2010):

1. Resolution of standard nomenclature and terminology by the ISO.
2. Consider establishing specific data requirements for nanomaterials under the NSNR.
3. Consider the use of Significant New Activity notices for substances already on the DSL.

Canada, through Environment Canada, is the lead for the ISO TC229 WG1 Task Group on Nomenclature. This Task Group includes representatives from the United States, Japan, Germany, the Chemical Abstracts Service, and IUPAC, and includes regulators, industry, and academia. The Group is tasked with developing a nomenclature system which meets the needs of regulators, industry, and academia. Representatives from the nomenclature taskforce presented a discussion on the definition of nomenclature as well as nomenclature needs from regulatory, industrial and academic perspectives at the ISO TC 229 meeting in May 2008 (Bordeaux, France).

Canada, through NRC-CISTI (National Research Council – Canada Institute for Scientific and Technical Information) is developing, under ISO TC/229 JWG1, a taxonomy system for nanomaterials which involves an intelligent organization of terms used in various communities pertaining to nanomaterials (e.g., tubes, rods, nanoscale, etc). Also, Canada through NRC-SIMS (National Research Council – Steacie Institute for Molecular Sciences) is proposing to lead a project to develop definitions for core terms resulting from the taxonomy system.

2. Developments on Voluntary or Stewardship Schemes in Canada

Based on the discussions at the multi-stakeholder workshop (September 2007), Environment Canada and Health Canada opted to conduct a mandatory survey under the authority of Section 71 of the *Canadian Environmental Protection Act, 1999*. The information gathering effort will focus on obtaining information on nanomaterials from industry and on building a knowledge base to inform risk assessment and management approaches.

Respondents will be required to submit information on:

- Identification of nanomaterials in or soon to enter Canadian commerce;
- Basic use patterns including volumes, sectors of use, types of products; and
- Any toxicological data available.

In parallel, a voluntary initiative is planned to gather more specific information such as stewardship practices and physical-chemical property data. Environment Canada and Health Canada are working toward harmonization and facilitated information exchange with the US EPA.

The Canadian approach will be informed by discussions within Steering Group 5 of the WPMN.

Nanotechnology Market Penetration in Canada

There is a limited understanding of the current Canadian market for nanotechnology. A formal use pattern survey and product inventory has not been conducted for Canada; however, Industry Canada has undertaken some preliminary investigations.

Industry Canada has examined its Strategis database and conducted independent web searching to identify Canadian companies engaged in nanotechnology. Industry Canada also contracted a study, in collaboration with Environment Canada, Health Canada, and the Canadian Food Inspection Agency, to investigate US companies exporting nanotechnology-related products to Canada.

Analysis of all the data collected through these projects identified 79 domestic companies with 107 distinct product lines and 63 US companies which include Canada in their business with 127 distinct products lines. Of the 234 product lines, 151 had nanomaterial identity information available on-line and these products represented 88 distinct nanomaterials with 85 distinct uses. The products included a range of constituent nanomaterials, including elemental, alloy, carbon-based, and mineral nanomaterials. Furthermore, these nanomaterials represent a range of industrial sectors including consumer products, life sciences, chemicals, plastics, semiconductors, construction, transportation, security, energy, earth science and environment.

3. Risk Assessment Decisions

A small number of notifications have been received by some regulatory programmes.

- Industrial or commercial chemicals
  - In December 2007, the Minister of the Environment Canada issued a Significant New Activity Notice for a substance identified as a nanomaterial. The Notice requires the submission of additional, prescribed data if the substance will be used for a purpose other than the notified use which will allow Environment Canada and Health Canada to assess potential risks.
- Pharmaceuticals
  - Two nanomedicines have received approval from Health Canada under the current regulations and policies.
- Pesticide applications
  - Some inquiries have been made, but no notifications have been submitted.
- Food related applications
  - Some food related applications in the natural health products field are currently under review by Health Canada.
  - No notifications on food additives or food packaging have been received to date.
- Others
  - No notifications with respect to fertilizers, veterinary biologics, or animal feed have been received to date.

4. Developments of Good Practice Documents

The Workplace Hazardous Materials Information System (WHMIS) is implemented through coordinated federal, provincial and territorial (FPT) legislation. Supplier labeling and Material Safety Data Sheet (MSDS) requirements are set out under the Hazardous Products ACT (HPA) and associated Controlled Products Regulations. The HPA and its regulations are administered by Health Canada. The compliance and enforcement program for the WHMIS supplier labeling and MSDS requirements of the HPA is conducted by the 13 FPT Occupational Safety and Health (OH&S) agencies in Canada in conjunction with the WHMIS employer requirements established by these 13 OH&S agencies. To ensure Canadian workers are protected from possible hazards specific to manufactured nanomateirlas, a WHMIS working group has been set up. A number of FPT OH&S representatives sit on the working group. The objective of this Nanomaterils WHMIS Working Group is to investigate the possible need to:

1. Implement changes to WHMIS hazard criteria to address manufactured nanomaterials,
2. Implement changes to WHMIS disclosure requirements on MSDSs; and/or
3. To develop guidelines or best practices for workers in the field of nanotechnology with a view to publishing these document on Health Canada's national WHMIS website.

Institut de recherche Robert-Sauvé en santé et en sécurité du travail (IRSST) has developed two documents for occupational safety: (1) Development of a best practices guide for the safe handling of nanoparticles; and (2) safe handling of nanomaterials. These documents are a combination of similar documents developed around the world. ISO TC/229 WG3 will be putting forth similar documents with support from IRSST to get an ISO standard for safe handling of nanomaterials for workers.

5. Research in Canada

Scientific research

Environment Canada supported two projects under the Strategic Grants Program of the Natural Sciences and Engineering Research Council (NSERC) which were approved in September 2007. The first project will focus on aqueous related research examining the fate and effects of nanomaterials on aquatic invertebrates, characterize their physiological effects, in addition to developing detection and characterization methodology. The second project will focus on the terrestrial fate of nanomaterials including toxicity to sentinel organisms (such as earthworms), particle transformation, and transport. Another objective of this research is to develop predictive tools generalized for nanoparticles.

In May 2008, a three-year joint Health Canada-Environment Canada project will focus on developing analytical tools and test methods for biomoniroting of nanomaterials in products covered under the *Food and Drugs Act* (e.g., pharmaceuticals, personal care products). Both invertebrate and mammalian cell lines will be studied by exposure to well characterized (e.g., physical chemistry) and representative nanomaterials on the OECD list of representative nanomaterials.

Environment Canada laboratories are also conducting some limited research on fate and ecotoxicity of nanomaterials in aquatic systems. A departmental research strategy is under development to focus on ecological and environmental research needs as mandated under the *Canadian Environmental Protection Act, 1999*. The objectives of the strategy are to build and improve upon research expertise and capacity for nanomaterials.

Health Canada is engaged in both in-house and collaborative research projects involving a range of different nanomaterials (zero-valent iron nanoparticles, nanoparticulate carbon black and nanoparticulate

quartz, single walled carbon nanotubes, and C_{60} fullerenes). Testing includes pulmonary and cardiovascular injury; reproductive and development effects; exposure and tissue penetration, interactive effects with microorganisms, and genotoxicity. In vitro techniques play an important part of the repertoire for such investigations. In line with expected goals for a forthcoming broader inter-departmental initiative, Health Canada is working with Environment Canada to help establish a research capacity to support regulation of manufactured nanomaterials (i.e., in regulation, health and safety monitoring, and ecotoxicology). This would also be in support of international EHS and R&D efforts, and involve the application of new tools for those priority nanomaterials identified by OECD countries and consistent with directions that OECD and ISO work is taking.

The National Research Council of Canada is involved in research and development of nanotechnologies on a wide range of topics which probe our fundamental understanding of their physical and chemical properties to areas of fabrication and application. Research is ongoing to develop capabilities for measurement and characterization of nanomaterials and nanoscale features. Canada is actively involved in international R&D collaborations with the USA and other countries. The National Research Council of Canada-Taiwan partnership focuses on research projects which underpin and apply nanotechnologies, one of which involves the development of techniques and instrumentation for accurate primary calibration of nanoscale length for application in scanning probe microscopy. Cooperation and harmonization of accurate measurement techniques and calibrations aid in establishing internationally-recognized client services and measurement capabilities.

The National Research Council of Canada (NRC) has launched new R&D initiatives which support collaborative projects between Institutes (http://www.nrc-cnrc.gc.ca/institutes/index_e.html). These cross-Institute Programs in Nanotechnology exploit the multi-disciplinary strengths of the NRC with focus on fundamental R&D topics which underpin EHS research. One of the supported projects focuses on: airborne nanoparticles (nano-aerosols) that contribute to poor air quality.

Policy research

The Council of Canadian Academies is a non-profit organization which acts as a source of independent, expert assessment of the science underlying pressing issues and matters of public interest. The Council is undertaking an assessment of the current state of knowledge regarding the health and environmental risks potentially associated with nanotechnology. This work began in February 2007 and the report will be delivered to Health Canada on June 2, 2008, with a public release shortly thereafter.

Canadian Institutes for Health Research, in partnership with Natural Sciences and Engineering Research Council, the Social Sciences and Humanities Research Council of Canada, Health Canada, Environment Canada, Industry Canada, and other federal departments, held a workshop on nanotechnology in January 2008. The workshop promoted discussion on developments in the field of nanotechnology and the policy challenges that they may present (i.e., nano ethical, economic, environmental, legal, and social issues (NE^3LS)). The workshop identified a number of research priorities in the field of nanotechnology and health impacts, for consideration by various participating agencies and departments.

6. Public and Stakeholder Consultations

Environment Canada and Health Canada hosted a multi-stakeholder workshop on a proposed regulatory framework for nanomaterials under the *Canadian Environmental Protection Act, 1999* involving industry, non-governmental organizations, academia, and other interested parties in September 20007. Additional consultative meetings will be conducted as part of the normal process in the development of a regulatory regime for nanomaterials.

CZECH REPUBLIC

Highlight of developments since the 3rd meeting of the WPMN

- Establishment of the team on the occupational health and safety aspects of nanomaterials (NanOSH) at the Centre of Occupational Health, National Institute of Public Health
- Initialization of presentation activities to raise awareness among the public health authorities related to nanotechnologies and health risks associated with use of nanomaterials

Work completed, underway or planned

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

2. Developments related to voluntary or stewardship schemes

No activities documented

3. Developments related to risk assessment decisions

The NanOSH team at the National Institute of Public Health (NIPH) (see point 5) is developing a questionnaire to collect information on the use of and exposure to nanomaterials and on the risk management at workplaces of the industrial companies as well as of research institutions. The questionnaire will be distributed via regional public health authorities in June 2008. The feedback from the companies will be evaluated, summarized and made available to the Ministry of Health.

4. Information on any risk assessment decisions

No activities documented

5. Information on any developments related to good practice documents

No activities documented

6. Research programmes or strategies designed to address human health and/ or environmental safety aspects of nanomaterials

The Team on the Occupational Health and Safety Aspects of Nanomaterials (NanOSH) has been established at the Centre of Occupational Health, National Institute of Public Health, in January 2008. Its mission is primarily to collect and critically evaluate the available data on the nanomaterials and nanotechnologies and the health related aspects of their use, and to make this data available to the national public health sector and regulatory authorities. The NanOSH team at the NIPH also serves as a contact point for other agencies and institutions.

The Technology Centre of Academy of Sciences of the Czech Republic, the National Information Centre for European Research, is currently updating a brochure "Nanotechnology in the Czech Republic 2008", listing a) companies involved in nanomaterial production or use, b) research institutions and particular research projects associated with nanomaterials, including those dealing with environmental and health related aspects thereof. The brochure will be published later in 2008.

7. Information on any public/ stakeholder consultation

The NanOSH team at the NIPH is distributing basic information on nanomaterials and health-related aspects of their use to public health specialists at the meetings, seminars, and national conferences. In September 2008, a specialized half-day seminar "Occupational health and safety aspects of nanomaterials and nanotechnologies" will be held in NIPH.

DENMARK

Please identify work completed, underway or planned in your country or organisation, which relates to activities in the chemicals regulatory area on health and environmental safety aspects of manufactured nanomaterials:

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;**

At present there is no regulation specifically addressing nanomaterials in Denmark.

In the summer 2006, the Danish Board of Technology published a report concerning environmental and health aspect of nanotechnology (http://www.tekno.dk/pdf/projekter/p06_nanoteknologi_rapport.pdf - summary in English). The authors behind the report concluded that the existing regulation has to be further developed to specifically address the potential risks from nanomaterials. In the present chemical regulation and in REACH the tonnage levels for data requirement have to be reassessed because of the low weight of nanomaterials. Furthermore industrial use of nanomaterials should be subjected to approval from the authorities and it is proposed that the authorities provide specific risk assessment guidance and that obligatory risk assessment should be required from industry in case of possible environmental or human exposure to nanomaterials. The different proposals in this report are under discussion by the relevant authorities.

In Denmark, the Ministry of the Interior and Health in December 2007 published a survey of the existing regulation in the different sectors (environment-sector; chemical sector, food-sector, pharmaceutical-sector, occupational environment sector, and health sector) examining to which extent the current legislation also cover potential health risks associated with nanotechnological processes and nanomaterials. English summary included in the report available at:

http://www.nano.dtu.dk/upload/centre/nanodtu/nanoteknologiske_horisonter/supplerende%20undervisningsmateriale/kap1/nanoteknologi%20og%20sundhed_dec07.pdf

The report concludes that the regulation within the different administrative sectors in general covers nanomaterials although there are no specific mentioning of nanomaterials as such. It is recognised, however, that in order to address aspects specifically related to nanomaterials there may be a need for specific technical adjustments in the regulation.

In March 2007 and again in May 2008, the Danish parliament has debated a regulatory proposal concerning the use of an enhanced precautionary principle in connection with regulation of nanotechnological products and processes. Both times the proposal was rejected most of all because the proposal only addressed some general and overall concern and could not identify or verify specific situations of concern in which the precautionary principle would apply. Furthermore it was argued that also a present we have the possibility to use the precautionary principle in situations of some specific concern. The debate in May 2008 additionally concerned a proposal for establishing a national research program for EHS of nanomaterials. There was a general agreement that research is needed, however, the majority of politicians was against the proposal, because initiatives should be on international level and because sufficient resources already are allocated to the field.

The Danish EPA together with the Danish Working Environment Authority has initiated work in order to examine the possibility to include nanomaterials in the mandatory notifications to the Danish Product Register in which hazardous chemical products and their content is registered.

During 2008 the Danish EPA has initiated a project to describe and possibly to develop a declaration guide or standards for chemical products and articles containing nanomaterials.

2. Developments related to voluntary or stewardship schemes;

At present there are no specific initiatives in relation to voluntary or stewardship schemes in DK.

3. Information on any risk assessment decisions;

No risk assessments on specific nanomaterials have been conducted in Denmark and no specific risk assessment decisions have been taken in relation to nanomaterials.

4. Information on any developments related to good practice documents;

In Denmark, we are not yet at a stage to develop good practice documents as more specific knowledge concerning nanomaterials and situations for guidance-request are needed. However future projects (see below item 5) may give further valuable input in order to further evaluate the need and the areas/ situations where guidance or good practice documents may be relevant.

The Nordic Council of Ministers has issued a project aimed at "Evaluation and control of occupational health risks from nanoparticles". The project report was finalized in November 2007; see http://norden.org/pub/miljo/miljo/sk/TN2007581.pdf

5. Research programmes or strategies designed to address human health and/ or environmental safety aspects of nanomaterials;

There is no specific overall research programmes or strategies in this area, however several governmental research institutions and university institutes have now issued a series of projects addressing aspects concerning health and environmental risks in relation of nanomaterials. Especially the testing of nanomaterials both in existing and alternative ecotoxicological and toxicological test systems is in focus in these projects. In relation to the occupational environment an important and extensive contribution to this research is carried out by the National Research Centre of Working Environment (the former National Institute of Occupational Health) where a research group was established in 2005 with focus on health risks associated with fabrication and use of nanoparticles and nanoparticle products (see

http://www.arbejdsmiljoforskning.dk/Forskningsresultater/Nye%20teknologier.aspx

Also research concerning human health and use of nanomaterials in food packing materials is in progress.

The Danish EPA, in 2006, established a national network for risk assessment and risk management of nanomaterials. The network includes authorities from different sectors and scientific institutions experienced in chemical testing and risk assessment. The network is meant to support national coordination and also to support Danish contribution to the work in EU and OECD.

Knowledge about use and exposure is as important as knowledge about the intrinsic properties of nanomaterials. In spring 2007, the Danish EPA finalized a project in which the presence of nanomaterials

in consumer products in Denmark was identified. About 250 different articles and chemical products were identified which were claimed to contain nanomaterials. Nearly all products containing nanomaterials were imported and the majority of the products were only available via the internet. For most products, however, it was not possible to get documentation/ verification regarding the content and an identification of the nanomaterial. For those products/ articles where the nanomaterials could be verified it was well-known substances such as titanium dioxide, zinc oxide, silver, fullerenes, carbon-nanotubes. (See http://www2.mst.dk/common/Udgivramme/Frame.asp?pg=http://www2.mst.dk/Udgiv/publications/2007/978-87-7052-536-7/html/default_eng.htm , in English).

Currently the Danish EPA are finalising two projects concerning automobile care products and textile impregnation products, respectively. Both projects have analysed the content of several products including products claming to contain nanomaterials and risk assessments is attempted

In November 2007, the Danish EPA finalized a project in collaboration with industry with the aim to identify industrial branches in which nanomaterials is used; how they are used, and how aspects concerning environment and human health is considered. The project was conducted by the use of a combination of questionnaires and interviews of the relevant industries.

(See http://www2.mst.dk/common/Udgivramme/Frame.asp?pg=http://www2.mst.dk/Udgiv/publications/2007/978-87-7052-648-7/html/default_eng.htm , in English)

Through the funding of the Nordic Council of Ministers now Denmark take part in the Nordic contribution to the OECD sponsorship programme for testing of nanomaterials. The Nordic contribution will be in the area of ecotoxicological testing of nanomaterials.

Although not fully established yet, the Danish EPA considers that knowledge exchange and cooperation with industry and research laboratories is important in order to obtain relevant knowledge for targeting the work concerning risk assessment and risk management of nanomaterials.

6. Information on any public/ stakeholder consultation.

Danish Standards Association has started a network group for nanomaterials with various stakeholders (authorities, industry, universities, advisors etc) in relation to the standardization work concerning nanomaterials in ISO and CEN.

The Danish EPA has just started a project with the aim of analyzing the information need with regard to use of nanomaterials and knowledge about nanomaterials and to propose a strategy how information from the authorities should be coordinated and made public available.

