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**ENVIRONMENT DIRECTORATE  
JOINT MEETING OF THE CHEMICALS COMMITTEE AND  
THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY**

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

**Tour de Table at the 3rd Meeting of the Working Party on Manufactured Nanomaterials**

**Paris, France, 28-30 November 2007**

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**OECD Environment, Health and Safety Publications  
Series on the Safety of Manufactured Nanomaterials**

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**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*  
Paris, France, 28-30 November 2007

**Environment Directorate  
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT  
Paris, 2007**

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## 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 38<sup>th</sup> 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], the 39<sup>th</sup> Joint Meeting recommended that the OECD Council consider the establishment of a Working Party as a subsidiary body of the Chemicals Committee, to address the health and environmental safety implications of manufactured nanomaterials. The OECD Council agreed to establish a Working Party on Manufactured Nanomaterials on 14<sup>th</sup> September 2006 as a subsidiary body of the Chemicals Committee.

The 1<sup>st</sup> meeting of the Working Party on Manufactured Nanomaterial (WPMN) was held 26-27 October in London to agree to the Programme of the Work 2006-2008 which was subsequently adopted by the Chemicals Committee (40th Joint Meeting) in November 2006. The WPMN also agreed to six specific projects to implement the Programme of the Work and started its work by preparing the operational plans for these six specific projects. The operational plans were agreed at its 2<sup>nd</sup> meeting held 25-27 April 2007 in Berlin, Germany. The meeting also recognized the progress on projects which had been made in parallel to the development of operational plans. In addition, a drafting group to draft operational plan for “Exposure Measurement and Exposure Mitigation” was established in order to be discussed at the 3<sup>rd</sup> meeting.

The 3<sup>rd</sup> meeting was held 28-30 November 2007 in Paris, France. An earlier version of this document was originally provided to the meeting as background information in considering the operational plans for the six specific projects. 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) (section II). In addition, delegations added a short bulleted list of highlights at the top of their submissions to give readers a general idea of key events since the 1st meeting of the Working Party.

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 4 (the Tour de Table) at the 3<sup>rd</sup> 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 manufactured nanomaterials. This was intended to facilitate the implementation of the six projects by allowing delegations to share their experiences and preoccupations with respect to safety. This was also an opportunity to identify possibilities for future co-operation and co-ordination.

**Headings for the Tour de Table**

2. In considering the Tour de Table, the information from 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 last meeting of the Working Party.

Firstly, please provide a list of the latest developments in your delegation since the 2nd meeting of the WPMN (April 2007) as an highlight to appear on top of your document (see recommended format below), and then 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;
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 2nd meeting of the WPMN (April 2007)*

- Establishment of Australia's National Nanotechnology Strategy (NNS) and a Health, Safety and Environment (HSE) Working Group therein.
- Completion of an independent review into the suitability of Australia's regulatory frameworks to manage any risks posed by nanotechnology.
- Establishment of an Advisory Committee on Health and Nanotechnology (ACHN) under Australia's national medical research funding agency, the National Health and Medical Research Council (NHMRC).
- Development of an Occupational Health and Safety (OHS) Research and Development (R&D) Program by the Australian Department of Employment and Workplace Relations (DEWR).

#### *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 NNS, announced in May 2007 (<http://www.industry.gov.au/nano>) and administered by the Australian Office of Nanotechnology (AON), places a high priority on addressing the HSE impacts of nanotechnology. A key activity in the Strategy includes analysis of the impact of nanotechnology on regulatory frameworks. Funds are being provided under the Strategy to the Australian Federal Departments of Health and Ageing, DEWR, and the Environment and Water Resources to ensure regulatory systems adequately address the health, workplace and environmental implications of nanotechnology.

The HSE Working Group, established to help facilitate nanotechnology HSE work in support of the National Nanotechnology Strategy, commissioned an independent report completed in September 2007 entitled "A Review of the Possible Impacts of Nanotechnology on Australia's Regulatory Framework". The findings of the report are being considered by government agencies presently.

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

The data collected by Australia's industrial chemicals regulator, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) in its voluntary call for information of December 2006 on the use of nanomaterials in the Australian industrial chemicals area, has been used to inform the focusing of metrology initiatives under the National Nanotechnology Strategy and the WPMN's HSE database.

#### **3. Information on any risk assessment decisions - No developments since 2<sup>nd</sup> WPMN**

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

Australia's Committee on Nanotechnology (NT-001), established under the national standards authority, Standards Australia, continues to provide input to the International Standards Organisation (ISO) Nanotechnology Committee (TC229) for the development of international nanotechnology standards and good practice documents.