In November 2007, the Danish EPA together with the Confederation of Danish Industries industry were hosting a public conference/workshop for industry, NGOs and other stakeholders concerning a responsible development of nanotechnology with the focus on nanomaterials and issues in relation to use, handling and risk management. An information booklet was published in connection with the conference (see http://www2.mst.dk/common/Udgivramme/Frame.asp?pg=http://www2.mst.dk/Udgiv/publikationer/2007/978-87-7052-647-0/html/default.htm, in Danish only)

In relation to the conference, two focus groups had been held and their discussions have been analysed in order to describe the public perception of nanotechnology. The analysis was performed by Information center for Environment and health (see http://www.miljoeogsundhed.dk/filarkiv/NanorapportWeb.pdf, in Danish only). The report showed that in general the public do not feel that they know very much about nanotechnology and nanomaterials.

Additional Information

In general there is awareness in worker organizations, in NGOs, some parts of the public; in the media and in the political system in DK concerning nanotechnological products and processes in relation to potential environmental and health risks. In relation to further development in this area the Danish authorities support and refer to the work and the strategic approach by the OECD, as we consider a global and collaborative effort as crucial in order to gain more knowledge as quick as possible and to achieve a common understanding for an administrative/ regulatory approach for handling nanomaterials.

FINLAND

Work completed, underway or planned

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

The Ministry of the Environment, assisted by the Finnish Environment Institute, has published a report on nanotechnology and protection of environment (in Finnish only) in 2008.

2. Developments related to voluntary or stewardship schemes

No information provided

3. Information on any risk assessment decisions

No information provided

4. Information on any developments related to good practice documents

No information provided

5. Research programmes or strategies designed to address human health and/ or environmental safety aspects of nanomaterials

Finland is contributing to the Nordic group of health and environmental risks of nanomaterials both in the in the project starting in 2008, related to the OECD work, and in a steering group

A nanotechnology project group has been established at Finnish Environment Institute. The group should initiate regulatory research activities in the ecotoxicology and fate area including socio-economic and policy issues, participate in international discussions and future regulatory work.

6. Information on any public/ stakeholder consultation

No information provided

Additional General Information

Finland is participating in OECD test guideline programme and in subgroups of WPMN. Jukka Ahtiainen is chairing a section group 3 of SG4.

Finnish Institute of Occupational Health (FIOH) organised an EuroNanosh Conference in Helsinki in December 3-5, 2007. Co-organisers were TEKES (Finnish funding organisation for technological innovations). US NIOSH, and the Italian Institute of Occupational Health, ISPESL. In the congress, results of a survey on nanosafety aspects and needs in Finland, as a part of the *FinNano* Nanoscience and Nanotechnology programme, were published.

FIOH will also organise the NanOEH2009 Conference 26-29 August 2009 in Helsinki.

Representatives of the Finnish chemicals regulators with interest in WPMN work have in 2008 participated in meetings of a steering group for the Finnish representatives in the WPN work (business case studies and business dialogue).

GERMANY

Highlight of developments since the 3rd meeting of the WPMN

The NanoCommission (NanoDialog) continues its work with the help of three working groups:

1. The first Working Group "Opportunities for Health and Environment“ concentrates on the question: How can the use nanomaterials contribute to sustainable economic and social development in Germany, in particular to environmental/health and consumer protection? The Working Group wants to identify and describe selected nanoproducts or applications which deliver a special benefit for the environment or for consumers. These opportunities will be checked concerning their sustainability throughout their life cycle, at least qualitatively.

2. A second Working Group is called "Risks and Safety Research" and consequently deals with the possible risks posed by nanomaterials, especially the gaps in our knowledge, which we need to fill as soon as possible. The aim is to develop a programme for future safety research plus suggestions for concrete projects. Since many products containing nanomaterials are already on the market and we expect a further increase in the future, this working group will assess the risks for some selected nanomaterials based on present knowledge.

3. In order to provide preventive protection to employees, consumers and the environment, a third Working Group develops "Guidelines on the Responsible Use of Nanomaterials". The group started the work on a Guideline for worker protection and is now working on basic principles on which all Guidelines should be based and on indicators to monitor their implementation. The aim of Working Group 3 is, that industry and user companies adopt these Guidelines as a “Code of Good Practice.”

The output of the working groups will be summarized in the report of the NanoCommission in summer 2008. This will include recommendations for research priorities, a commitment to the responsible use of nanomaterials based on respective guidelines and a report on nanomaterial based opportunities for sustainable development. In November 2008 a closing event will take place in Berlin.

Since 2007, the "Nano Initiative - Action Plan 2010" gives a framework across all government departments. The leading Ministry “Education and Research” (BMBF) has started this initiative, together with six others (Environment (BMU), Labour and Social Affairs (BMAS), Food, Agriculture and Consumer Protection (BMELV), Defence (BMVg), Health (BMG) and Commerce and Technology (BMWi)). The NanoDialog Project is part of this action plan.

Work completed, underway or planned

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

The Federal Government identified, that - for the moment and based on the current state of knowledge - our legislation can principally protect humans and the environment concerning applications with nanomaterials and that it covers many flexible instruments for this task. At the same time the required tools

for example for risk assessment need to be further developed. As nanotechnology will be more and more used in many applications legislation and regulation will need to be checked again in the future, whether they are sufficient to protect man and environment.

Since some of the EU provisions relating to foodstuffs are currently under revision (e.g. food additives, novel foods) not only the German Delegation attached specific importance to a potential need of further clarification and/or more detailed provisions regarding the use of nanotechnologies/ nanoparticles. Specific wording has already been added to some of the proposed regulations under discussion.

2. Developments related to voluntary or stewardship schemes

The Federal Institute for Occupational Safety and Health (BAuA) developed in collaboration with the Chemical Industry Association (VCI) a questionnaire to collect information on exposure of nanomaterials and risk management at workplaces of the chemical industry and research institutions. The feedback from industrial and research companies was evaluated, summarized and published as a report in German in the magazine "Gefahrstoffe-Reinhaltung der Luft" 10/2007, pp. 419-424: www.technikwissen.de/gest/currentarticle.php?data[article_id]=38107&PHPSESSID=45f53091cdd716651169e251e2462e73. The English version "Exposure to nanomaterials in Germany – Results of the corporate survey of the Federal Institute for Occupational Health and Safety (BAuA) and the Association of the Chemical Industry (VCI) using questionnaires" is available under: www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/Nanotechnology/Nanotechnology.html

3. Information on any risk assessment decisions

Not applicable due to lack of information

4. Information on any developments related to good practice documents

The Chemical Industry Association (VCI) has developed in collaboration with the Federal Institute for Occupational Safety and Health (BAuA) a handling guideline for the responsible handling of nanomaterials during production and use. The draft was discussed at a work shop to consider further input from a variety of stakeholders. A finalized version is available under:

www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/Nanotechnology/Nanotechnology.html

5. Research programmes or strategies designed to address human health and/ or environmental safety aspects of nanomaterials

The joint German research strategy, developed by the BAuA (Federal Institute of Occupational Safety and Health) together with BfR (Federal Institute for Risk Assessment) and UBA (Federal Environment Agency) considering health issues of workers and consumers and the environment issues had been discussed with stakeholders from industry, science, policy, and NGOs. The finalized version was published in 2007 and is publicly available on the web site of the BAuA (including a version in English language: www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/Nanotechnology/Nanotechnology.html) and UBA (http://www.umweltbundesamt.de/technik-verfahren-sicherheit/nanotechnologie/index.htm).

The Ministry of Education and Research (BMBF) is starting a research programme on benefits for environment and environmental safety aspects of nanomaterials, NanoNature.

6. Information on any public/ stakeholder consultation

In 2007, the Federal Institute for Risk Assessment (BfR) issued two projects on public perception of nanotechnology. The first project is an opinion poll in the German public linked with a fundamental psychological study. The results show that the majority of consumers view the development of nanotechnology favourably. However, at present, most of the consumers do not accept the use of nanoparticles in food. The study also revealed that over the last three years consumers have become far more familiar with nanotechnology. Consumers source information from all major media – TV, daily newspaper, magazines. The amount of trust which consumers place in information about nanotechnology depends on where the information comes from. The highest level of trust is enjoyed by consumer associations. The BfR conducted this project together with Vierboom & Härlen, Business Psychologists and the University of Bonn.

In the second project the BfR is currently conducting a study on a media analysis of articles on nanotechnology published in German daily newspapers and popular magazines. The project is intended to investigate how nanotechnology is framed in mass media debate, who is taking part in the debate, which arguments dominate and which metaphors illustrate the debate. The project is carried out together with the University of Muenster and will be finished in June 2008.

In the context of the BMBF-project NanoCare on effects of nanomaterials on human health, a stakeholder dialogue has been performed in Nov. 2007, a second one will take place in Nov. 2008. A dialogue with the public took place in April 2008; two additional public dialogues are scheduled for Sept. and Nov. 2008.

IRELAND

Highlight of developments since the 3rd meeting of the WPMN

- The Science Foundation Ireland, the Higher Education Authority and the Environmental Protection Agency provided funding to research programmes in nanoscience
- The 7th EU Framework Programme funded the project NeuroNano
- The Health and Safety Authority together with Forfás, Enterprise-Ireland, Academia, Irish Industry, Irish Business and Employers Confederation, and other Irish departments continue to participate in the ad-working group on Nanotechnology to develop a strategy on the safe use of nanoparticles in the workplace.
- Opening of Ireland 's first purpose built Nanoscience Research Institute
- Annual Congress 2008: Nanotechnology - organised by the Institute of Chemistry
- NanoImpactNet Events in 2008 – 2 workshops will be hosted University College Dublin

Work completed, underway or planned

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

At present there is no specific national regulation addressing nanomaterials in Ireland.

In June 2007, the Technical and Scientific Advisory Committee (TSAC) of the Health and Safety Authority (HSA) approved the set up an ad-hoc working group on Nanotechnology to discuss and develop a HSA strategy on the safe use of nanomaterials in the workplace. The ad-hoc working group on Nanotechnology consists of stakeholders from academia, industry, employee representatives and several Irish departments.

Since the 1st October 2007 the ad-hoc working group on Nanotechnology has met three times to discuss the Terms of Reference, which was agreed, and the drafting of the HSA strategy on the safe use of nanomaterials in the workplace. At the 3rd ad-hoc working group meeting further discussions took place on the drafting of individual chapters and the future development of the HSA strategy.

The National Policy & Advisory Board for Enterprise, Trade, Science, Technology & Innovation (Forfás) has prepared a report 'NanoIreland', which looks at developing a national nanotechnology approach for Ireland and will include the aspiration that Ireland should be at the forefront of the debate on Regulation and Safety. The NanoIreland report is currently under consideration for publication.

2. Developments related to voluntary or stewardship schemes

At present there are no specific initiatives in relation to voluntary or stewardship schemes in Ireland.

3. Information on any risk assessment decisions

Ireland has not received any notification for a nanomaterial. Consequently no risk assessment has been carried out.

4. Information on any developments related to good practice documents

At present there is no Irish guidance or good practice documents.

5. Research programmes or strategies designed to address human health and/ or environmental safety aspects of nanomaterials

In 2007, Ireland included in their research programmes on Nanotechnology specific research programmes to address human health and/or environmental safety aspects of nanomaterials.

The Science Foundation Ireland (SFI) funded ca. 30 research project in the area of nanotechnology (mainly in the ICT sector) including three projects in Life Science research:

- BioNanoInteract (Research Cluster led by Prof. Kenneth Dawson, University College Dublin (UCD))
- Nanopharmacology in platelet research: Focus on nitric oxide & matrix metalloproteinases (led by Prof Marek Radomski,Trinity College Dublin)
- The Functions of Nanoscale Complex Systems (led by Prof. Suzanne Jarvis, UCD)

The Higher Education Authority (HEA) funded the project NanoTEIRE up to a level of €31.6M via the Programme for Research in Third-Level Institutions, 4th cycle (PRTLI 4). NanoTEIRE is a consortium of all Irish universities with international leading research capability in nanoscience and nanotechnology (led by Prof. John J. Bolan, Centre for Research on Adaptive Nanostructures and Nanodevices (CRANN).

Furthermore, the Irish EPA launched a call for research proposals in the area of environmental & human health with a closing date by 23rd January 2008. The technical description of the Science, Technology, Research & Innovation for the Environment (STRIVE) programme 2007-2013 includes research opportunities, such as:

- Potential health impacts of engineered nanomaterials - including predicting the behaviour of nanoparticles, during usage, handling and disposal
- Development of alternatives to animal-based techniques for toxicology testing
- Ecotoxicology research in support of the REACH Directive

No details on the number of approved and funded projects are currently available.

In addition, Ireland received approval and funding from the EU for a project under the seventh Framework Programme (FP7) for research, technical development and demonstration activities -Theme 4 – NMP - Nanosciences, Nanotechnologies, Materials and new Production Technologies. This program is currently under negotiation. The project NeuroNano will focus on study of the risk encountered by people exposed to NanoParticles and the development of neurodegenerative diseases, and is led by Prof Kenneth Dawson (UCD). Several European and/or international partners in the US, Asia, Central and South America are involved in this project.

On 23rd January 2008 the Taoiseach, Bertie Ahern TD officially opened the Naughton Institute, a €100 million state-of-the-art new science facility at Trinity College Dublin which will house Ireland's first purpose-built Nanoscience Research Institute, CRANN and the world's first Science Gallery.

A new BioNanoScience Centre building at UCD was also funded (€23M) by HEA by PRTLI 4.

The Institute of Chemistry (ICI) held the Annual Congress 2008 in Athlone on 16th May 2008 which focused on Nanotechnology. The conference was attended by ca. 60 people and speakers were from both academia and industry. Research perspectives from academia included an overview of the human and environmental impacts of nanomaterials. The industrial applications of nanotechnology included talks regarding e.g. NanoCrystal Technology in Drug Formulation and Nanomaterials in the Recycling of Plastics.

On 19-20 June 2008, on behalf of the European Network on the Health and Environmental Impact of Nanomaterials, the University College Dublin will host two discussion workshops related to current research needs for assessment of the safety of nanoparticles for human health.

6. Information on any public/ stakeholder consultation

The Interdepartmental Committee (IDC) has requested Forfás to conduct a feasibility study on the building of a Nano Fabrication (NanoFab) facility in Ireland. The Terms of Reference are currently been framed.

Forfás, which is also involved in the OECD Working Party on Nanotechnology (WPN), and the WPN's steering group 'Impacts on Companies and the Business Environment' is currently doing a survey of 13 nominated companies. Results of this survey are expected by the end of June 2008.

JAPAN

Highlight of developments since the 3rd meeting of the WPMN

- 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" 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.
- 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.

Work completed, underway or planned

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

Japan has no safety regulation focusing on the chemical's size effects at this moment. In terms of the existing regulatory system, the Chemical Substance Control Law obliges manufacturers/importers to notify the authorities all newly developed chemical substances they develop/import. Some notifications of manufactured nanomaterials (e.g. fullerene derivatives) have been observed in the small quantities exemption notification scheme[1] under the Law.

2. Developments related to voluntary or stewardship schemes;

Japan has no voluntary/stewardship scheme on health and environment safety of manufactured nanomaterials so far.

[1] Newly developed/imported chemicals up to one tonne in total can pass through a simpler regulatory procedure with prior notification to the authorities.

3. Information on any risk assessment decisions;

Japan has no risk assessment decision on manufactured nanomaterials so far.

4. Information on any developments related to good practice documents;

The Ministry of Economy, Trade and Industry (METI) conducted a preliminary survey on safety handling of nanomaterials at manufacturing sites and research laboratories. The survey reviewed existing good practices both in domestic and overseas sites and compiled them into a report in 2007 (in Japanese). The report proposed a draft basic guideline, which gave some ideas for sound handling of nanomaterials to manufacturers and laboratories.

Furthermore, METI's five-year programme on the "Evaluation of the Potential Risks of Manufactured Nanomaterials based on Toxicity Tests with Precise Characterization" (see 5.) could lead to guidance documents for appropriate handling methods of manufactured nanomaterials.

The Ministry of Health, Labour and Welfare (MHLW) issued the notification for the exposure prevention in the workplace handling nanomaterials in February, 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.

5. Research programmes or strategies designed to address human health and/ or environmental safety aspects of nanomaterials;

The promotion and the social acceptance of nanotechnology has been considered as an important issue, and the R&D for the social acceptance of nanotechnology has been focused on as a strategic Science and Technology Priority in the 3rd Science and Technology Basic Plan in Japan.

Also, The Cabinet Office established a committee that coordinates research and development policy on nanotechnology. One of its targets is to establish an 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.

Four national institutes[2] and some universities jointly conducted surveys on public acceptance of nanotechnology. They focused 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 and economic assessment for promoting the public acceptance of nanotechnology. The survey was funded by the Ministry of Education, Culture, Sports, Science and Technology (MEXT). The survey team issued a report in 2006, which contains a series of recommendations to public institutes, the private sector and the government. In fiscal year 2006, funded by MEXT, a project named "The multidisciplinary experts panel for nanotechnology implication" was 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

[2] The National Institute of Advanced Industrial Science and Technology (AIST), the National Institute of Health Science (NIHS), the National Institute for Environmental Studies (NIES), and the National Institute of Materials Science (NIMS).

nanotechnology implication for health, environment and social acceptance." The additional objective is the establishment of a researchers' network on the implications of nanotechnology.

METI launched a five-year programme on the "Evaluation of the Potential Risks of Manufactured Nanomaterials based on Toxicity Tests with Precise Characterization" in 2006, which focuses on toxicity test protocols (mainly an inhalation test) and a risk assessment methodology of manufactured nanomaterials. The programme aimed at: establishing preparation methods of test samples; developing methods for measuring shapes and sizes of tested nanomaterials, for testing toxicity, and for analysing exposure; publishing such results in the form of manuals; carrying out risk assessment on typical of nanomaterials; and proposing a risk management policy with formulating risk assessment documents. Fullerene and carbon nanotubes (CNTs) are given priority as targeted nanomaterials. Literature survey on nanomaterials toxicity and social acceptance studies are also conducted. The programme is coordinated by the National Institute of Advanced Industrial Science and Technology (AIST), which also conducts much of this research in cooperation with the University of Occupational and Environmental Health and other universities. AIST together with OECD and NEDO (the New Energy and Industrial Technology Development Organisation) organised an international symposium on the "Risk Assessment of Manufactured Nanomaterials" in April 2008, which attracted more than 500 attendees. It was held back-to-back the OECD Tokyo workshop on the Sponsorship Programme for the Testing of Manufactured Nanomaterials.

MHLW conducted a preliminary project in 2005, and 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 methodologies of nanomaterials in biological samples, ADME analysis, dermal exposure experiments, long-term health implication analysis using genetically modified animals, and the development of a transpulmonary/inhalation experiment system. In addition to this project, other research projects have been adopted to strengthen research on nanomaterials, including inhalation toxicity tests and dermal toxicity tests. In fiscal year 2007, MHLW conducted a survey on manufactured nanomaterials used in consumer products. The volume and uses of nanomaterials used in Japan were surveyed and the summary of the results will be made available in English. In March, 2008, 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.

The National Institute of Occupational Safety and Health Japan (JNIOSH) started a three-year project study on possible health issues due to exposure to manufactured nanomaterials in the workplace since April 2007. This project includes 1) a questionnaire survey on occupational health practices for handling and use of nanomaterials in the workplace, 2) studies on sampling and analytical methods, and 3) toxicological studies in vitro with human cultured cell lines and in vivo by intratracheal administration.