- NT-001 is contributing to development of the ISO Technical Report on "Health and safety practices in occupational settings relevant to nanotechnologies", and is represented on the ISO Steering Group for this project. This Technical Report will provide advice relating to health & safety issues when working specifically with nanomaterials.
- NT-001 is also represented on the ISO TC229 HSE Working Group, which coordinates the development of international HSE related nanotechnology standards.

NanoSafe Australia, which brings together HSE-related research organisations around Australia, has prepared a Position Paper on "Current OH&S Best Practices for the Australian Nanotechnology Industry", published as "Safe Practices for Australian Nanomaterials – September 2007" *Journal of Occupational Health and Safety — Aust NZ 2007*, 23(4): 315–331.

A State-based OHS authority, WorkCover NSW (New South Wales), published the document: "NANOTECHNOLOGY. Occupational Health and Safety Overview", indicating growing interest in good practice at the workplace level – see [http://www.workcover.nsw.gov.au/NR/rdonlyres/3DCF2F55-9836-4097-820B-769D434301F2/0/nanotechnology\\_overview\\_may\\_2007\\_5309.pdf](http://www.workcover.nsw.gov.au/NR/rdonlyres/3DCF2F55-9836-4097-820B-769D434301F2/0/nanotechnology_overview_may_2007_5309.pdf)

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

The NNS places a high priority on addressing the HSE impacts of nanotechnology. Key activities in the Strategy include:

- ensuring a whole of government approach by establishing a Nanotechnology HSE Working Group consisting of policy, regulatory and research funding agencies across the Australian Government. The Working Group will coordinate the assessment of existing regulations with all relevant agencies and non government bodies. Where appropriate it will liaise with research bodies on areas of potential scientific and policy research. The HSE Working Group will work closely with the Public Awareness and Engagement program of the NNS on the provision of balanced and factual information to the public, including industry.
- The HSE Working Group will coordinate international engagement activities to enable Australia to leverage off technical and policy developments in other countries and to influence the development of international regulatory guidelines and standards.

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

- In OHS, DEWR developed a Nanotechnology OHS R&D Program (**Attachment A**), to support the implementation of the NNS. This Program will be implemented over the period 2007-11.
- In the area of human health, and further to the Nanotechnology Roundtable hosted by the NHMRC in December 2006, the NHMRC has established the ACHN, which will provide expert advice regarding the health related aspects of nanotechnology. The ACHN's first meeting identified opportunities for future NHMRC activity, and it is most likely that the NHMRC will target specific research areas through a request for applications. Priorities for research will be identified by the ACHN and through consultation with the research community. Possible areas of research include:

- Biomedical applications of nanotechnology (diagnosis, delivery, treatment and tissue regeneration, scaffolding, kinetics);
- increasing the evidence base in regard to risk; and
- life cycle analysis.
- Australia's premier industrial research organisation, the CSIRO (formerly called the Commonwealth Scientific and Industrial Research Organisation), is in the process of establishing a new research program into the health, safety and environmental effects of nanotechnology as part of its Niche Manufacturing National Research Flagship (<http://www.industry.gov.au/content/itrinternet/cmscontent.cfm?objectID=41600FC8-BE76-1714-7F4149588C1D143A>).

## **6. Information on any public/ stakeholder consultation**

As part of the AON, a coordinated Public Awareness and Engagement Program is to be developed and implemented over the next four years. The program is aimed to raise awareness and develop knowledge of the opportunities and potential of nanotechnology, and to encourage an informed debate based on balanced and factual information.

The objectives of the Public Awareness and Engagement Program are:

- to increase awareness and understanding among the general public about nanotechnology and its potentials;
- to enable an informed public debate through improved awareness and understanding of social and ethical issues regarding the use of nanotechnology;
- to provide the Australian public with timely updates on the Government's response to emerging nanotechnology issues; and
- to create public awareness and understanding of Australian regulatory bodies and practices concerning nanotechnology and related health and safety issues.

The Public Awareness and Engagement Program will arrange public forums, promotional materials, conference events and mobile exhibitions with targeted publicity in metropolitan, regional and rural media to support these initiatives. Industry surveys were undertaken in 2005 and 2006 to gauge the level of awareness and understanding of nanotechnology issues among targeted firms with a potential interest in nanotechnology; and public awareness studies undertaken in 2005 and 2007 surveyed the community on their understanding of nanotechnology related issues (<http://www.industry.gov.au/nano>).