In 2006, the National Institute for Environmental Studies (NIES) launched a nanotoxicology programme where both in vitro and in vivo toxicities of nano-structured particulate materials are to be revealed. The programme includes (1) interaction of nano-fibers including CNT with cell membranes, (2) transepithelial and transpulmonary migration of nanoparticles, (3) in vitro and in vivo toxicity assay of nanomaterials using heat-treated asbestos as reference samples. Some in vitro studies on toxicity of nano-carbons and nanotubes have been completed. NIES is now moving on to in vivo toxicological study on nanotubes and nano-metals.

6. Information on any public/ stakeholder consultation

Japan has not implemented any official public/stakeholder consultation programme focusing on the safety aspects of manufactured nanomaterials. However, during the survey that was concluded in 2006 (see 5.), a series of workshops were organised, in which the public and NGO members actively participated.

KOREA

Highlight of developments since the 3rd meeting of the WPMN

- Surveys on inventory of nanomaterials and the perception of the nanotechnology were completed in 2007 and the report is on preparing (as elaborated below in #5, worked by MoE)
- The projects on "the Surveys on inventory of nanomaterials and an initiative to manage manufactured nanomaterials" were started in 2008.

Work completed, underway or planned

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

The Korean government does not have any national regulatory development on human health and environmental safety on manufactured nanomaterials as yet. However, MEST (Ministry of Education, Science and Technology commenced investigating any needs in the new regulatory system and possibilities to apply the existing law and rules to issues related to nanomaterials.

2. Developments related to voluntary or stewardship schemes

The Korean government does not have any national developments related to voluntary or stewardship schemes as yet.

3. Information on any risk assessment decisions

The Korean government initiated a few research projects as elaborated below in #5 this year including risk assessment part, but these are still in the initial stage.

4. Information on any developments related to good practice documents

The Korean government does not have any information on developments related to good practice documents as yet.

5. Research programmes strategies designed to address human health and/ or environmental safety aspects of nanomaterials

The Korean government has well recognized the importance of potential risks of nanomaterials, and is conducting several projects on human health and environmental of nanomaterials.

<u>Ministry of Environment (MoE)</u>

MoE has conducted the Eco-technopia21 project to promote the development of environmental technologies since 2001. MoE commenced a project on human health and environmental safety of nanomaterials such as fullerene (C_{60}), MWCNT, silver nanoparticles, TiO_2, and SiO_2 as prior materials in the framework of Eco-technomia21 from April 2007, which will be continued until 2010. In addition, surveys on inventory of nanomaterial (658 nanomaterial manufacturing companies and researchers) and the perception of the nanotechnology (599 public peoples and 165 experts) were completed in 2007 and the report is on preparing. The project on "the Surveys on inventory of nanomaterials and an initiative to manage manufactured nanomaterials" started in 2008. The ultimate goal of the research is to support the establishment of infrastructure in order to minimize potential risks possibly occurred from the

manufacture, distribution and disposal of nanomaterials and nanomaterials-containing products. The research project includes 1) A close examination of sources of nanomaterials in environment 2) Development/achievement of nanomaterials' LCA 3) Characterization of physico-chemical properties, 4) Development of monitoring methods in environment and sources, 5) exposure assessment, 6) Selection of prior managing nanomaterials and 7) Survey on the perception of the nanotechnology hazard / Drawing up road-map / Supporting international cooperation of Ministry of Environment.

National Institute of Environmental Research (NIER), a subsidiary body of MOE, has been conducting a project on the development of test methods and a database for risk assessment of manufactured nanomaterials. The prototype of the database and the toxicity tests for silver nanoparticles are on progress.

Ministry of Education, Science and Technology (MEST)

In 2007, MEST has performed 2 projects on EHS (Environment, health and Safety) and ELSI (Ethical, Legal, and Social Issue) of nanomaterials, which was continued from second half of 2006. MEST is conducting a research to assess of safety of biocompatible nanomaterials through NCRC (National Core Research Center) Program from 2004 through 2011 as well. The major research fields include 1) syntheses of nanomaterials to be applicable for medical purpose, 2) toxicokinetics, acute, repeated toxicity and carcinogenicity tests on nanomaterials, 3) Development of PB-PK (Physiologically Based Pharmaco-Kinetics), and 4) development of test guidelines and standards for toxicokinetics and carcinogenicity.

Korea Research Institute of Standards and Science (KRISS), a subsidiary body of MEST, is developing reference methods to assess properties of nanomaterials such as size, agglomeration, composition, surface bioconjugated layer composition, and optical properties. The *ex-situ* reference methods are being developed at this time, but would be extended for *in-vitro and/or in-vivo* measurements. To tackle the irreproducibility problems in EHS assessment, KRISS is developing a standard sample, for example, Au nanoparticles with stable and well-characterized bioconjugated surface layers.

Ministry of Knowledge and Economy (MKE)

As a Korean representative for ISO, Korean Agency for Technology and Standards (KATS), a subsidiary body of MKE, has conducted all works related to ISO TC 229. KATS is planning to make a presentation under the title “Monitoring of multi-walled carbon nanotube exposure” in the ISO/ TC 229 meeting Bordeaux, France 5/26-30, 2008. KATS recently organized a “Workshop to ensure safety of nanomaterials/nanotechnology” on May 15, 2008. The subjects of the workshops include 1) Trends of Nanotechnology, 2) Antimicrobial effects of silver nanoparticles and ambient air exposure monitoring of nanomaterials, 3) Ecotoxicity assessment of silver nanoparticles, 4) Nano cosmetics and Human safety, 5) Exposure assessment of multiwalled carbon nanotubes, 6) OECD WPMN activities, 7) Toxicity evaluation of silver nanoparticles and MSDS, and 8) ISO TC 229 (Nanotechnology) activities.

Korea Environment & Merchandise Testing (KEMTI), a subsidiary body of MKE, conducted several GLP tests such as acute and 90 day inhalation toxicity, 28 days of repeated oral toxicity, in vivo micronucleus study for silver nanoparticles in accordance with OECD TGs.

KEMTI is currently conducting a 90 days of inhalation toxicity study for gold nanoparticles.

Ministry of Labour (MoL)

Korea Occupational Safety and Health Agency (KOSHA), a subsidiary body of MoL, conducted the projects on (1) developing biomarker for the exposure of silver nanoparticles, (2) monitoring MWCNT exposure in CNT research facilities (3) nanotoxicity and risk assessment of the nanoparticles and

approaches for occupational health and (4) hazard identification of nanoparticles and prevention strategy for occupational health problem. KOSHA is carrying out the project on developing the measuring method for nanoparticles. KOSHA is preparing the safe guidance of nano safety for workers.

Korea Food & Drug Administration (KFDA)

KFDA has performed the Nanotoxicology Program from 2007 to FY 2011. Nanotoxicology Program is mainly focused on preparation of testing guidelines for nanomaterials in biomedical applications and sound promotion of related industry. Nanotoxicology Program consists of four main sub-projects which are toxicological evaluation, risk assessment, kinetics, and material synthesis and physico-chemical characterization.

6. Information on any public/ stakeholder consultation

MEST and Ministry of Knowledge and Economy (MKE) will co-host 6th International Nanotech Symposium & Exhibition in Korea with a theme of nanotechnology for sustainable world between 26-29 August 2008 in Ilsan, Korea.

THE NETHERLANDS

Highlights of developments since the 3rd meeting of the WPMN (Nov 2007, Paris)

In November 2006 the Dutch government issued a cabinet view on nanotechnologies. The aim of this cabinet view is to indicate whether the frameworks necessary for responsible developments are adequate or in need of adjustment or revision. This assessment will be made on the basis of the main areas of Opportunities, Dealing with Risks, Ethical and Legal Issues, Research Agenda, Coordination and Support base and Communication. The view can be briefly summarised as follows: nanotechnologies are new technologies that are already the subject of a great deal of research worldwide and that are being increasingly applied. It is important that the Netherlands participates in this, not only by keeping up with the development of knowledge in the field but also by securing a position in the vanguard. Furthermore, we must be alert to the possible risks that nanotechnologies entail. The Netherlands will only be able to take optimum advantage of the opportunities by dealing cautiously and carefully with the associated risks.

Based on this cabinet view a.o. the following actions have been taken:

- An interdepartmental working group on possible risks of nanotechnology has been established, which will produce an action plan for both applications and risks of nanotechnology (June 2008) and a document for the Government on the risk strategy by the end of 2008.

- A National Observatory dealing with the possible toxicological risks of nanoparticles has been established at the National Institute for Public Health and the Environment (RIVM). Its main tasks are signaling the major scientific developments on toxicological risks of engineered, unsoluble, non-biodegradable free nanoparticles. Hereto it participates in (inter)national working groups (a.o. OECD, ISO, SCENIHR, EFSA, ICON, SETAC) and (networking)projects (a.o. FP-7) and informs government and professionals. The Observatory does not perform research itself, but advices on research agendas.

- The Netherlands Nanotechnology Initiative (NNI), arising from the NanoNed consortium which is active in the area of possible applications of nanotechnology, has started working on a National Research Agenda. This agenda will include a section on possible risks, and is expected to be finished mid 2008.

Work completed, underway or planned

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

The Netherlands participate in the REACH CA Subgroup on nanomaterials.

The current opinion in the Netherlands is that the present regulatory framework in principle gives a good coverage; different aspects of production and products are at the same time subject to various Community provisions. Therefore, although there is no legislation specifically relating to nanotechnologies, generic legislation that applies to engineered nanosized materials in principle enables authorities to take prompt action if products pose a risk to health, safety or the environment. But since many knowledge gaps have been identified, and no data on which to determine the possible risks are available, it is not possible to assess the full extent to which the implementation of current regulations addresses any potential risks. In short the legislation is adequate but the implementation of it is inadequate due to lack of specific measures, parameters or control devices.

2. Developments related to voluntary or stewardship schemes

The VNO/NCW (Bussiness organization of the Netherlands) has taken the initiative together with the VNCI (United Dutch Chemical Industry) and has indicated they are working on a Letter of Intend to enter into a voluntary agreement with the Dutch government. Initiatives for a structural dialogue with multiple stakeholders has started in 2008. Update is expected before the 5th WPNM meeting in 2009.

3. Information on any risk assessment decisions

No information Provided

4. Information on any developments related to good practice documents

The SER (Dutch Socio Economic Council = existing of business rep., Union rep. and independent Academia) will be asked to advice on good practice on workplace exposure, start foreseen late 2008.

The Netherlands subscribes the Code of Conduct for responsible Nanosciences and Nanotechnologies Research, adopted by the EC (press release IP/08/193, Brussels, 8 Feb 2008).

5. Research programmes or strategies designed to address human health and/ or environmental safety aspects of nanomaterials

A survey (requested by the Ministeries of Labour and Environment) has been performed to give insight into the places where people work with nanomaterials in The Netherlands. In addition, the measures that are being taken and the communication of "best practices" has been studied. The final report is expected in July 2008.

A working group of the Ministries of Agriculture (food), Health (consumer goods, medicine), Labour (working conditions), Economic Affairs, Environment (substances) and Transport, Public Works and Water Management will prepare a paper which addresses the risk management strategy on nanotechnologies (focusing first on nanoparticles). This paper will then be discussed with stakeholders (Business, NGO's United Trade Unions) amended and sent to parliament by mid 2008.

A national research agenda including a "risks section" is being drafted by the Netherlands Nanotechnology Initiative (NNI) and the National Observatory.

The Netherlands will participate in the Sponsorship Programme developed by the OECD WPMN and be a co-sponsor of the performance of toxicological testing for the development of a risk assessment dossier for cerium oxide.

6. Information on any public/stakeholder consultation

The Dutch cabinet view on nanotechnology includes the foreseen installation of a so called "broad commission" with stakeholders from both science and the public. Individual actions to start a public debate have already been undertaken e.g. between employers' organizations, NGOs and the government.

The SER (Dutch Socio Economic Council = existing of bussines rep. Union rep. and independent Academia) has been asked to comment on a study regarding the exposure to nanoparticles in the workplace. Result of this study expected early 2009.

NEW ZEALAND

Highlight of developments since the 3rd meeting of the WPMN

- Funding decisions will be announced by July that are likely to include support for one or more research projects that investigate aspects of risks associated with manufactured nanomaterials.
- Environmental Risk Management Authority (ERMA) Emerging Technology Conference in May 2008.

Work completed, underway or planned

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

It has been established that if a nanomaterial has a known hazard or risk, there are regulatory systems in place in New Zealand that can regulate, eliminate or manage this hazard or risk. Depending on the circumstance in how the nanomaterials is used or poses a threat, a nanomaterial would be regulated under:

- the Hazardous Substances and New Organisms (HSNO) Act 1996 by the Environmental Risk Management Authority (ERMA);
- the Health and Safety in Employment (HSE) Act 1992 by the Department of Labour;
- the Food Act 1981, via the NZ (Maximum Residue Limits of Agricultural Compounds) Food Standards 2008[3], and the Australia New Zealand Food Standards Code[4], by the NZ Food Safety Authority.

The legislation in the above Acts is sufficiently broad enough to include manufactured nanomaterials and covers the majority of the potential exposure pathways of manufactured nanomaterials.

ERMA intends to establish a formal position on the regulation of nanomaterials under the HSNO Act. Specific data requirements for the risk assessment of nanomaterials will be developed which will take into account international harmonisation efforts on regulatory requirements for nanomaterials.

Further information on the HSNO Act and ERMA is available from:

- http://www.mfe.govt.nz/issues/hazardous/
- http://www.ermanz.govt.nz/index.html

2. Developments related to voluntary or stewardship schemes

There are currently no voluntary or stewardship schemes.

[3] http://www.nzfsa.govt.nz/policy-law/legislation/food-standards/nz-mrl-fs-2008-consolidation.pdf

[4] http://www.foodstandards.gov.au/thecode/foodstandardscode.cfm

3. Information on any risk assessment decisions

ERMA has not received any applications to import or manufacture a hazardous substance that contains manufactured nanomaterials. There have not been any applications to allow residues of nanomaterials in foods.

4. Information on any developments related to good practice documents

Cosmetics containing nanoparticles (other than zinc oxide or titanium dioxide[5]) must be notified to ERMA as a condition of the Cosmetic Products Group Standard[6]. The purpose of this provision is to provide information to inform technical review of such substances in the future, so that if necessary, the group standard can be amended to put in place controls relating to such substances. To date no notifications have been received from importers or manufacturers of cosmetics.

"Nanoparticle" is defined in the group standard as "a particle having three dimensions in the nanoscale and a diameter of less than 100 nanometres". This is an interim definition that can be readily revised when international consensus on definitions emerges.

5. Research programmes or strategies designed to address human health and/ or environmental safety aspects of nanomaterials

Research investment decisions for 2008/2009 are currently being finalised. At least one project has been funded that will investigate environmental fate and impacts of some manufactured nanomaterials (plant uptake of quantum dots and the flow on effects to other flora and fauna).

The MacDiarmid Institute for Advanced Materials and Nanotechnology[7], a New Zealand Centre of Research Excellence, received renewed funding for a further six years commencing in July 2008. They have introduced a new research theme with this new funding that will look at biological applications and implications of nanotechnologies, so has the potential to investigate risk-related issues.

A New Zealand company (Australo Ltd[8]) is developing a technology platform that offers a portable, robust and cheap tool for rapid particle detection at the nanoscale. The platform has potential for significant environmental applications and the company is engaged in several research collaborations with universities and science/technology companies in New Zealand and overseas to demonstrate proof of concept for a range of applications.

[5] The provision has not been applied to nanoparticles containing zinc oxide and titanium dioxide on the basis of a review by the Australian Therapeutic Goods Administration (TGA) which concluded that there was no cause for health concern at this time.

[6] http://www.ermanz.govt.nz/appfiles/orgctrl/pdf/HSR002552Con.pdf

[7] http://www.macdiarmid.ac.nz

[8] http://www.australo.com/

6. Information on any public/ stakeholder consultation

No public/stakeholder consultation has been conducted on the safety of nanomaterials; however an Emerging Technology Conference hosted by the Environmental Risk Management Authority in May (involving researchers, policy makers and members of the New Zealand Maori community) provided a forum for useful discussions of risk and regulatory issues of nanotechnologies.

Additional Information

The Ministry of Research, Science and Technology (MoRST) is continuing to run a scanning network that identifies emerging science trends and developments[9]. Nanotechnology is an area of active interest.

A nanotechnology regulatory subgroup is being established out of the Science and Technology Officials Group that MoRST has been convening. This will have representatives from relevant policy and regulatory agencies, as well as other interested organisations, and will coordinate nanotech regulatory and related activities across government.

The Bioethics Council will continue to investigate the cultural, ethical and spiritual implications of nanotechnology as part of their "future watch" function.

[9] http://www.morst.govt.nz/current-work/futurewatch/

NORWAY

Highlight of developments since the 3rd meeting of the WPMN

- Norway will participate in a Nordic project lead by the Danish Environmental Protection Agency. The project will focus on contributing OECDs work on nanomaterials regarding health and environmental risks.
- The Norwegian Pollution Control Authority has made an initial evaluation of the general use of nanomaterials and assessed the national regulations to cover protection of health and environment by use and release of nanomaterials.
- The Norwegian Pollution Control Authority has published a literature review on fate, mobility and ecotoxicity of manufactured nanoparticles in May 2008.

Work completed, underway or planned

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;

As a member of the European Economical Areas (EEA), Norway follows the regulation in EU.

2. Developments related to voluntary or stewardship schemes

For the time being there are no voluntary or stewardship schemes.

3. Information on any risk assessment decisions

No risk assessments on specific nanomaterials have been conducted in Norway.

4. Information on any developments related to good practice documents

Documents related to good practice have not been developed in Norway.

5. Research programmes or strategies designed to address human health and/ or environmental safety aspects of nanomaterials;

The Research Council of Norway has since 2002 had a research program called NANOMAT, for nanotechnologies and new materials, which also support research on health and environmental effects. The Council published in 2005 a report where questions related to human health, environmental safety, ethics and social aspects on nanotechnologies and new materials are discussed. A national strategy for nanoscience and nanotechnology was adopted by the Council in autumn 2006 and forward to the Minister of Education and Research.

With support from The Norwegian Research Council, Bioforsk Soil and Environment has established a national network for health, environment and ethic aspects of nanotechnology. The aims of the network are among other things, to define research needs and exchange ideas on research projects both nationally and internationally and to communicate contact between scientists and trade and industry in relation to any need for health, environmental and ethical assessments.

The Norwegian Pollution Control Authority has published a literature review on fate, mobility and ecotoxicity of manufactured nanoparticles in May 2008.

6. Information on any public/ stakeholder consultation

The report from the Research Council of Norway has been presented at an open meeting. The work on the national strategy has also been an open process and a draft strategy was put out for public hearing.

Additional Information

For exchange of information on ongoing activities and possible coordination of work it has been established a network group between different authorities responsible for the regulation of production and use of nanomaterials.

SLOVAK REPUBLIC

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;**

There is exists the system of national legislation in Slovakia which protects the human health and environment from negative impacts of products. These legally binding instruments can be applied for protection of environment and human health in relation to the nanomaterials and nanotechnology. However in the present time the inventory of existing nanomaterials in market as a source of potential risks for environment and human health is needed. From our point of view it is urgent need and demand for internationally acceptable methodology for nanomaterials risks establishing and evaluation. The international exchange of information at the field of physical and chemical properties and environmental and health risks of nanomaterials is needed for better protection of our environment and human health, from possible negative impacts of nanomaterials and nanotechnologies.

2. **Developments related to voluntary or stewardship schemes;**

At present there are no specific initiatives in relation to voluntary or stewardship schemes in Slovak republic.

3. **Information on any risk assessment decisions;**

No risk assessments on specific nanomaterials have been conducted in Slovakia and no specific risk assessment decisions have been taken in relation to nanomaterials.

4. **Information on any developments related to good practice documents;**

In Slovakia we are not in a position to develop good practice documents, which needs more specific knowledge and information exchange concerning manufactured nanomaterials, but such internationally accepted guidance are needed for our decision making process and we are opened for share our experiences and for international cooperation at this field.

5. **Research programmes or strategies designed to address human health and/ or environmental safety aspects of nanomaterials;**

There is no existing joint governmental strategy for nanomaterials in Slovak republic or specific overall research programmes in this area. However several strategies dealing partly with nanomaterials such as Economic development strategy, Research strategy and nanoparticles such as Sustainable development strategy or Health care strategy was worked out and approved by Government or Parliament. In this time we have not common specific strategy which is dealing with human health or environmental safety aspects of nanomaterials.

It was established the new governmental advisory body for nanomaterials. This body was created from stakeholders and experts of environment, health and economy ministries, experts from scientific institution and universities, stakeholders from producers and consumers associations. The main goal of this advisory body is work out the common strategy for nanomaterials.

At the field of research Ministry for the environment and Slovak academy of sciences sign up an agreement and create the working group for nanomaterials as an advisory body for research development at this area. Research institutions and universities have now issued a series of projects addressing aspects of

further research on nanomaterials, including their health and environmental risks. Created working group for nanomaterials is used for exchange of knowledge and further cooperation between national authorities and producers of nanomaterials in Slovak republic. Under the preparation is a project for mapping the existing producers and products containing nanomaterials in our market and for subscribing their possible negative impacts environment and human health.

One of the most important part of research at the field of nanomaterials are construction ceramics, such as silicon nitride, titanium nitride, boron nitride, silicon carbide and titanium carbide and colour pigments. Ultra fine nano scale powders for construction ceramics are prepared by chemical vapour deposition or sol – gel methods.

6. Information on any public/ stakeholder consultation;

Slovak Institute for Standardization created the new technical commission for nanomaterials. Technical commission set up a new network expert group for nanomaterials with various stakeholders represented by national authorities, industry representatives, universities and Slovak academy of sciences. This technical commission was created in relation to the standardization work concerning nanomaterials in ISO and CEN.

SPAIN

Highlight of developments since the 3rd meeting of the WPMN

- Spain has announced its willingness to join the *OECD Sponsorship Program to Test Manufactured Nanomaterials*, which was launched following the 3rd Meeting of the WPMN (Paris, Nov. 2007).
- Several international scientific events on N&N have been organized.
- Public awareness is increasing.

Work completed, underway or planned

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

No regulations specifically addressing nanomaterials are present in Spain yet. EHS issues related to Manufactured Nanomaterials are currently under discussion by different organizations, including the Spanish REACH Reference Center (SpRRC) which follows the mandate of the Ministry of the Environment, Rural and Marine Affairs supporting the Ministry on technical and scientific issues.

2. Developments related to voluntary or stewardship schemes

At present there are no voluntary or stewardship schemes in Spain.

3. Information on any risk assessment decisions

At present, Spain has not conducted any specific risk assessments or taken any risk assessment decisions.

4. Information on any developments related to good practice documents

Spain will follow the recommendations in *Code of Conduct for Responsible Nanosciences and Nanotechnologies Research* adopted by the EC (Press Release IP/08/193, Brussels, 8 Feb., 2008).

5. Research programmes or strategies designed to address human health and/ or environmental safety aspects of nanomaterials

The Ministry of Science and Innovation is expected to publish shortly the bases for the Nanoscience/Nanotechnology specific program, considered as strategic objective in the R&D+I National Plan 2008-2011, including topics related to their potential impact on human health and the environment among its lines (e.g., nano-ecotoxicity). At the same time, Ministry of Environment and Rural and Marine Affairs has encourage, and will partially support, with the technical and scientific support of the SpRRC, the participation of Spain in the OECD Sponsorship Program to Test Manufactured Nanomaterials, by cosponsoring the testing of two types of nanomaterials.

6. Information on any public/stakeholder consultation

No public or stakeholder consultations have been conducted yet. However, SpRRC is contacting interested R+D in Spain, intended for gathering useful contributions on guidelines, standardization and assessment needs.

Additional Information

There has been an increasing awareness in general public, in media and in the political bodies in Spain concerning nanotechnological products and processes in relation to potential environmental and health risks. Thus, the workshop *Nanotechnology: Society, Health and the Environment*, was held in Complutense University (Madrid, 3-5 March, 2008) organized by ISTAS (Health, Environment and Work Place Union Institute) with the participation of representatives from Unions, EC, OCDE, Ministries of Science and of Environment, Research Centers in N&N and Social Sciences.

The following scientific events have been organized by Spanish platforms:

- *NanoSpain 2008 – NanoIberian Conference* was held in Braga (Portugal, Apr. 14-18, 2008), coorganized by the networks NanoSpain and PortugalNano, and participation of C'Nano Grand Sud Ouest (France). www.nanospainconf.org/2008/index.php?conf=08
- The international event *Trends in NanoTechnology* 2008 edition (TNT2008) will be held in Oviedo (Spain, Sept. 01-05, 2008). www.tntconf.org/2008/index.php?conf=08

SWITZERLAND

Highlight of developments since the 3rd meeting of the WPMN

- Approval of the Swiss Action Plan on synthetic Nanomaterials by the Federal Council
- Launch of the National Research Programme ”Opportunities and Risks of Nanomaterials”

Work completed, underway or planned

Swiss Action Plan on Synthetic Nanomaterials

The action plan on synthetic nanomaterials was approved by the Federal Council on 9 April 2008. The package of measures pursues four objectives:

The action plan will create regulatory framework conditions for the responsible handling of synthetic nanoparticles. The development of a methodology allowing risk characterisation of nanomaterials based on existing knowledge will be a first goal. This methodology can be used by the industry to assess their products and for the decision on risk management measures. Only when the methodological foundations and well-grounded risk assessments of synthetic nanomaterials are available, can additional statutory framework conditions for the safe handling of synthetic nanomaterials be developed.

Possible risks for humans and the environment arising in the course of the manufacture, use and disposal of these nanomaterials cannot yet be conclusively evaluated, as the scientific and methodological basis is currently lacking. The action plan aims to foster research to narrow the knowledge gaps. The National Research Programme ”Opportunities and Risks of Nanomaterials” that has been launched by the Federal Council on 28 November 2007 will contribute substantially to this aim.

Communication and public dialogue are key prerequisites for the rational engagement with nanotechnology, and should therefore be encouraged. Including the public, industry and science in the debate about the opportunities and risks of nanotechnology must be an integral part of its development.

The potential of nanotechnology for efficient use of resources and health protection is of major social and economic relevance. The collaboration of research and industry to invest is such applications of nanotechnology should be promoted. Existing Federal funding schemes can be used for funding.

Developments related to voluntary or stewardship schemes

No governmental activity so far.

Information on any developments related to good practice documents

An important goal of the Swiss action plan is the development of a method based on existing knowledge to estimate health and environmental risks form production use and disposal of nanomaterials or its applications. The development of this so called "safety matrix" is ongoing.

Trade and industry are obliged to assess their products and applications as part of the existing provisions on self-supervision, if necessary to take measures to reduce risk, and to inform their customers of such measures. As employers they must take all the required measures to protect their employees. Corresponding instructions are being drawn up on the basis of the safety matrix.

Research programmes or strategies designed to address human health and/ or environmental safety aspects of nanomaterials

The new National Research Programme "Opportunities and Risks of Nanomaterials" was launched by the Federal Council on 28 November 2007: The call for research projects is planned for spring 2009.

Some Federal agencies and universities have given safety research on nanomaterials a high priority.

Selected ongoing projects:

Title: *Nanoinventory*
Project leader: Michael Riediker, Institute for Occupational Health Sciences (IST) Lausanne (Michael.Riediker@hospvd.ch)
Duration: 2006-2009
Link:http://www.i-s-t.ch/fileadmin/users_datas/recherche/advancement_of_nanoinventory_www.pdf

Title: *Cytotoxicity of Nanoparticles*
Project leader: Wendelin Stark, Institute for Chemical and Bioengineering, ETH Zürich (wendelin.stark@chem.ethz.ch)
Duration: 2005-2008

Title: *Analysis of the human exposure to nanomaterials in Switzerland*
Project leader: Konrad Hungerbühler, Institute for Chemical and Bioengineering, ETH Zürich (hungerb@chem.ethz.ch)
Duration: 2006-2009

Titel: *Ecotoxicology of Nanoparticles: Biota-Nanoparticle-Pollutant Interactions in aqueous systems - Comparison of Black Carbon and Carbon Nanotubes*
Project leader: Bernd Nowack , EMPA Material Science and Technologies (nowack@empa.ch)
Duration: 2008-2011

Titel: *Interplay of lung cells and their cellular responses upon exposure to combustion-generated ultrafine particles and manufactured nanoparticles*
Project leader: Barbara Rothen-Rutishauser, Institute for Anatomy, University of Bern (rothen@ana.unibe.ch)
Duration: 2007-2010

Information on any public/ stakeholder consultation

Communication and promotion public dialogue is a goal of the Swiss action plan. It is planned to improve communication with the different stakeholders on possible risks and opportunities of nanotechnologies. Communication should allow opinion-forming which may influence technology development. On the other approaches to the safe handling of synthetic nanomaterials must be debated and discussed among the different stakeholders to be accepted and to be successful.

UNITED KINGDOM

1. Developments in the UK's Voluntary Reporting Scheme (VRS) for Manufactured Nanomaterials

A total of 9 submissions have been received since the launch of the VRS in September 2006, seven from industry and 2 from academia. The VRS will conclude in September 2008, after which recommendations on further initiatives will be put to UK government ministers.

The VRS is targeted at any company or organisation involved in manufacturing, using, importing or managing wastes consisting of engineered nanoscale materials. Information requested includes any data on: physico-chemical, toxicology, ecotoxicology and risk management practices.

Following the review of the scheme by the Advisory Committee on Hazardous Substances (ACHS) which recommended that the scheme's objectives and data requirements be more clearly articulated, new guidance prepared by the Institute of Occupational Medicine was published in March 2007. This clarified the aims and focuses of the scheme and provided detailed technical advice to those wishing to submit data. To coincide, the UK government wrote to a number of specifically targeted companies and research bodies, enclosing the updated guidance and urging support for the scheme.

The UK Government, in partnership with the UK Technology Strategy Board, is funding a telephone survey of recipients of the above letter. This survey will be undertaken between May and August 2008 and will attempt to find out more about the nature of these companies/researchers' activities and their attitudes to the VRS. As part of this process, assistance will be offered to those wishing to submit data to the scheme, in the form of telephone advice or site visits. All

2. Information on any developments related to good practice documents

At the end of 2007, the British Standards Institution (BSI) published 9 nanotechnologies documents – 6 terminologies (for: medical, health and person care applications of nano; the bio-nano interface; nanoscale measurement and instrumentation; carbon nanostructures; nano-fabrication; and nano materials), and three guides (guidance on labeling of manufactured nanoparticles and products containing manufactured nanoparticles; a good practice guide to specifying manufactured nanomaterials; and a guide to safe handling and disposal of manufactured nanomaterials). These documents have been available on the www for free download since the beginning of 2008 and can be obtained at www.bsigroup.com/nano . All of these documents will be used to support new work item proposals, or existing work items, in either CEN (the European Committee for Standardization – guidance on labeling) or ISO (all other documents).

Work is currently underway on a research project to support the development of a guide to nanoparticle exposure assessment, which is expected to be published by mid 2009. This document will complement the guide to safe handling which has already been published.

The Responsible Nano Code is a framework of best practice for organisations working on the development, manufacture, retail or disposal of products using nanotechnologies. It has been developed by a non government multi stakeholder group in the UK. An interim update is available, which outlines the Seven Principles of the Responsible Nano Code to be adopted by organisations; this will be developed into a more detailed benchmark for organisations to be assessed against. This more detailed framework and information on the benchmark is likely to be available from October. Further details are available at: http//www.responsiblenanocode.org.

Characterising the potential risks posed by engineered nanoparticles – a second UK Government research report **http://www.defra.gov.uk/environment/nanotech/research/reports/index.htm**.

Full details of ongoing research addressing environment, health and safety issues of nanomaterials can be found in the UK's 2nd Government Research report: Characterising the Potential Risks posed by Engineered Nanoparticles (see below)

This report, published on 19 December 2007, provided details of progress made on the UK Government's 19 nanotechnology research objectives. Substantial work has been carried out to further characterise the potential risks to human health and the environment from manufactured nanomaterials. Gaps in our knowledge for the effective appraisal of these risks are being addressed by the co-ordinated work of government departments and agencies, research councils, academia and industry whose work this report provides and account of.

Feedback on the report included particular reference to the potential risks that gaps in our knowledge of the nature and behaviour of nanoparticles might have on the application of nanotechnology to food and farming. Other comments from the Royal Society and the Woodrow Wilson Centre were favourable to the report although concern for a need for further funding towards nanotechnology research was voiced.

Some projects that have commenced during 2008 include:

An outline scoping study to determine whether high aspect ratio nanoparticles (HARN) should raise the same concerns as do asbestos fibres.

This study was commissioned by Defra to review the existing literature and set out a research strategy towards determining whether the health concerns about HARN are well-founded. The work was carried out by the Institute of Occupational Medicine and the report will be published in June 2008.

A study to identify the physico-chemical factors controlling the capacity of nanoparticles to penetrate cells.

Two grants were made under this research topic funded by Defra.

The first project, being carried out by the Institute of Occupational Medicine, set out to scope the existing and required research into mechanisms of translocation of nanoparticles across the respiratory epithelium and the resulting possible toxic effects in and beyond the lung and to advise on the feasibility of achieving the following outcomes:

- Identifying which features of nanoparticles are important in particle-cell interactions, considering the potential role of surface chemistry, structure, mass, numbers, shape, surface area, surface charge and surface functionalisation
- Suggesting how nanoparticles may be modified to enhance or reduce their capacity to enter cells
- Suggesting how interactions between nanoparticles and cultured human cells might be studied.

The second project, experimentally based and being undertaken at Imperial College, London, set out to determine:

- Which (combination) of factors influence nanoparticle uptake and/or translocation by/into human alveolar epithelium - particle size, surface area, surface charge?
- The fate/cellular location of internalised nanoparticles and whether particle uptake is active or passive
- The influence of the lung lining fluid (lung surfactant) on these processes.

Reports from both studies are due in June 2008.

A review of completed and near-completed environment, health and safety research on nanomaterials and nanotechnology – EMERGNANO

The objectives of this study, being undertaken by the Institute of Occupational Medicine and funded by Defra, are to provide:

- A detailed review and analysis of research carried out worldwide on Environment, Health and Safety aspects of engineered nanomaterials including issues relating to hazard, exposure and risk assessment and regulation
- An evaluation of how far research objectives outlined in the 2005 Government Research Report have been met to identify which gaps still remain to be filled
- An appraisal of research results with a view to highlighting any new information on hazards and risks to human health and/or the environment from nanomaterials that may trigger a consideration for the need for regulation of nanomaterials
- An interim position regarding the magnitude of risk and associated uncertainty given the evidence to date (and where the largest uncertainties lie), noting that this will almost certainly be a qualitative risk assessment process that is under review wrt fitness for purpose
- An opinion of whether there is sufficient information to invoke the precautionary principle for one or pore nanomaterials
- Specific recommendations for new research to fill gaps in the understanding of the potential risks posed by engineered nanomaterials taking into consideration, as far as practicable, work currently in progress.

National Physical Laboratory – Chemical and Biological Metrology Programme

Four projects within this programme funded by the Department for Innovation Universities and Skills commenced in April 2008.

1. Cell imaging for nanotoxicology

   The objectives for this project are:

- To support the safe development of nanotechnology products by developing standard protocols for assessing the cytotoxic effects of nanoparticles *in vitro*, in liaison with other nanotoxicology and nanosafety initiatives in the UK
- To develop a capability for the imaging of cells and their interactions with nanoparticles, to support nanotoxicology studies
- To develop standard protocols for the tracking of the uptake, localisation and fate of fluorescent nanoparticles within cells

To develop standard protocols for measuring the response of cells to exposure to nanoparticles

2. Toxicology of Nanoparticles

Project objectives:

- To assist UK industry in developing safe nanomaterials and assist Government in developing risk assessment strategies for managing public/workplace/environmental health and safety
- Promote nationally or internationally agreed protocols to investigate toxicology of nanoparticles and integrate with other UK and international researchers and regulators for standardisation of toxicology assays.
- Assess parameters that cause variability in epithelia exposure assays, including the manipulations during routine cell maintenance and their state when harvested for the assay.
- Select appropriate endpoint parameters for the chosen assay, based on imaging of cell morphology, viability or oxidative stress

3. Nanoparticle characterisation: surface area and other parameters.

Project objectives:

- Comparison of techniques and assessment of measurement uncertainties in rapid surface area measurement of samples of nanoparticles
- Standard procedures and measurements on an agreed reference sample for: water solubility, representative TEM pictures, zeta potential, specific surface area and particle size distribution.
- Selective investigation of other parameters such as agglomeration/aggregation, crystalline phase, crystallite size and storage.

4. Nanoparticle characterisation: discrimination of engineered nanoparticles

Project objectives:

- Development of air and aqueous pre-treatment methods to remove carbonaceous and sulphurous particles (e.g. products of incomplete combustion and other environmental particles)
- Prototype UV/ozone pre-treatment chamber for removal of environmental nanoparticles by oxidation, leaving engineered inorganic nanoparticles in their highest oxidation state for subsequent counting and characterisation
- Protocol for operation in conjunction with commercial particle counting and sizing instruments (including flow rates, UV intensities, cross-sections and ozone concentrations)

The UK Government's Department of Health is in the process of commissioning work on:

- determining the characteristics of nanomaterials that confer toxicity
- inhalation studies using nanomaterials
- studies of the transfer of nanoparticles across skin

In the current round £650k is being committed with a further £600k to be spent in 2009.