For industrial chemicals, NICNAS is establishing a Nanotechnology Advisory Group comprising industry, the community and experts to assist it in ensuring that Australia's chemical assessment framework is able to address nanomaterials.

In OHS, DEWR consults widely on the proposed Nanotechnology OHS R&D Program, and on nanotechnology OHS generally.

**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 (2007-11) has been developed. Specific projects will be developed over the life of the workplan to reflect national priorities.
2. The program will be 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 Employment & Workplace Relations, Office of the Australian Safety and Compensation Council (ASCC).
4. A draft plan for the program has been defined in outline, 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
5. The program leader is:

Dr Howard Morris  
Assistant Director, Research  
Phone: (02) 6121 9127  
Email: [howard.morris@dewr.gov.au](mailto:howard.morris@dewr.gov.au).

***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.

## ***BELGIUM***

In November 2006 and April 2007, Belgium submitted a report on work completed, underway and planned (it was included in the compilation on the OECD public website). The highlights here are for actions between April 2007 and November 2007.

### ***Highlight of developments since the 2nd meeting of the WPMN***

- Launched a national call for tenders for a geno/eco/tox study of nanopolymers
- BE researchers now involved also in SG3 and SG6 of WPMN
- BE acquired a new electronic microscope useful also for nanomaterials characterisation
- Discussions between nanotechnologists, natural and social scientists, stakeholders, and citizens

### ***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 regulation specifically addressing nanomaterials in Belgium.

In Belgium, the Public Federal Service (Ministry) for Health, Safety of the Food Chain and Environment will be the leading competent authority to assess and manage risks in connection with handling and use of nanomaterials and this according to the existing regulations. However, currently no legislation activities are undergone to address it specifically as there is no definition of the nanomaterial in place under the current legislation framework. The point was raising several time during the ongoing negotiation of the REACH proposal and Belgium is waiting for a further initiative taken at EC level.

The interface 'environment and health' has already considered the nanotechnology as a potential action point for the upcoming yearly work programmes.

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

At present very little information is available about the presence of nanomaterials on the Belgian market. Therefore, it is envisaged to carry out a "market" survey by convening the related sector (from R&D till manufacturers and down stream users). Those stakeholders will be invited to participate in declaring the purpose/extent/concerns of their current research and development of products/articles.

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

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

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

In Belgium we would like first to collect these information during the survey planned and thereafter develop good practice documents based on best available practice, as more specific knowledge concerning nanomaterials and situations for guidance-request are first needed.

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

A ad-hoc nanomaterials working group as been established by the Belgian Ministry of Health, food safety and environment, with a first meeting in February 2007. Group members are presently scientifics from Universities and public research centers, and representatives of CA. In the future this group will possibly be integrated to the framework of the Belgian Cooperation Agreement Act for Environmental policy. This group is informed in first instance about developments at international level (e.g. OECD). As a second goal, collection of scientific information would allow the Belgian CA to decide how to best answer to the potential safety concerns linked to the production and use of nanomaterials for human health and the environment. Contacts between researchers in nanomaterials safety in Belgium are promoted by this group.

Belgian researchers are now involved in OECD SG1 and SG2, SG3 and SG6; a draft listing of Belgian research on nanomaterials toxicology is started; WPNM is now known by researchers in Belgium; Research priorities are currently being identified

During the 2<sup>nd</sup> meeting of the Belgian nanomaterials working group, current Belgian research projects descriptions were collected:

Institution	Title	Financing	Duration	Partners & Contact
Katholieke Universiteit Leuven, Department of Public Health	Physico-chemical determinants of toxicity: A rational approach towards safer nanostructured materials	Belspo: CONTRACT NR SD/HE/02A	01/01/2007 – 31/12/2010	UCL - KUL – VUB P. Hoet, B. Nemery
Idem	Safe production and use of nanomaterials	EU IP; Nanosafe2: Contract no 515843-2	01/04/2005 – 31/03/2009	24 partners P. Hoet, B. Nemery
Idem	Nanotechnology Capacity Building NGOs	EU NANOCAP: Contract no 036754		16 partners P. Hoet, B. Nemery
Idem	Improving the understanding of the impact of nanoparticles on human health and the environment	EU Impart: Contract no:013968I	01/02/2005 – 31/01/2008.	20 partners P. Hoet, B. Nemery
Idem	Mechanisms of lung and cardiovascular effects of air	FWO Vlaanderen G.0165.03N	01/01/03 – 31/12/07	P. Hoet, B. Nemery