4. Information on any public/ stakeholder consultation

The UK government has funded a consultation to assess the potential for a new organisation to co-ordinate public engagement on nanotechnologies, through multi-stakeholder debate and encouraging all organisations to play their part in minimising the risks and realising the benefits of nanotechnologies. The final report will be available shortly.

Additional Information

UK Advisory on Carbon Nanotubes issued by Environment Agency and Health and Safety Executive

On May 20th, and in response to research published in the UK, the Environment Agency wrote to the UK Nanotechnologies Industry Association and Research Councils advising that, with immediate effect, waste containing free i.e. unbound carbon nanotubes be classified as hazardous.

The Environment Agency has issued guidance on the preferred disposal option for waste containing unbound carbon nanotubes. This entails designating the waste an appropriate List of Waste Entry code to ensure it is appropriately consigned as hazardous waste, and incineration of the waste at 850°C for a minimum of 2 seconds to ensure complete carbon nanotube breakdown.

The Environment Agency is taking this as a precautionary measure and will revise this position in light of new evidence as and when more information becomes available.

In addition, the UK Health and Safety Executive (which is responsible for occupational health and safety in the UK) is advising users of carbon nanotubes to treat these as substances of very high concern unless they have sound evidence that this is not the case.

UNITED STATES

Highlight of developments since the 3rd meeting of the WPMN

- The NNI released *Strategy for Nanotechnology-Related Environmental, Health, and Safety Research* (February 2008).
- NIST signed a cooperative with the European Commission Joint Research Centre Institute for Reference Materials and Measurements to advance the development and availability of international measurement standards for EHS of engineered nanomaterials (December 2007)
- NIST issued three nanoscale gold reference materials to evaluate and qualify methodology and/or instrument performance related to the physical/dimensional characterization of nanoscale particles used in pre-clinical biomedical research. (December 2007)
- NIST published guidelines for making measurements on samples of SWCNTS (March 2008)
- NIOSH released updated draft Strategic Plan for NIOSH Nanotechnology Research for public review (March, 2008)
- NIOSH posted a series of brochures and fact-sheets describing NIOSH recommendations and efforts in nanotechnology (2008)
- NIOSH released a draft document of interim guidance concerning the medical screening of workers potentially exposed to engineered nanoparticles in the manufacture and industrial use of nanoparticles for public review (December, 2007)
- EPA launched the Nanoscale Materials Stewardship Program (NMSP) (January 2008)
- EPA issued its draft *Nanomaterial Research Strategy* (February 2008)

Work completed, underway or planned

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

In January 2008, EPA released the final version of a paper entitled TSCA Inventory Status of Nanoscale Substances – General Approach. The purpose of the paper was to assist manufacturers of nanoscale materials to make the distinction between "new" and "existing" chemicals on the TSCA Inventory.

EPA has received and reviewed a number of new chemical notices for potential nanoscale materials under TSCA. EPA has permitted manufacture of these nanoscale materials under limited conditions.

2. Developments related to voluntary or stewardship schemes

In December 2007, NIOSH posted for public review a draft document of interim guidance concerning the medical screening of workers potentially exposed to engineered nanoparticles in the manufacture and industrial use of nanoparticles on the NIOSH Web page (http://www.cdc.gov/niosh/review/public/115/). The guidance was developed to generate discussion, fill current knowledge gaps and provide interim recommendations until further scientific information becomes available. This document is undergoing external peer-review in the first half of 2008.

On January 28th 2008, EPA launched the Nanoscale Materials Stewardship Program (NMSP). The NMSP was designed for Companies that manufacture, import, process, or use nanoscale materials for

commercial purposes to voluntarily submit data to EPA and also to participate in the development of additional data. To date EPA has received three submissions for nanoscale materials under the basic program. EPA has also received a commitment by ten additional companies to submit data on nanoscale materials under the basic program.

3. Information on any risk assessment decisions

EPA has assessed a number of new chemical notices for potential nanoscale materials under TSCA. In 2008, NIOSH is preparing a final Current Intelligence Bulletin (CIB) on occupational exposure to titanium dioxide, following two public meetings, public comment period, and scientific peer review of the November 2005 draft CIB.

4. Information on any developments related to good practice documents

NIST held an International Workshop on Documentary Standards for Measurement and Characterization in Nanotechnologies with ISO, IEC, and OECD. Sessions included foci on identification of documentary standards needs for nanomaterials in human health and the environment. 02/08

NIST published guidelines for making measurements on samples of single-walled carbon nanotubes (SWCNTs). The new guide constitutes the current "best practices" for characterizing SWCNTs. 03/08

NIST and the Canadian National Metrology Institute are developing a publication on sample preparation protocols for carbon nanotube characterization.

NIOSH has been developing a series of brochures and fact-sheets describing NIOSH recommendations and efforts in nanotechnology. The first brochure in this series, "Safe Nanotechnology in the Workplace: An Introduction for Employers, Managers, and Safety and Health Professionals," is available on the web at http://www.cdc.gov/niosh/docs/2008-112/pdfs/2008-112.pdf. First three fact sheets The Nanotechnology Field Research Team Update (http://www.cdc.gov/niosh/docs/2008-120/), NIOSH Nanotechnology Field Research Effort Fact Sheet (http://www.cdc.gov/niosh/docs/2008-121/), NIOSH Nanotechnology Metal Oxide Particle Exposure Assessment Study (http://www.cdc.gov/niosh/docs/2008-122/) were published in March, 2008. Additional nanotechnology fact sheets will be available at http://www.cdc.gov/niosh/whatsnew.html.

In December 2007, NIOSH posted on the NIOSH Web page, http://www.cdc.gov/niosh/review/public/115/, a draft document of interim guidance concerning the medical screening of workers potentially exposed to engineered nanoparticles in the manufacture and industrial use of nanoparticles for public review. The guidance was developed to generate discussion, fill current knowledge gaps and provide interim recommendations until further scientific information becomes available. This document is undergoing external peer-review in the first half of 2008.

5. Research programmes or strategies designed to address human health and/ or environmental safety aspects of nanomaterials

The interagency Nanoscale Science, Engineering, and Technology (NSET) Subcommittee of the National Science and Technology Council's Committee on Technology released in February 2008 the *Strategy for Nanotechnology-Related Environmental, Health, and Safety Research* (http://www.nano.gov/NNI_EHS_Research_Strategy.pdf). The document lays out the National Nanotechnology Initiative's (NNI) strategy for addressing priority research on the environmental, health, and safety (EHS) aspects of nanomaterials and reflects a strong consensus and commitment among the NNI member agencies on the roles they will assume, consistent with their respective missions and responsibilities, to move the Federal efforts in nanotechnology-related EHS research forward.

The strategy, prepared by the subcommittee's Nanotechnology Environmental and Health Implications (NEHI) working group, presents a path for coordinated interagency implementation of research to address the priority nanotechnology-related EHS research needs identified in earlier reports. It is based in part on a detailed analysis of the Federal Government's FY 2006 nanotechnology-related EHS research portfolio, a $68 million investment in 246 projects. Experts from the NEHI Working Group analyzed how these activities addressed the priority research needs and then proposed emphasis and sequencing for future research efforts. Agency-specific research and regulatory needs, public comments on the prior documents, and considerations of the state of EHS research in the national and international nanotechnology communities all played an important role in shaping the strategy

The NNI released its draft strategic plan in December 2007. The plan represents a consensus of the participating agencies as to the goals and priorities of the NNI.

The President's Council of Advisors on Science and Technology (PCAST) released its second assessment and recommendations for the NNI.

NIST is developing characterization methods and standards for nano EHS in the U.S. Work is underway to develop analytical methods for quantifying the type and amount of nanomaterials in biological matrices, the environment, and the workplace. Efforts are focused to evaluate the scope and suitability of technologies to quantify nanomaterials across biological media indicative of exposure. In addition to nanomaterial characterization, the development of reference materials and methods to validate toxicity testing are part of this program. Selected activities to date include:

- Development and issue of gold reference nanoscale particles for labs studying the biological effects of nanoparticles.
- Delivery and installation of the World's first commercial helium ion microscope for the analysis and characterization of nanoparticles.
- Development of a new microscope design to allow researchers to track the motions of nanoparticles in fluids in three dimensions.
- Investigations of carbon nanotube length effects on their cellular uptake and optical properties.
- Determine cooperative behavior (chain formation) of magnetic nanoparticles which impacts nanomedicine applications.
- Studies of nanoparticle and cell interactions monitored by quartz crystal microbalance and optical spectroscopy.
- Studies of nanoparticle cytotoxicity in collaboration with the US Food and Drug Administration.
- Investigations on the behavior of engineered nanomaterials in aquatic environments.

The U.S. Environmental Protection Agency's draft *Nanomaterial Research Strategy* was released in February 2008 and underwent external peer review. The review is intended to be a compilation of individual reviewers' comments and not a consensus review. A peer review report is expected in May, and during the summer EPA will address reviewers' comments in a next draft of the Strategy.

A 2007 paper co-authored by U.S. EPA's Bellina Veronesi and published in ***Environmental Science & Technology*** has been designated a "Hot Paper" based on the high number of citations it received in the past two-month period. In addition, an earlier 2006 publication received recognition as a highly cited, influential publication soon after it was published. The two papers are:

> Long, Thomas C, Tajuba, Julianne, Saleh, Navid, Sama, Preethi, Parker, Joel, Swartz, Carol, Lowry, Gregory V, and Veronesi, Bellina. (**2007**). Nanosize Titanium Dioxide Stimulates Reactive Oxygen Species In Brain Microglia And Damages Neurons In Vitro, *Environmental Health Perspectives* 115 (11) 1631-1637.
>
> Long, T., Saleh, N., Tilton, R., Lowry, G. V., Veronesi, B. (**2006**) "Titanium Dioxide (P25) Produces Oxidative Stress in Immortalized Brain Microglia (BV2): Implication of Nanoparticle Neurotoxicity" *Environ. Sci. Technol.* 40 (14) 4346-4352."

In 2008, NIOSH assessed state of knowledge in occupational safety and health aspects of nanotechnology and conducted a critical gap analysis of research needs using Progress Toward Safe Nanotechnology in the Workplace (http://www.cdc.gov/niosh/docs/2007-123/). An updated draft Strategic Plan for NIOSH Nanotechnology Research was released for public review in March, 2008 (http://www.cdc.gov/niosh/topics/nanotech/strat_plan.html).

In 2007 and 2008, NIOSH researchers have published several leading scientific papers pertaining to occupational health and safety of workers producing or using nanomaterials. These papers include:

Schulte PA, Trout D, Zumwalde RD, Kuempel E, Geraci CL, Castranova V, Mundt DJ, Mundt KA, Halperin WE (2008). Options for Occupational Health Surveillance of Workers Potentially Exposed to Engineered Nanoparticles: State of the Science. J Occup Environ Med 50(5):517-526.

Schulte P, Geraci C, Zumwalde R, Hoover M, Kuempel E (2008). Occupational risk management of engineered nanoparticles. J Occup Environ Hyg 5(4):239-249.

6. Information on any public/ stakeholder consultation

NIST continues to leverage nanotechnology standards development work among other Federal programs, establish direct collaborations with other Federal agencies, and work with representatives from the risk assessment and regulatory communities represented by government, academia, industry, and the international community. Specific meetings at NIST with other agencies to strengthen collaborations on the characterization of nanomaterials and the development of reference materials have occurred with the NIOSH,U.S. FDA, and the National Cancer Institute's Nanotechnology. NIST continues to participate in and lead efforts on the development of nanotechnology standards in standard development bodies: ISO TC 229 Nanotechnologies, IEC TC 113 Nanotech. Stand. for Electrical and Electronic Products & Systems, ASTM E56 Nanotechnology, IEEE Nanotechnology Council Standards Committee, and the OECD Working Party for Manufactured Nanomaterials. NIST continues to participate as a member agency with the National Nanotechnology Initiative and provide service to the NEHI WG.

Recent examples of stakeholder workshops include:

i. Interagency Working Group on Manufacturing Research and Development workshop on Instrumentation, Metrology, And Standards for Nanomanufacturing - report due 2008

ii. Workshop on Material Standards for EHS for Engineered Nanoscale Materials to identify standard materials needed to address toxicology and risks of engineered nanoscale materials 09/07

iii. Workshop with NASA on Nanotube Measurements to focus on issues of nanotube quality and characterization 09/07

iv. Second Tri-National Workshop on Standards for Nanotechnology with National Measurement Institutes of Canada and Mexico to cover the state of nanotechnology in all three North American nations and the limits of current technology and standards – both documentary and physical. 02/08

v. Workshop on Cross Industry Issues in Nanomanufacturing with EHS as a cross-cutting issue for industry 04/08

Examples of cooperative agreements are:

vi. NIST signed an agreement with the European Commission Joint Research Centre Institute for Reference Materials and Measurements which included a focus to advance the development and availability of international measurement standards for EHS of engineered nanoscale materials. 12/07

vii. NIST signed a cooperative agreement with the College of Nanoscale Science and Engineering of the University at Albany-State University of New York for future cooperative efforts to develop science and technology for measuring materials at the nanometer scale. 4/08

NIOSH invites public comments on its nanotechnology-related documents posted on NIOSH nanotechnology web-page (http://www.cdc.gov/niosh/topics/nanotech/), such as "Strategic Plan for NIOSH Nanotechnology Research: Filling the Knowledge Gaps" (http://www.cdc.gov/niosh/topics/nanotech/strat_plan.html) and "Interim Guidance on Medical Screening of Workers Potentially Exposed to Engineered Nanoparticles" (http://www.cdc.gov/niosh/review/public/115/).

The U.S. Environmental Protection Agency's held a public meeting on April 11, 2008 to conduct an external peer review on its draft *Nanomaterial Research Strategy.*

EUROPEAN COMMISSION

Highlight of developments since the 3rd meeting of the WPMN

- The European Commission has published on 17 June 2008 the "Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee: Regulatory aspects of nanomaterials". The Communication is accompanied by a more detailed document "Commission Staff working document: Summary of legislation in relation to health, safety and environment aspects of nanomaterials, regulatory research needs and related measures". The documents can be found on http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0366:FIN:EN:PDF and http://www.euractiv.com/29/images/SEC(2008)%202036_tcm29-173474.pdf

- On 1 June 2008 REACH (Registration, Evaluation, Authorisation of Chemicals) became operational and the six month pre-registration period for phase-in substances commenced. For further information consult the website of the European Chemicals Agency (ECHA); http://echa.europa.eu/home_en.asp.

- On 30 May 2008, the Commission Regulation (EC) No 440/2008, laying down test methods pursuant to the REACH Regulation (EC) No 1907/2006, was adopted. The regulation reinforces the 3R approach to animal testing and aim at an adoption of new alternative methods in a more expedient way than in the past. The Commission is preparing a proposal for the first adaptation to technical progress of this Regulation by the end of 2008

- The European Commission organised on 17 – 18 April 2008 in Brussels a "*Workshop on research projects on the safety of nanomaterials: reviewing the knowledge gaps*", The agenda, proceedings and presentations, please consult: http://cordis.europa.eu/nanotechnology/src/publication_events.htm

- The REACH Competent Authorities Group established on 27 March 2008 a sub-group on Nanomaterials to exchange views on existing and arising implementation issues and other matters in relation to nanomaterials under REACH. It is composed of experts from the Competent Authorities in the EU Member States, ECHA and from stakeholders from industry and NGOs. On this basis, the CASG-Nano will provide recommendations to the REACH CAs and the Commission. The group is planned to meet at twice yearly intervals starting on 1-2 July 2008.

- The European Commission adopted on 7 February 2008 a "*Recommendation to the Member States on a Code of Conduct for Responsible Nanosciences and Nanotechnology Research*", in line with the objective of the Community's Nanotechnology Action Plan. Based on seven principles; i) meaning (activities should be comprehensible); ii) sustainability; iii) precaution; iv) inclusiveness (with regard to stakeholders); v) excellence; vi) innovation; and vii) accountability (with regard to social and other impacts). The Code of Conduct contains suggestions for actions to be taken on good governance and due respects for precaution for responsible nanosciences and nanotechnology research. For further information see: ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/nanocode-recommendation-pe0894c08424_en.pdf

- The EU Scientific Committee on Consumer Products has adopted an opinion on "Safety of Nanomaterials in Cosmetic Products" in December 2007, the EU Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) adopted in June 2007 an opinion on "the appropriateness of the risk assessment methodology in accordance with the Technical Guidance Documents for new and existing substances for assessing the risks of nanomaterials" and in November 2007 an opinion a Scientific review of definitions related to the products of nanotechnology.

- A draft Regulation proposal on the classification and labelling of chemicals based on the Global Harmonised System, adopted by the Commission on 27 June 2007 repealing the EU Directives 67/548/EEC and 1990/45/EC on classification and labelling of substances and preparations. The proposal is now examined by the Council and Parliament, see http://ec.europa.eu/enterprise/reach/ghs_en.htm

- The first call for proposals in the 7th EU Research Framework Programme (FP7) was published on 22 December 2006. The proposals received on these topics have been evaluated and the research projects begin this year. Of particular interest is the coordination action "NanoImpactNet" (http://www.nanoimpactnet.eu/). The objective of the NanoImpactNet is to create a scientific basis to ensure the safe and responsible development of engineered nanoparticles and nanotechnology-based materials and products, and to support the definition of regulatory measures and implementation of legislation in Europe. The following basic forms of activities are planned:

  - Promotion of coordination on test strategies and methods; screening tools; risk assessment tools; and risk assessment methodologies.

  - Sharing and discussing existing knowledge in order to identify knowledge gaps; define strategies to address these gaps; and train staff and students.

- The second call for proposals in the 7th EU Research Framework Programme (FP7) was published on 30 November 2007. The proposals received will be evaluated in autumn. Updates on research projects open in 2008 funded by the European Commission can be found at:

ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/call-2008_nano.pdf

Work completed, underway or planned

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

According to the new regulatory review, existing EU legislation covers in principle the potential health, safety and environmental risks in relation to nanomaterials. The protection of health, safety and the environment needs mostly to be enhanced by improving implementation of current legislation. The Commission and EU Agencies will therefore in the first place review current documents that support implementation, such as implementing legislation, standards and technical guidance with regard to their applicability and appropriateness to nanomaterials.

Knowledge on essential questions such as characterisation of nanomaterials, their hazards, exposure, risk assessment and risk management should be improved. As knowledge becomes the critical factor for implementation and, eventually, legislation, targeted actions in a number of areas and at different levels,

particularly in the field of research and development, were launched as a matter of priority, particularly through FP 6 and 7, and the European Commission's Joint Research Centre. Activities are coordinated with international partners and stakeholders in the appropriate fora, such as the OECD and ISO.

Commission working groups in charge of coordinating implementation of legislation are examining on an ongoing basis whether regulatory change on specific aspects is necessary, taking into account the continuously generated information linked with the identified knowledge gaps. They will take into consideration work that has been carried out in this respect at national and international level.

Authorities and Agencies in charge of implementing legislation should continue to carefully monitor the market, and use Community market intervention mechanisms in case risks are identified for products already on the market.

A new sub-group under REACH (CASG Nano) focussing on nanomaterials has been set-up with a view to discuss how REACH applies to nanomaterials. The objective is to exchange views on existing and arising implementation issues and other matters in relation to nanomaterials under REACH. On this basis, the group will provide recommendations to the REACH Competent Authorities advising the Commission.

2. Developments related to voluntary or stewardship schemes

The European Commission has not developed any voluntary programmes or stewardship schemes. These and general issues regarding information on nanomaterials will be discussed in the CASG Nano.

3. Information on any risk assessment decisions

The European Commission has not taken any risk assessment decisions since the last Tour de Table document issued in November 2007 (ENV/CHEM/NANO(2007)16) of relevance in the context of nanomaterials. However, the European Commission has requested the Scientific Committee on Emerging and Newly Identified Human health Risks (SCENIHR) to identify and assess new information and update the opinions on potential risks of products of nanotechnologies, in particular, with respect to characterisation, eco-toxicology and toxicology as well as exposure assessments. The update should:

1. Provide, on the basis of the results obtained, recommendations on:
   - improvements of existing test methods and/or on the development of new ones, including in vitro and in vivo methods, to address aspects specific to nano in characterization and hazard assessment.
   - improvements in exposure assessment (including, amongst others, also relevant information on sampling, detection tests, instrumentation, modelling) to address aspects specific to nano and provide a list of specific nanomaterials/particles with possible substantial exposure noting current activities within the OECD Working Party on Manufactured Nanomaterials.
   - improvements in risk assessment in general including specifically information linked to mechanistic information to address aspects specific to nano.

2. Recommend further prioritised needs for short, medium and long-term research in areas related to the possible risks of products of nanotechnologies based on a knowledge gap closure analysis.
3. Identify, as much as possible scientific evidence permits, direct or indirect health risks with regard to current and foreseeable applications of nanomaterials based on information related to volume of production in different sectors. For the sector of cosmetics and medical devices indications from patents should also specifically be taken into account. Risks and specificities of different nanomaterials serving the same purpose shall, in as much as possible, be compared.

The opinion should be delivered in November 2008. For more information, please see http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_q_015.pdf

4. Information on any developments related to good practice documents

The European Commission's Code of Conduct (CoC) adopted on 7 February 2008 provides EU Member States, employers, research funders, researchers and more generally all individuals and civil society organisations involved or interested in nanosciences and nanotechnologies (N&N) research ("all stakeholders") with guidelines favouring a responsible and open approach to N&N research in the Community. The CoC:

- invites all stakeholders to act responsibly and cooperate with each other, in line with the N&N Strategy and Action Plan of the Commission, in order to ensure that N&N research is undertaken in the Community in a safe, ethical and effective framework, supporting sustainable economic, social and environmental development;
- covers all N&N research activities undertaken in the European Research Area;
- is voluntary. It offers a set of general principles and guidelines for actions to be taken by all N&N stakeholders. It should facilitate and underpin the regulatory and non-regulatory approaches outlined in the 2005-2009 N&N Action Plan for Europe, improving the implementation of current regulation and coping with scientific uncertainties;
- should also be a European basis for dialogue with third countries and international organisations.

The CoC is complementary to existing regulations. It does not limit or otherwise affect the possibilities of Member States to grant a wider measure of protection with regard to N&N research than is stipulated in this Code of Conduct.

Stakeholders who adhere to the CoC should also be inspired, where applicable, by the principles set out in the Charter of Fundamental Rights of the European Union. The CoC will be regularly monitored and revised every two years by the Commission in order to take into account developments in N&N worldwide and their integration in European society.

For more information, please consult: ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/nanocode-recommendation-pe0894c08424_en.pdf

5. Research programmes or strategies designed to address human health and/ or environmental safety aspects of nanomaterials

Also in the second year of FP7 several topics were launched specifically addressing the safety of nanomaterials. The proposals received for these topics have not yet been fully evaluated.

NMP-2008-1.3- 1 (Large scale integrating projects)	Validation, adaptation and/or development of risk assessment methodology for engineered nano-particles
NMP-2008-1.3- 2 (Small or medium-scale focused research projects)	Impact of engineered nanoparticles on health and environment

The European Commission has released a publication on nanotechnology research funding addressing potential health and environmental impacts of nanoparticles: EU nanotechnology R&D in the field of health and environmental impact of nanoparticles <ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/final-version.pdf>. The compilation aims at gathering the most complete overview of past and ongoing research projects funded by the Framework Programmes, EU Member States, Candidate Countries and Countries associated to FP6 or FP7 in the area of possible impacts in health, environment and safety of nanoparticles. It will be updated in the autumn to include new projects and additional information.

The JRC is developing a research activity in collaboration with EU partners on risk assessment of engineered nanomaterials. The activities in FP7 focus on the development and harmonization of methods for toxicity testing of nanomaterials, the *in vitro* test of a representative set of MN on critical cell lines and encompass related studies on nanometrology and reference materials as well as the development of databases and studies on the applicability of *in silico* methods adapting the traditional QSAR paradigm.

The Commission is considering supporting the development of a database containing substance information specific to nanomaterials. IUCLID could serve as a basis and could be further developed and adapted to the requirements related to nanomaterials datasets.

6. Information on any public/ stakeholder consultation

The Commission considers that dialogue is indispensable for emerging technologies such as nanotechnologies. Public trust in and acceptance of nanotechnologies are crucial for the long-term development. The Commission and a number of the Member States have also actively promoted multi-stakeholder dialogues on nanotechnologies, and numerous other outreach activities. These events have involved, depending on the special themes of the conferences, participation of public authorities, scientists, industry associations, consumers, environment and other non-governmental organisations. Furthermore these activities complement and are coordinated with various other activities at Member State level and by international organisations. Nevertheless, surveys have indicated that European public is not yet sufficiently aware of nanosciences and nanotechnologies. However, these surveys also show that public confidence in European public authorities' ability to ensure good governance for nanotechnology is higher in Europe than elsewhere.

The opinions from EU Scientific Committees, SCENIHR and SCCP are always submitted to public consultations before final adoption.

In the second year of FP7 several topics were launched specifically addressing outreach activities and public engagement. The proposals received for these topics have just been evaluated in June.

NMP-2008-1.1-2 Support to outreach and communication in nanotechnology

SiS-2008-3.0.3.1 Encouraging co-operation and networking between scientific events organisers on public engagement with science

7. Additional Information

The Commission passed a mandate (M/409) to CEN, CENELEC and ETSI for the elaboration of a programme of standards to take into account the specific properties of nanotechnology and nanomaterials in 2007 and received in May 2008 the final report, which includes information on:

- the programme of standardization items relevant to nanotechnologies;
- the legal status of foreseen standardization documents;
- an assessment of the feasibility of standardization work carried out at the international level;
- a draft roadmap of the progress of standardization activities considered necessary.

This report will now be discussed within the Commission with a view to decide on possible further action

RUSSIAN FEDERATION

Highlights

- Further participation in the work of some International organisations
- Further research initiatives
- Some national regulatory developments
- Some events devoted to Nanotechnology risks and benefits
- Activities regarding information dissemination

Work completed, underway or planned

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

Federal Consumer Rights and Human well being Department (Rospotrebnadzor) issued some regulations in 2007 (http://www.rospotrebnadzor.ru**)**:

- Regulation № 54 concerning the inspection of new products containing nanomaterials (23-d of July 2007).
- Regulation № 280 regarding the approval and implementation of methodological recommendations on the assessment of Nanomaterials safety" (12 of October 2007)
- Regulation № 79 regarding the Conception of the toxicological studies, risk assessment methodology, methods of identification and quantitative description of Nanomaterials (31 of October 2007)

2. Developments related to voluntary or stewardship schemes

No information

3. Information on any risk assessment decisions

No information

4. Information on any developments related to good practice documents

Documents related to good practice have not been developed in Russia until now.

5. Research Programmes or strategies designed to address human health and/or environmental safety aspects of nanomaterials

There are no current research programmes underway to address human health and/or environmental safety aspects of nanomaterials, but a number of R&T projects on impacts of nanoparticles on health and environment are funded by:

- Russian Foundation for Basic Research
- Federal Agency for Science and Innovation (ROSNAYKA) within the thematic priority "The industry of nanosystems and materials" of the Federal Target-oriented Programme "Research and Development in Priority Fields of S&T Complex of Russia for 2007-2012";

Studies of physico-chemical properties of Nanomaterials (in particular, nanoparticles) have been carried out by a number of Institutes of Russian Academy of Sciences (RAS) and Universities. Some researchers are including toxicological, ecotoxicological and metrological aspects on nanotechnology in their research , but there is no official network for these areas.

Some international projects on analysis of toxicity of nanomaterials have been funded by ISTC. A number of Russian organizations are the partners of these projects http://search.istc.ru/index.jsp?v=7.

6. Information on any public/ stakeholder consultation

No public/stakeholder consultation has been conducted on the safety of nanomaterials, however some events in Russia provided a forum for useful discussions of these problems:

6.1 The thematic workshop on Nanotechnology. Part 2. Impact of Nanomaterials on Environment, Health and Safety. "SCOPE-EAST" Conference, Moscow, December 3-4, 2007; http://scope-east.net/?p=conference_w_nano

6.2 SAFE FOODS Seminar, Russia Seminar on recent developments in the field of
Early identification and prevention of risks in food safety and the role of these develop-ments in risk analysis, Moscow, February 05-06, 2008; www.safefoods.narod.ru

6.3 Representatives of Russia participated in Workshop on research projects on safety
of Nanomaterials; reviewing the knowledge gaps. Brussels, April 17-18 2008.
The Workshop was organised by Directorate G-Industrial Technologies Nano- and Converging Sciences and Technologies European Commission

6.4 Representatives of Russia participated in NATO ARW "Nanomaterials:

Environmental Risks and Benefits and Emerging Consumer Products", Faro, Portugal, April 27-30 2008. **http://www.risk-trace.com/portugal2008/index.php**

Additional Information

In January 2008, a non-commercial organization «National Nanoindustry Association» (NCO «NNA») was established in Russia **http://www.nanotech.ru/nan/**

One of the critical directions of the work is to promote studies of Manufactured Materials impacts on EHS. NCO NNA organized two relevant events:

- "Waste Management using Nanotechnologies", Workshop, Concern Nanoindustry, National Association of Nanoindustry (NAN), Moscow, March 24, 2008

- "Nanotechnology in Chemical industry", Workshop, Concern Nanotechnology, National Association of Nanoindustry, Moscow, April 23, 2008.

Some events devoted to the problem of nanotechnology risks will be held in the future:

1. The 2-d International Conference on NanoBioTechnologies - NanoBio'2008 (www.spbcas.ru/nanobio), Saint-Petersburg, June 16-20, 2008;
The special session in the frame of this Conference: "The International Dialog on Nanotechnology Risk Assessment and Management. Opportunities for Russia"

2. NATO Advanced Research Workshop on Biological and Environmental Risks of Nanotechnology, Nanobionics and Hybrid Organic-Silicon Devices (Silicon vs. Carbon), Saint-Petersburg, June, 2007

3. "EU-Russia Co-operation in Biotechnology, Agriculture, Forestry and Food", V International Symposium, Pushchino, October 1-3 2008.
Special session "Nanotechnology in food industry"

4. The Nanotechnology International Forum will be held in Moscow (December 3-5, 2008). The organizer of this event is Russian Corporation of Nanotechnologies

The Programme of Forum includes the following topics:

- Metrology, standardization and certification in the sphere of nanotechnology and nanomaterials;

- Social and safety aspects of nanotechnology development.

http://www.rusnanotekh.com/nanoforum/

Activities regarding information dissemination

The expert analytical group for .nanosafety and nanorisks. based at the Center for Advanced Studies at the Saint-Petersburg State Polytechnic University (http://www.spbcas.ru) has prepared the book on potential risks of Nanotechnologies for human health and environment encompassing the international experience in this area (in press)

The article "International dialog on risks of manufactured nanomaterials" (M. Melkonyan) will be published in "Poisk" newspaper of Scientific Society of Russia (June, 2008)

Some Russian thematic web-sites includes the special section on nanorisks http://www.nanonewsnet.ru/; http://www.nanometer.ru/; http://www.nanoware.ru/

SINGAPORE

This was the first time that Singapore has been represented at the WPMN. We hope to further human health and safety research in Singapore to keep up with the rapid development of our nanotechnology sector. This is important as there may still be many companies at the conceptualisation and design stage of nanotechnology application. It would be ideal if sound health and safety measures can be implemented at this stage.

According to a report by SPRING (an enterprise development agency), the nanotechnology industry in Singapore is growing at about 8 to 21% annually. The number of companies dealing with nanomaterials has tripled within the past 3 years, and there are now 41. Every year, the Singapore government spends about $20 million on research and manpower development related to nanotechnology. The number of potentially exposed workers is currently not publicly known. However it is not likely to be small, considering that Singapore is gearing towards becoming a niche area for manufacture of high tech new generation products and that manufacturing already accounts for 25% of our GDP. We also do not yet know if most of the nanomaterials are synthesized on-site or purchased from elsewhere. Currently there are no formal regulations directly related to nanotechnology or nanomaterials handling in Singapore.

Singapore is a member of the Asia Nano Forum (ANF) as well as a participating member of the International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) Technical Committees on nanotechnology. Singapore has also formed a national working group on nanotechnology to monitor the work of the ISO TC 229 and IEC TC 113 on standardisation for nanotechnology. Singapore also chairs the standardisation working group in the ANF.

There are a number of nanotechnology research institutions such as the National University's Nanotechnology Initiative (NUSNNI), the Institute of Bioengineering and Nanotechnology under the umbrella of the Agency for Science, Technology and Research (A*STAR) as well the Nanyang Technological University's (NTU) Nanocluster.

Numerous research projects involving nanomaterials are being carried out in these groups. However, most focus on nanomaterial development and application in areas such as nanomedicine and semiconductor device manufacture. A diverse range of nanomaterials are used in the research projects, including carbon nanotubes, zinc oxide nanorods/nanoparticles, silicon and germanium nanoparticles and nanocrystals, nitride and arsenide nanostructures (for application in semiconductors). There is a nanotoxicology research focus group in NUSNNI studying health and environmental impact of gold nanoparticles using animal models, but as yet no research into the human health and safety aspect.

Within NUS alone there are an estimated 750 persons involved in nanomaterials research. The NTU Nanocluster has about 90 faculty members who conduct research on nanomaterials.

There is a large knowledge gap between nanotechnological advances and their occupational health and safety aspect in Singapore that urgently needs to be bridged.

THAILAND

Since the 3rd meeting of WPMN, there have been a number of nano-safety activities occurred in Thailand.

Nano-safety Activities of Government Agency/ Organization/ Research Institute:

The National Nanotechnology Center (NANOTEC)/ National Science and Technology Development Agency (NSTDA)

The National Nanotechnology Center (NANOTEC) has established:

- 5-year nano-materials Safety Program (2008-2012)
- strategic goals for nano-safety research
- research and development of measurement methods for airborne nanomaterials
- series of research projects; i.e. survey of nanomaterial uses and researchers exposed, exposure assessment pilot studies of TiO_2 nanoparticles and carbon nanotubes in the laboratory workplace with various measurement methods.
- collaborative research programs with Swiss Federal Institute for Materials Testing and Research (EMPA) and participating in the ISO/TC229 Nanotechnologies standard development activities
- collaboration with steering group of Intergovernmental Forum on Chemical Safety (IFCS) forum VI with the lead of Ministry of Health and Ministry of Science and Technology.

The strategic goals are:
1. Conduct research on exposure and dose as it relates to nanomaterials including determining the fate of nanomaterials in the work environment, quantitatively assessing worker exposures to nanomaterials, and determining the internal dose of workers to nanomaterials. 2. Conduct research on measuring nanomaterials in the workplace, including developing new measurement methods and validating measurement methods. 3. Conduct research on the toxicity of nanomaterials including investigating key factors for bioactivity; identify pulmonary, systemic, and dermal response; and elucidate mechanisms. Develop screening tests and predictive models for toxicity, and determine the metrics of dose. 4. Conduct risk assessments relevant to nanomaterials. Evaluate the role of nanoparticle properties in exposure-dose-response relationships, develop and validate models for nanoparticle risk assessment, and determine risk estimates of occupational exposures.

Thai Industrial Standard Institute (TISI)

Thai Industrial Standard Institute (TISI) and NANOTEC have participated in ISO TC229 and planned to set up a steering committee for the National Terminology of Nanomaterials (July, 2008)

Nano-safety in Thailand Q&A:

1. **Any national regulatory development on human health and environmental safety including recommendations or discussions related to adapting existing regulatory systems or the drafting of laws/ regulations/ guidance materials**.

As of March 2007, nanosafety and nanoethics were being considered in the forums of local ISO TIS (Thai Industrial Standard). Currently, Nanomaterials Safety Projects has been established under the Director's Initiative Program of NANOTEC.

Back in 2004, the newly drafted NANOTEC strategic plan called for a national policy body to handle nanosafety issues. This established policy body then initiated a drafting of a nanosafety and nanoethics guideline in 2005. Consequently, NANOTEC has Chulalongkorn University drafted the nano-safety status report, the drafting would commence at the beginning of 2007 and run for 9 months with a budget of approximately $30,000. The project was done in 2007.

The main objective of this report was to gather international information on all aspects of nanosafety and nanoethics. Data sources include university centers that receive US government grants related to nanosafety/ nanoethics, independent policy research institutes, independent academics, e.g. in South America, and international organizations such as OECD, ISO, and APO (Asian Productivity Organization).

In addition to the main objective, Phase 1 attempts to familiarize a dozen of experts in a various fields with nanotechnology. These experts from the fields of environmental law, consumer protection law, economics, and political science, are expected to contribute to the second and third phases of the project, where local status and trends will be assessed and the nanosafety/ nanoethics guidelines will be drafted, respectively.

2. **Developments related to voluntary or stewardship schemes**

No information

3. **Information on any risk assessment decisions**

NANOTEC has investigated side effects of TiO_2 coated materials i.e. on fabric and ceramics and decided to postpone technology transfer of TiO2-coated fish tank to the private sectors until safety data are available.

4. **Information on any developments related to good practice documents**

The guideline mentioned in Item 1 will refer to all domestic and foreign good practice documents that are found during the literature review stages (Phase 1 and 2).

5. Research programs or strategies designed to address human health and/ or environmental safety aspects of nanomaterials

During the past couple of years, NANOTEC as a funding agency has urged researchers to add the safety aspects to all nanomaterial R&D grant proposals. For example, nanoparticle-coated fabrics under development were subject to wash-water contamination tests. Nano-titanium dioxide (TiO_2) coated fish tanks were tested for toxicity to fish. Skin creams containing titanium dioxide nanoparticles were also tested for skin pentration through mode (pig) skins. Moreover, the data of the nanomaterials safety program specifically designed to address human health and/ or environmental safety aspects should be available through NANOTEC after the research works are completed.