	pollution particles			
Idem	Particles translocation through the lung epithelium: development and use of an in-vitro model	FWO Vlaanderen G.0169.04	01/01/04 – 31/12/07	P. Hoet, B. Nemery
University of Namur	Nanotoxicology : evaluation of the potential toxicity of nanoparticles of interest to the industry (in vitro, in vivo, physical characterisation, chemical modifications, communication)	Région Wallonne and University of Namur	5 Years	O. Toussaint
Scientific Institute for Public Health	Optimization and adaptation of an in vitro strategy for the assessment of human toxicity of nanoparticles	Scientific Institute for Public Health	3 years project , Started in Nov-2006	P. Troisfontaines

Ecotoxicology is not currently addressed by those projects (while human toxicology is well represented), so the Belgian Ministry of Health, food safety and environment is considering the feasibility of funding a research project in that field.

A small budget national tender as been launched by the Belgian Ministry of Health, food safety and environment in november 2007 for a study of the toxicity, ecotoxicity, and genotoxicity of nanopolymers used in the biomedical domain for genetic applications.

The VAR (Veterinary and agrochemical research center), part of the Belgian Ministry of Health, acquired a new electronic microscope, which has been tested for nanomaterials characterization. This instrument is potentially useful for the characterizations planed by WPMN/SG3.

## 6. Information on any public/ stakeholder consultation

The working group referred in point 1 will be extended to the stakeholders including NGO and industrial federation.

The following research project includes public consultation: *Nanotechnologies for Tomorrow's Society (NanoSoc) brings together nanotechnologists, natural and social scientists, stakeholders, and citizens in the region of Flanders, Belgium, to discuss and reflect on the opportunities and challenges involved in the constructive social shaping of nanotechnologies in three particular fields of application: smart environment, bio on chip, and new materials. The research project is funded by the Flemish Region Government.*

## CANADA

### *Highlight of Developments since the 2<sup>nd</sup> Meeting of the WPMN*

The following activities have taken place since the 2<sup>nd</sup> meeting of the OECD Working Party on Manufactured Nanomaterials in April 2007:

- Environment Canada and Health Canada hosted a multi-stakeholder workshop to consult with industry, non-governmental organizations, academia, and other interested parties on the proposed approach to a regulatory framework for nanomaterials under the *Canadian Environmental Protection Act, 1999* (see Section 1).
- Environment Canada issued an advisory note on the application of the *New Substances Notification Regulations (Chemicals and Polymers)* for nanomaterials (see Section 1).
- Industry Canada, in conjunction with Environment Canada, Health Canada, and the Canadian Food Inspection Agency completed a contract study to identify US companies exporting nanotechnology-related products to Canada (see Section 2).
- In the area of scientific research, funding for two environmental effects projects has been approved and there are more opportunities to obtain funding for environmental and health related research on nanotechnology. Several National Research Council Institutes are collaborating to exploit multi-disciplinary strengths to focus on fundamental R&D topics which underpin EHS research. (See Section 5).
- In the area of policy research the Council of Canadian Academies has begun an assessment of the current state of knowledge of potential human health and environmental risks of nanotechnology. The Canadian Institutes of Health Research, in conjunction with various federal government departments, is planning a workshop to examine the nano ethical, economic, environmental, legal, and social issues. (See Section 5).

## 1. Regulatory Developments in Canada

### Federal government actions

- A. In September 2007, Environment Canada and Health Canada hosted a multi-stakeholder workshop on a proposed approach for a regulatory framework for nanomaterials under the *Canadian Environmental Protection Act, 1999*. The one-day meeting brought together members of industry, non-governmental organizations, academia, and other interested parties to obtain their feedback on the overall proposed approach and the possible options for information gathering initiatives (see Section 2). The final workshop report will be issued in late November 2007.

The proposed approach to develop a regulatory framework for nanomaterials consists of two phases with near and longer term objectives.

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.