6. Information on any public/ stakeholder consultation.

This is related Phases 2 and 3 of the project mentioned in Item 1 (see above).

The National Nanotechnology Center, Thailand, (NANOTEC) was founded on August 13th, 2003 as an autonomous agency under the umbrella of the National Science and Technology Development Agency (NSTDA), Ministry of Science and Technology (MOST). Our vision is to create micro- and nanotechnologies that would enrich Thai industries, protect the environment and give rise to niche innovative products, processes, and competitiveness in the global market. Our missions are established, support and promote the nanotechnological development of the country through research innovations, technology transfer, human resource development, and infrastructure. Specifically, we (1) prepare the National Nanotechnology Road Map, (2) act as the national coordinating body between academia, industry and government, (3) set up collaborative network by assembling a critical mass of high-caliber researchers and educators on nanotechnology, (4) identify and focus on niche areas and products in nanotechnoloogy thus enhancing Thailand's competitiveness, (5) disseminate knowledge and transfer nanotechnoogy to industrial and governmental sectors, (6) carry out research in certain core or common areas in nanotechnology, and (7) provide essential analytical nano-scale instruments for sharing with other nanotechnology research laboratories.

May 2008

THE BUSINESS AND INDUSTRY ADVISORY COMMITTEE TO THE OECD (BIAC)

members CEFIC, VCI, ACC

PART I: EUROPEAN CHEMICAL INDUSTRY COUNCIL (CEFIC)

Highlights

- Through its Long-range Research Initiative (LRI), Cefic will be sponsoring safety research on nanomaterials
- Cefic will be organising an external stakeholder event on nanomaterials and nanotechnology
- Cefic is actively contributing to a REACH Competent Authority sub-group on nanomaterials

Background

The European Chemical Industry Council, Cefic, and its members have defined a strategy for sustainable nanomaterials and nanotechnology. Our mission is to offer innovative and exciting nanomaterials, nanotechnologies and nano-enabled products that help answer the toughest social and environmental challenges and respond to the changing needs of society to improve quality of life of this and future generations. We will ensure that our nanomaterials, products and technologies are researched, designed, manufactured and used safely and responsibly throughout their entire life cycle. We will conduct market research and initiate dialogue and engagement with stakeholders to ensure that the products we market answer the needs and priorities of our customers and stakeholders and make a strong contribution to boosting the European economy.

Work underway or planned

To achieve their vision for sustainable nanomaterials and nanotechnology, the European Chemical Industry Council, Cefic, and its members, are undertaking a range of activities. A few of these activities are highlighted below:

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;

Cefic and its members are actively contributing to the REACH Competent Authority subgroup on nanomaterials that has been created by the European Commission. The aim of the subgroup is to consider REACH requirements and how they apply to nanomaterials. In particular, the chemical industry will contribute by providing Chemical Safety Reports for selected nanomaterials that contain a risk assessment for its own use and the downstream user's use of such substance, as well as an exposure scenario along with appropriate recommended risk assessment measures to adequately control the identified risks across the entire life cycle of the material.

Research programmes or strategies designed to address human health and/or environmental safety aspects of nanomaterials

Through its Long-range Research Initiative (LRI), Cefic will be sponsoring safety research for nanomaterials. A request for proposals (RfP) has been published for a tiered approach to testing and assessment of nanomaterials' safety to human health. The total budget is €1.5 million. This project will be carried out for nanoscale zinc oxide and nanoscale amorphous silicon dioxide particles. A second RfP for the environmental impact of nanomaterials is currently in preparation and will be published shortly. The planned budget is €0.5 million.

Information on any public or stakeholder engagement

Cefic is organizing an event for external stakeholders by the end of June. The Cefic strategy for nanomaterials will be presented, thus providing our perspective on nanomaterials and nanotechnologies and giving us the opportunity to "sound out" the chemical industry's approach to this new technology with its stakeholders. The aim is an open and frank exchange of information so that industry and its stakeholders can better understand each other. In addition a map of stakeholders expectations and concerns will be developed, which may result in the need to adapt our strategy.

Additional information

At the United Nations International Conference of Chemicals Management, the International Council of Chemical Associations (ICCA), affirmed the chemical industry's proactive approach to product stewardship by launching the Global Product Strategy (GPS), and the Responsible Care® Global Charter (RCGC). Both initiatives are complementary in nature. These actions reflect the industry's long-standing commitment to product stewardship and are built upon several ongoing voluntary initiatives, including the ICCA's High Production Volume (HPV) chemicals programme, the Responsible Care programme and the Long-range Research Initiative.

The Responsible Care® ethic helps our industry to operate safely, profitably and with due care to future generations.

For further information please contact: Johan Breukelaar, Director International Chemicals Policy, jbr@cefic.be

PART II: GERMAN CHEMICAL INDUSTRY (VCI)

The German Chemical Industry has committed itself to a responsible production and use of nanomaterials. To support member companies, and customer companies in the value chain, to manage the health, safety and environmental aspects of nanomaterials throughout the life cycle, the German Chemical Industry Association VCI has issued the following series of documents. They provide guidance on all aspects of a good product stewardship on nanomaterials.

Principles document:

- Implementing Responsible Care® for a Responsible Production and Use of Nanomaterials

Regulatory documents:

- Requirements of the REACH Regulation on Substances which are Manufactured or Imported also as Nanomaterials
- Guidance for a Tiered Gathering of Hazard Information for the Risk Assessment of Nanomaterials
- Guidance for Handling and Use of Nanomaterials at the Workplace
- Guidance for the Passing on of Information along the Supply Chain in the Handling of Nanomaterials via Safety Data Sheets
- Strategy Paper of the German Chemical Industry on the Standardisation of Nanomaterials

Documents on safety research:

- Roadmap for Safety Research on Nanomaterials
- Environmental Aspects of Nanoparticles

These documents have been discussed with the public as well as national and European authorities. The "Guidance for Handling and Use of Nanomaterials at the Workplace" and the "Guidance for the Passing on of Information along the Supply Chain in the Handling of Nanomaterials via Safety Data Sheets" have been developed together with stakeholders in dialogue activities. The "Roadmap for Safety Research on Nanomaterials" and the paper on "Environmental Aspects of Nanoparticles" have been developed together with representatives from science. "

PART III: AMERICAN CHEMISTRY COUNCIL (ACC)

Members of the American Chemistry Council's Nanotechnology Panel (Panel) are actively participating in the voluntary EPA Nanoscale Materials Stewardship Program (NMSP). To date, the following companies have submitted or committed to provide information for the basic program on nanoscale materials by the late July submission date: DuPont, BASF, Bayer Material Science, Dow, Evonik/Degussa, PPG, and Sasol North America. Additional companies are expected to participate in the basic program. The Panel continues to discuss with EPA the further implementation of the basic and in-depth components of the NMSP, and the data to be generated by the contributions of BIAC to the OECD testing program.

The Panel has provided input to the reauthorization process of the US National Nanotechnology Initiative. Focusing on supporting increased funding and prioritization of environment, health, and safety (EHS) research at the federal level, the Panel and its members participated on review committees of the National Research Council and NIOSH, and testified before the US House of Representatives Committee on Science and Technology. The Panel continues to support the development of a "top-down" preparation of a roadmap for EHS federally funded research with progress markers clearly identified that are measurable over specified time intervals."

SECTION II
CURRENT ACTIVITIES IN OTHER ORGANISATIONS RELATED TO NANOTECHNOLOGIES/ NANOMATERIALS

INTERGOVERNMENTAL FORUM ON CHEMICAL SAFETY (IFCS)

IFCS Sixth session (Forum VI)
15-19 September 2008, Dakar, Senegal

Plenary session on Nanotechnology and manufactured nanomaterials: opportunities and challenges (16 September 2008)

The objective of the plenary session on nanotechnology and manufactured nanomaterials is to exchange information in order to help raise the awareness of participants to the potential new opportunities, the new challenges and the new risks posed by nanotechnology. The meeting will provide a forum to share information on known and emerging issues, on the work of the OECD, ISO and UNESCO on nanotechnology and to foster an understanding of issues (applications and implications). The Forum will also be an opportunity to discuss the potential contributions of nanotechnology to sustainable development and pollution prevention, and to discuss how to achieve an equitable distribution of benefits and risks and role of responsible stewardship in addressing nanotechnology. The outcome of the plenary session will be submitted to the second session of the International Conference on Chemicals Management (ICCM-2) in May 2009 for its consideration as well as other relevant bodies, organizations and institutions.

Forum VI meeting documents can be downloaded from IFCS website: http://www.who.int/ifcs/forums/six/en/index.html

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO)

The International Organisation for Standardization Technical Committee (ISO/TC) 229 - Nanotechnologies - was established in June 2005 with a UK secretariat and chair. It has held six meetings to date - November 05 in London, June 06 in Tokyo, December 06 in Seoul, June 07 in Berlin, December 07 in Singapore and May 08 in Bordeaux, France. The next meeting will be in at in November 08 in Shanghai, China. The committee currently has 40 members - 30 "P" and 10 "O".

The TC structure consists of 4 working groups, two of which are Joint Working Groups (JWG) with IEC/TC 113 (Nanotechnology standardization for electrical and electronic products and systems): Terminology and Nomenclature (JWG1, convened by Canada); Measurement and Characterization (JWG2, convened by Japan); Health, Safety and Environment (WG3, convened by USA), and Materials Specification (WG4, convened by China). The work programme at the beginning of July 2008 contained 25 work items – 4 in JWG1, 12 in JWG2, 4 in WG3, and 3 in WG4 (Annex 1), with a further 3 New Work Item Proposals out for ballot. At the last meeting, two documents were approved for publication: a Technical Specification - Terminology and definitions for nano-objects – nanoparticles, nanofibres and nanoplates; and a Technical Report - Health and Safety Practices in Occupational Settings Relevant to Nanotechnologies. Of the existing work items, the most relevant to the WPMN are those in WG3, though both the terminology work, in JWG1, and the measurement and characterization work, in JWG2, have broad relevance.

The TC works closely with the IEC (International Electrotechnical Commission) TC 113, chaired by the US, with Germany providing the secretariat. The two Technical Committees hold joint plenary meetings at least every two years, starting in December 2007. TC 229 also works closely with the CEN (European Committee for Standardization) TC in the area (TC 352 – Nanotechnologies, also chaired by UK), using the Vienna agreement where appropriate. Liaisons have been established with 15 other ISO TC's, with the OECD (Working Party on Manufactured Nanomaterials and Working Party on Nanotechnology), with the EC Joint Research Centres (IRMM and Institute for Health and Consumer Protection, Ispra), with the Asia Nano Forum and with VAMAS.

In autumn 2006, the TC undertook a survey of standardization needs of members, which identified over 100 high priority topics, with 54 being relevant to JWG2, 31 relevant to WG3, 5 relevant to a new working group on materials specifications, and 18 relevant to other ISO TCs. The information gathered has been used to prepare a committee standardization road map and to provide input to the committee business plan.

Given the number of ISO and other committees and working parties with an interest in nanotechnologies standardization, and in particular in the development of test methods for measurement and characterization, a Joint International Workshop on measurement and characterization for nanotechnologies was held in February 2008 in cooperation with IEC, OECD and NIST (US National Institute of Standards and Testing) to identify needs and to provide a forum for discussions on harmonization and coordination issues. Details of this workshop, including presentations and a summary report, are available at http://www.iso.org/nanotech-workshop. One important outcome was agreement to establish a Nanotechnology Liaison Coordination Group to ensure coordination of activities and harmonization of deliverables amongst liaison organisations. This group held its first meeting in Bordeaux during the last week of May 2008.

The development of standards in ISO Technical Committees is undertaken on the basis of New Work Item Proposals (NWIP) received from, and approved, developed and adopted by members according to the procedures defined in the ISO/IEC Directives. The requirements for the submission and approval of NWIP are summarized below:

A new work item proposal within the scope of an existing technical committee or subcommittee may be made in the respective organization by:

- a national body;
- the secretariat of that technical committee or subcommittee;
- another technical committee or subcommittee;
- an organization in liaison;
- the technical management board or one of its advisory groups;
- the Chief Executive Officer.

Acceptance requires

a) a minimum of 5 P-members approving the work item and giving a commitment to participate actively in the development of the project; and

b) approval of the work item by a simple majority of the P-members of the technical committee or subcommittee voting.

ISO standards are voluntary. As a non-governmental organization, ISO has no legal authority to enforce their implementation. A certain percentage of ISO standards - mainly those concerned with health, safety or the environment - has been adopted in some countries as part of their regulatory framework, or is referred to in legislation for which it serves as the technical basis. Such adoptions are sovereign decisions by the regulatory authorities or governments of the countries concerned; ISO itself does not regulate or legislate. However, although ISO standards are voluntary, they may become a market requirement, as has happened in the case of ISO 9000 quality management systems, or of dimensions of freight containers and bank cards.

ISO/TC 229 believes that close cooperation with the OECD WPMN will lead to valuable synergies and avoid duplication of effort by the two organisations. As indicated, ISO standards can support regulation and legislation by, for example, providing validated and verifiable measurement methods for demonstrating compliance with regulatory requirements. However, whilst the Technical Committee has plans to develop standards that are relevant to and appropriate for the activities of the Working Party, the process for New Work Item adoption, described above, means that TC 229 members must be fully aware of Working Party needs and are able to identify experts to participate in project development. In order to help assure the development of standards that the Working Party identifies as being essential, members of the WPMN are strongly encouraged to contact their national representatives on ISO/TC 229 in order to coordinate activities in this area. A list of national contact points for ISO/TC 229 is available on the password protected website of the WPMN.

Annex: ISO/TC 229 Work Programme at 30 June 2008

JWG1

- *ISO/TS: Terminology and definitions for nanoparticles* ***(Approved for publication at plenary meeting on 30.05.2008 as Terminology for nano-objects – nanoparticles, nanofibres and nanoplates)***
- *ISO/TR: Terminology and nomenclature for nanotechnologies — Framework and core terms*
- *ISO/TS: Outline of Nanomaterials classification ("Nano tree")* ***(status changed to internal committee support document at plenary meeting on 30.05.2008)***
- *ISO/TS: Terminology and definitions for carbon nanomaterials*
- *ISO/TS: Core Terms - Terminology and Definitions*

JWG2

- *ISO/TS: The Use of Transmission Electron Microscopy (TEM) in the Characterization of Single-walled Carbon Nanotubes*
- *ISO/TS: The Use of Scanning Electron Microscopy (SEM) and Energy Dispersive X-ray Analysis (EDXA) in the Characterization of Single-walled Carbon Nanotubes*
- *ISO/TS: Technical Specification for the Use of UV-Vis-NIR absorption spectroscopy in the Characterization of Single-walled Carbon Nanotubes*
- *ISO/TS: Technical Specification for the use of NIR-Photoluminescence (NIR-PL) Spectroscopy in the Characterization of Single-Walled Carbon Nanotubes*
- *ISO/TR: Use of Thermo Gravimetric Analysis (TGA) in the purity evaluation of Single Walled Carbon Nanotubes*
- *ISO/TR: Use of Evolved Gas Analysis-Gas Chromatograph Mass Spectrometry (EGA-GCMS) in the Characterization of Single-Walled Carbon Nanotubes*
- *ISO/TS: Use of Raman Spectroscopy in the Characterization of Single Walled Carbon Nanotubes.*
- *ISO/TS: Measurement Methods for the Characterization of Multi-Walled Carbon Nanotubes*
- *ISO/TR: Guide to nanoparticle measurement methods*
- *ISO/TR: Guide to methods for nano-tribology measurements*
- *ISO/TS: Determination of meso-scopic shape factors of multiwalled carbon nanotubes (MWCNTs)*
- *ISO/IS: General framework for determining nanoparticle content in nanomaterials by generation of aerosols*

WG3

- *ISO/TR: Health and Safety Practices in Occupational Settings Relevant to Nanotechnologies* ***(Approved for publication at plenary meeting on 30.05.2008)***
- *ISO/IS: Endotoxin test on nanomaterial samples for in vitro systems* ***(under Committee Draft ballot)***
- *ISO/IS: Generation of nanoparticles for inhalation toxicity testing* ***(under Committee Draft ballot)***
- *ISO/IS: Monitoring of nanoparticles in inhalation exposure chambers for inhalation toxicity testing* ***(under Committee Draft ballot)***
- *ISO/TR: Guidance on physico-chemical characterization of engineered nanoscale materials for toxicologic assessment – Harmonized with WPMN list – woking closely with Noriko Oki on this to ensure that we complement each other's work and avoid duplication*

WG4

- *ISO/TS: Format for reporting the engineered nanomaterials content of products*
- *ISO/IS: Material specification - Nano-calcium carbonate*
- *ISO/IS: Material specification - Nano-titanium dioxide*

IS = International Standard; TS = Technical Specification; TR = Technical Report.

Several New Work Item Proposals are currently under consideration:

- Terminology and definitions for nanostructured materials
- Terminology for the bio-nano interface
- Terminology for medical, health and personal care applications of nanotechnologies
- Terminology for nanofabrication/nanomanufacturing
- Guide to safe handling and disposal of manufactured nanomaterials
- Guide to specifying nanomaterials

Preliminary Work on a nanomaterials nomenclature has now been elevated to a JWG1 Task Group activity, which will be led by Dr Andy Atkinson from Canada.

Dr Peter Hatto, Chairman, 30 June 2008

NORTH ATLANTIC TREATY ORGANIZATION (NATO)

Emerging Methods and Tools for Environmental Risk Assessment, and Decision-Making for Nanomaterials: Summary of NATO Advanced Research Workshop (ARW).

The NATO Advanced Research Workshop "Nanomaterials: Environmental Risks and Benefits and Emerging Consumer Products" brought together 70 scientists and engineers from 20 different nations and multiple fields, reflecting the global and interdisciplinary nature of nanotechnology and nanomaterials research. A unique feature of this workshop was its interdisciplinary nature and focus on the practical needs of policy decision makers. Workshop presentations and discussion panels were structured along four main themes: technology and innovation, human health risk, environmental risk, and policy implications.

Workshop attendees shared basic agreements on policy and risk assessment needs. Attendees identified the need for a common, standardized taxonomy and terminology for nanomaterials in which key aspects should include nanomaterial physical and chemical characteristics, with the view that such a system would facilitate the development of informational resources (e.g., publications, other documents, and databases) to provide easy access and sharing across international borders as regulators attempt to understand and assess the properties of these new materials. Attendees also agreed that assessments covering the entire lifecycle would best inform and guide risk assessment for engineered nanomaterials and related nanotechnologies, and that consumer and occupational health protection policies needed additional development as well. Given the proprietary nature of these rapidly evolving technologies, and current voluntary reporting requirements, a mechanism is needed for regularly providing and updating information to scientists and policy makers regarding the safety profiles and characteristics of these current and emerging nanomaterials. Attendees were very aware that a serious nanotechnology-related health issue in one nation or region of the world would greatly promote a negative public perception of nanotechnology risk in every other nation or area.

Simultaneous advances in different disciplines are necessary to advance nanotechnology risk assessment and risk management. Risk assessment is an interdisciplinary field, but progress in risk assessment has historically occurred due to advances in individual disciplines. For example, toxicology has been central to human health risk assessment, and advances in exposure assessment have been important for environmental risk assessment and risk management. Nanotechnology, however, ideally involves the planned and coordinated development of knowledge across fields such as biology, chemistry, materials science, and medicine.

Likewise, risk assessments of nanomaterials and related technologies requires a lifecycle approach, meaning a comprehensive assessment of the impact of nanomaterials at different stages of production, use, and disposal/recycling. The current state of knowledge makes the identification of major risk drivers challenging. This includes understanding environmental pathways, fate and transport processes, and reasonably foreseeable exposures. An integrated, holistic approach is needed to consider an individual's total exposure from relevant environments expressed in different units across receptor groups. This would lead to risk characterizations that are systematic and more inclusive, accommodating non-traditional information sources, measures, and endpoints.

The attendees agreed that while existing chemical risk assessment and risk management frameworks may provide a starting point, the unique properties of nanomaterials adds a significant level of complexity to this process. Several methodologies and frameworks have been proposed on how to best govern nanomaterial development in the face of heterogeneous information, uncertainty, and risk. Most of the frameworks are based on traditional quantitative methods (such as probabilistic assessment, Bayesian analysis, and multivariate statistical analysis) that have been applied in the field of risk assessment and

environmental management to chemicals and other stressors. In general, these methods can be characterized as data-intensive, and their application to nanomaterial risk assessment would require significant implementation efforts. Clear deficiency, if not practical impossibility, of these methods application to nanomaterials is their rigid data quality requirements that are part of risk assessment process and currently not achievable even for most studied nanomaterials. Nevertheless, once completed, such quantitative tools could provide a comprehensive information base for making technical decision and developing risk mitigation policies.

Current state of knowledge in nanomaterial risk assessment, as it is clearly acknowledged during the workshop and in scientific publications, requires to integrate expert judgment with multiple other factors to support the decision-making process. Even though substituting technical data by expert judgment may be not optimal solution, the current data availability in the field leaves no other alternatives. ERDC is currently applying multi-criteria decision analysis (MCDA) tools to characterize nanomaterials and to potentially guide military technology development. MCDA can help to generate and map technical data as well as individual judgments into organized structures that can be linked with other technical tools from risk analysis, modeling, monitoring, and cost estimation. The result of MCDA application is a comprehensive, structured process for selecting the optimal alternative in any given situation, drawing from stakeholder preferences and value judgments as well as scientific modeling and risk analysis.

WORLD HEALTH ORGANIZATION (WHO)

WHO Collaborating Centres for Occupational Health discussed work on occupational health and safety risks of nanotechnology at a meeting convened under the auspices of WHO Headquarters in December 2007 in Helsinki. The main conclusion of the meeting was that the lessons learnt from the first five years of studying occupational health and safety risks should be shared with other countries. The collaborating centres agreed to summarize lessons learnt in the United States, United Kingdom, Finland, Japan, Singapore, Italy and the Netherlands in a report to be developed by WHO. It is intended that the report will assist countries with emerging and transitional economies to incorporate occupational health and safety considerations into national strategies for the development of nanotechnologies.

The WHO Regional Office is participating in a joint WHO-EU project on "Enhanced policy advice on environment and health in Europe." Formulation of conclusions for policy making regarding nanotechnologies will be based on existing reviews, research and studies concerning potential environmental and health risks. Position statements and guidelines will be developed and information material, including fact sheets on health implications, will be prepared. It is anticipated that a jointly-agreed policy approach to nanotechnologies in relation to health will be achieved.

SECTION III
REPORT FROM THE SECRETARIAT

This section is intended to summarise progress on events associated with the WPMN since the 3rd meeting. It focuses on those activities which are not described in any other documents for the 4th WPMN. It is organised in two sections: **part one** describes other WPMN activities/ events; and **part two** addresses internal OECD co-ordination as well as outreach work with other organisations and events.

PART I: WPMN ACTIVITIES/ EVENTS

SPECIFIC PROJECTS

Project 1: Development of a Database on Human Health and Environmental Safety Research

1. This project has developed a *Database of Research into the Safety of Manufactured Nanomaterials as Phase 1* of its work. The database is intended to hold details of completed, current and planned environment, health and safety research projects on safety, which are to be updated (electronically) by delegations. This database is also intended to be an inventory of information on research programmes to help the other projects of the WPMN by identifying relevant research projects or storing information derived from the projects of the WPMN, including the sponsorship programme on the testing of manufactured nanomaterials. Following the 4th WPMN, delegations will be invited to populate the database by editing the project information in the database and adding any other projects into the database.

Project 2: Research Strategies on Manufactured Nanomaterials

2. Project Two is developing a research strategy for addressing human health and environmental safety issues associated with manufactured nanomaterials. The project has developed a comprehensive list of research themes and compiled the current/planned research projects and the urgent and medium/long term research priorities. From this collected data, it has identified research themes which already have wide current coverage ("hot spots") and research themes less covered ("gaps"), and proposed possible research projects for international co-operation. Those outputs were recommended to be declassified.

3. As scientific research in the area of nanomaterials safety is rapidly evolving, a regular update will be necessary for identified priorities, gaps, hot spots etc. It was also recognised that further analyses would need the Project one database as a data resource. Project two will therefore move forward in 2009-2012 with more detailed analysis once *the Database of Research into the Safety of Manufactured Nanomaterials* is fully operational.

Project 3: Safety Testing of a Representative Set of Manufactured Nanomaterials

4. The project has launched the first phase of a "sponsorship programme" for testing a representative set of manufactured nanomaterials for specific endpoints. At the 4th WPMN, delegations committed to or indicated interest in contributing to the 14 selected nanomaterials. Sponsors in the programme will produce Dossier Developments Plans for each nanomaterial tested. This work is being

supported by the development of a guidance manual for sponsors of the testing programme. In addition, it is expected that this will identify those cross-cutting issues or tests that will need further consideration for a second phase of testing.

Project 4: Manufactured Nanomaterials and Test Guidelines

5. This project is reviewing existing test guidelines [especially the OECD Test Guidelines (TGs)] with view to establishing whether they are suitable for MNs. It has finalised a preliminary review of test guidelines related to physical chemical properties, effects on biotic system, degradation and accumulation, and health effects. A major outcome is the decision to develop a guidance document for sample preparation and dosimetry, and a guidance document on the use of pulmonary instillation studies and consideration of their advantages and disadvantages compared to studies using the inhalation route. It also supports Project 3 in identifying existing testing methods (including international and national standards) for those identified endpoints for phase 1 of its testing programme (see project 3).

Project 5: Co-operation on Voluntary Schemes and Regulatory Programmes

6. This project analysed national information gathering programmes, whether voluntary or mandatory, to identify common elements relating to the risk assessment and risk management of manufactured nanomaterials. This project has already: i) identified similarities and differences of these initiatives, and ii) prepared recommendations on approaches and elements to consider for information gathering initiatives. Those outputs were recommended to be declassified.

7. This project also prepared a Questionnaire on Regulatory Regimes for Manufactured Nanomaterials, which aims to identify various components of regulatory regimes which are or may be applicable to nanomaterials. The Questionnaire on Regulatory Regimes for Manufactured Nanomaterials will be circulated amongst the WPMN delegations for its completion.

8. As an ancillary project to Project 5, the WPMN has sought possibilities for sharing and comparing the data on manufactured nanomaterials which has been received by delegations as part of their national reporting schemes. It will provide summary information on manufactured nanomaterials including the name; brief description of composition of nanomaterials; description of the nature of any further information held on the material; reported country; and contact sharing on the WPMN password protected website. The information will be updated by submissions from delegations to the Secretariat.

Project 6: Co-operation on Risk Assessment

9. The objectives of this project are: i) to exchange, collate and synthesise information on risk assessment approaches for chemicals that may apply to manufactured nanomaterials; ii) to undertake a gap analysis of current risk assessment approaches as these apply to manufactured nanomaterials; and iii) to prepare recommendations for addressing and filling identified gaps. The project has developed a report which addresses the first and second objectives.

Project 7: The role of Alternative Methods in Nanotoxicology

10. This project is examining alternative test methods and will analyse how they might be used in an overall assessment plan for hazard testing of manufactured nanomaterials. This activity is closely related to the testing programme of project 3.

11. This project will assess available *in vitro* methods (including their validation/development status) and evaluate how they might be used in an overall assessment plan for hazard testing of manufactured nanomaterials. It will then identify additional endpoints that should be considered by the sponsorship

programme (project 3). Consideration will be given to other alternative approaches and the broader issue of integrated testing strategies.

Project 8: Exposure Measurement and Exposure Mitigation

12. The objective of this project is to exchange information on guidance documents for exposure measurement and exposure mitigation and will develop recommendations on future work that needs to be undertaken. Specifically, the project aims to address: i) exposure in occupational settings; ii) exposure to humans resulting from contact with consumer products and environmental releases of MNs; and iii) exposure to environmental species resulting from environmental releases of MNs including releases from consumer products containing MNs. The WPMN recognizes that exposure measurement and exposure mitigation information developed for incidental nanoscale particles is highly relevant to this project and thus it will be considered.

13. Recommendations for specific work needed on exposure measurement and exposure mitigation in occupational settings has been prepared. Specific projects related to occupational settings have been identified and will be developed, while the projects move forward in analysing the other two kinds of exposure (human and environmental safety).

PUBLICATIONS

14. Since the 3rd WPMN, the following three WPMN documents have been declassified and made available on the public nanosafety website (http://www.oecd.org/env/nanosafety).

- *Manufactured Nanomaterials: Work Programme 2006-2008*: The Programme of Work described in this document was originally agreed at the 40th meeting of the Chemicals Committee [ENV/JM(2006)49]. In order to be transparent with respect to its work, the WPMN recommended at its 3rd meeting that this document be considered for declassification. This was subsequently agreed by the Chemicals Committee. Because the WPMN adopted two new projects in addition to the six originally described in the programme of work, summary information on these two new projects has been included on the introductory page on the OECD public website.

- *Current Developments/ Activities on the Safety of Manufactured Nanomaterials*: This document provides information on current/planned activities related to the safety of manufactured nanomaterials in countries and organisations. It is based on information provided during the tour de table at the 3rd WPMN.

- *List of Manufactured Nanomaterials and List of Endpoints for Testing*: This document is based on the annexes of the 3rd WPMN document [ENV/CHEM/NANO(2008)20]. It was declassified by the Chemicals Committee based on the discussion at its 42nd meeting. This document is available on the nanosafety web site.

QUESTIONNAIRE FOR THE SAFETY OF MANUFACTURED NANOMATERIALS

15. Following the 3rd WPMN, delegations additionally submitted the responses to the questionnaire/ information request. The submission mainly included the information on research projects which enable SG2 to move their work forward. While the original responses from delegations are stored at the WPMN password-protected website, the declassification of the SG2 output document was decided at the 4th WPMN, along with the declassification of some SG2 research matrixes.

WORKSHOP ON THE SPONSORSHIP PROGRAMME (TOKYO)

16. The Japanese delegation hosted a WPMN workshop in Tokyo, 24-25 April 2008. The results are described in the documents ENV/CHEM/NANO(2008)5 and ENV/CHEM/NANO(2008)6. In addition, an International Symposium on the Risk Assessment of Manufactured Nanomaterials was held the day before (23rd April). It was hosted by the Japanese New Energy and the Japanese Industrial Technology Development Organization (NEDO), the National Institute of Advanced Industrial Science and Technology (AIST), and OECD.

PART II: CO-ORDINATION AND OUTREACH

17. The WPMN has worked to co-ordinate its programme with other activities addressing nanotechnologies. It is important to build strong communication for identifying synergies and avoiding duplicative work. Co-ordination has two main levels: i) internal including the activities of other subsidiary bodies of the Chemicals Committee (such as the WTN) and OECD's Working Party on Nanotechnology; and ii) externally (with other international and /or national initiatives). As a result, there is strong communication with other international organisations such as the IOMC participating organisations (*i.e.* FAO, ILO, UNEP, UNIDO, UNITAR and WHO), as well as UNESCO and IFCS.

INTERNAL CO-ORDINATION WITH OTHER OECD BODIES

Projects of the WPMN

18. There are clearly many linkages among each of the projects of the WPMN. In particular, the newly launched Sponsorship Programme for the Testing of Manufactured Nanomaterials was designed to build upon the work already achieved by Project 3 and Project 4. It also expects to benefit from the discussions of Project 7 on alternative testing in nano toxicology. In fact, those projects and the Sponsorship programme are complementary to each other. Progress on the sponsorship programme will depend on the work of SG4 and SG7.

19. The Workshop for Sponsorship Programme (Tokyo, 24-25 April 2008) was a crucial opportunity for SG3, SG4 and SG7, and thus the participants of SG3, SG4 and SG7 were encouraged to participate in this workshop to ensure the linkage between those projects and the Sponsorship Programme.

Co-ordination with other activities of the Chemicals Committee

20. There are also linkages with other activities of the Chemicals Committee. Currently, the work of the Working Group of Test Guideline Coordinators (WNT) is of particular interest as it is relevant (in particular) to the work of SG3 and SG4.

21. At the same time, the Working Group on Chemical Accidents, the Task Force on PRTRs (Pollutant Release and Transfer Registers), the Task Force for the Safety of Novel Foods and Feeds and the Working Group on Pesticides have all expressed interest in aspects of the work of the WPMN. The secretariat has given an update of the work of the WPMN to these groups at their most recent meetings.

22. Notably, the Working Group on Pesticide and Task Force on Biocides is currently conducting a survey, a Questionnaire *on pesticides/biocides and nanotechnology activities in member countries: Overview of activities and current developments.* The Questionnaire was sent to delegates of the WGP (copied to the WPMN) on 15th April. The results of this questionnaire will be reported to the WPMN at its 5th meeting.

23. It is expected that the Chemical Committee, the supervisory body for each of the above bodies, will address co-ordination issues on nanomaterials at its 43th meeting, 4-7 November, 2008.

OECD's Working Party on Nanotechnology (WPN): Background, highlights and progress

24. The Working Party on Nanotechnology (WPN) is a subsidiary body of OECD's Committee for Scientific and Technological Policy (CSTP). Its third meeting was held 23-24 April 2008 at OECD Headquarters in Paris.

25. The objective of the WPN is to advise on emerging policy-relevant issues in science, technology, and innovation related to the responsible development of nanotechnology. The WPN complements the WPMN by focusing on nanotechnology developments from the viewpoint of science, technology and innovation policies and hence takes a more general and socio-economic approach. The WPN and WPMN are coordinating their activities to secure complementarities and synergies as the work progresses.

26. The work of the WPN is motivated by the rapid increase in public nanotechnology R&D investments globally, which are backed up by dedicated science and technology (S&T) programmes and other initiatives in many developed and developing countries. While private forecasts suggest huge socio-economic opportunities for nanotechnology applications, many aspects of the underlying developments are still poorly understood.

27. The measurement of nanotechnology suffers from a lack of internationally agreed statistical definitions. Nanotechnology may engender new types of business models and require tailored policies and research partnerships. Countries may also benefit from an exchange of initial experiences in outreach and public engagement activities. Engaging in a policy dialogue between countries is important for the support of coordinated and responsible policies that take into account the risks and challenges involved. At the same time, nanotechnology may offer opportunities to address some pressing global challenges, for example, those related to the provision of clean water.

28. The WPN is presently working on six projects under an overall framework to address some of the issues highlighted above:

- *Project A: Indicators and Statistics* seeks to provide reliable, validated and internationally comparable indicators and statistics in parallel with the identification and analysis of existing indicators, statistics and related methodologies;

- *Project B: Companies and Business Environments* complements the statistical work with a large set of company case studies across several nanotechnology application areas sectors and countries. It analyses the impacts of nanotechnology on business environments, aiming to identify potential new challenges for the business community. An internal workshop related to project B on challenges in the commercialization of nanotechnologies will be held on the 6-7th of October 2008 in Helsinki;

- *Project C: International Research Collaboration* is designed to facilitate research collaboration in the field by sharing information on available research infrastructures and S&T cooperation opportunities globally;

- *Project D: Outreach and Public Engagement* promotes the exchange of experiences in outreach and public engagement in nanotechnology through the identification of good practice, the analysis of existing information and the staging of targeted workshops. Preliminary results of project D will be discussed at a workshop in November 2008 in the Netherlands;

- *Project E: Policy Dialogue* has been set up to facilitate a policy dialogue and to aid the overall synthesizing of the work of the WPN. It is using information obtained through a questionnaire and related national data sources, in combination with dedicated workshops, to highlight policy responses to nanotechnology and the challenges across countries;

- *Project F: Global challenges* is focussing on the potential for nanotechnology to contribute to the solution of global issues. The first challenge being addressed is that of the availability of and access to clean water globally. The project is examining the policy barriers to the provision of water in developed and less developed countries through the application of nanotechnology. Expert discussions, supported by desk research and a conference workshop at Nanotech Northern Europe in September 2008 (www.ntne.net) are the main activities for 2008.

29. The fourth meeting of the WPN will be held 16-18 December 2008. The WPN is currently developing its work programme for 2009-2010, to be finalized at that meeting.

30. The WPN Secretariat attended the 4th WPMN to give an update on the work.

OTHER INTERGOVERNMENTAL ORGANISATIONS

31. OECD continues to work closely with other intergovernmental organisations on its work on manufactured nanomaterials and nanotechnologies. OECD is a Participating Organisation (PO) of the Inter-Organization Programme for the Sound Management of Chemicals (IOMC), which also includes FAO, ILO, UNEP, UNIDO, UNITAR and WHO. UNDP and the World Bank are observers. The OECD secretariat has kept these other organisations up to date with the work of the WPMN through the IOMC.

32. OECD has also been working with the secretariat of the Intergovernmental Forum on Chemical Safety (IFCS). Forum VI of the IFCS will be held in Dakar, 15-19 September, 2008. Forum VI will include a session on nanotechnology. OECD has prepared a paper for this meeting which summarises the activities of the WPMN and the WPN. At the same time, OECD has prepared a second paper on behalf of the IOMC organisations which will summarises the nanotechnology activities of each of the Participating Organisations. These papers have been translated into the six languages of the UN and are available on the IFCS web site.

Co-ordination with Standardisation Organizations

33. There was an "International Workshop on Documentary Standards for Measurement and Characterization in Nanotechnologies" (26-28 February 2008, in Gaithersburg, US) which was co-sponsored by ISO, IEC, NIST, and OECD. There were over 70 participants from national standardisation organisations or national measurement institutes in attendance. The Chair of the WPMN, the co-chair of SG3, the Chair of SG7, the Chair of SG8 and the Secretariat (on behalf of the Chair of SG4) presented their work during the workshop. In addition, various delegations to the WPMN attended the workshop and contributed to the discussion. The summary of the workshop has been available on the internet website http://www.iso.org/nanotech-workshop and detailed report will be available in June. The workshop has stimulated the relationship amongst standardization organizations and between those and the OECD WPMN.