- B. On July 16, 2007, Environment Canada issued an advisory note informing manufacturers and importers of nanomaterials of their regulatory responsibilities for nanomaterials under the *New Substances Notifications Regulations (Chemicals and Polymers)*. The advisory note provides information describing nanomaterials and which nanomaterials are subject to the current regulations. The advisory note can be found at [http://www.ec.gc.ca/substances/nsb/eng/a200706\\_e.shtml](http://www.ec.gc.ca/substances/nsb/eng/a200706_e.shtml).
- C. A nanotechnology workshop for the Health Portfolio was held in March 2007. Participants from Health Canada, the Public Health Agency of Canada, and the Canadian Institutes of Health Research met with invited experts to discuss the basis for a Health Portfolio Strategy on Nanotechnology. A Health Portfolio Nanotechnology White Paper will be produced based on a previously developed Health Portfolio Issue Paper and the findings of the workshop.
- D. An interdepartmental senior management committee is in place to engage federal science and technology departments. The committee has drafted a federal action plan for a coordinated and consistent approach to the regulation of nanotechnology in Canada. The plan includes recommendations to senior management to:
- Endorse and support the management structure for efforts on nanotechnology;
  - Enhance partnerships and linkages with industry, academia, and laboratories; and
  - Continue to participate actively in international efforts.
- E. A Federal Workshop on the Health and Environmental Implications of Nanoproducts (March 2006) brought together senior regulatory program managers, hazard and risk evaluators, and researchers to discuss regulatory science needs for nanotechnology. This workshop led to the formation of a Federal Working Group to:
- Develop consistent approaches to testing, assessment and management of nanomaterials;
  - Cooperate in research and testing of nanomaterial properties and effects;
  - Ensure adequate resourcing of Canada's participation in international activities; and
  - Ensure no duplication of efforts with respect to developing the necessary science to assess substances and products of nanotechnology.

## 2. Developments on Voluntary or Stewardship Schemes in Canada

Information gathering schemes aim to obtain information on nanomaterials in order to help direct the development of regulations, research, and risk assessments. Several options are being considered for information gathering initiatives: a voluntary program, a mandatory program, and a blend of voluntary and mandatory programs. A proposal for an information gathering initiative is expected to be issued in January 2008 based on feedback from the multi-stakeholder workshop (see Section 1).

The information gathering scheme will focus efforts on obtaining information on nanomaterials from industry and on building a knowledge base to inform risk assessment and management approaches. The objectives of the program would include:

- Identification of nanomaterials in Canadian commerce.
- Facilitated acquisition of information in industry possession.
- Provision of guidance on appropriate testing to identify potential health and environmental impacts of nanomaterials.

The Canadian approach will be informed by discussions within Steering Group 5 of the WPMN. The current tasks in preparation for a Canadian information gathering initiative:

- Considering incentives that would encourage notification within the initiative timeframe.
- Developing consultation documents to engage industry, the public, and other stakeholders.
- Targeting program launch in the first 6 months of 2008.

### 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. The final report can be at [http://www.ic.gc.ca/epic/site/aimb-dgami.nsf/en/h\\_03459e.html](http://www.ic.gc.ca/epic/site/aimb-dgami.nsf/en/h_03459e.html).

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
  - Recently, the New Substances Program of Environment Canada and Health Canada received notification for a substance identified as a nanomaterial. This substance is currently under review by the two departments.
- 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

No activities to report on this topic.

### 5. Research in Canada

#### Scientific research

Research on human health and environmental effects in Canada is limited, but efforts are currently ongoing to strengthen both government and academic initiatives, especially those emphasizing collaborations between these two groups of researchers.

- Environment Canada (EC) and Health Canada (HC) are supporting research proposals addressing environmental fate of nanomaterials. In October 2007, two projects on environmental effects have received funding from the Strategic Grants Program of the Natural Sciences and Engineering Research Council. These projects will involve a multi-university approach with input and financial support from EC, HC, and Agriculture and Agri-Food Canada.
- Natural Sciences and Engineering Research Council and the Canadian Institutes for Health Research are encouraging the inclusion of health and environmental impacts components for research proposals involving nanotechnology. In a special call for proposals, the National Research Council of Canada and the Business Development Bank of Canada have targeted nanotechnology research in part related to the environment. The competition is currently underway.
- The National Research Council of Canada has launched new R&D initiatives which support collaborative projects between Institutes ([http://www.nrc-cnrc.gc.ca/institutes/index\\_e.html](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; topics such as

metrology in support of nanotechnology. Proposals have been selected from competition and research work will be underway this fiscal year.

#### 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 is expected to be completed in the spring of 2008.
- 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, is planning a workshop on nanotechnology in early 2008. The objective of the workshop will be to promote 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<sup>3</sup>LS). The workshop will also seek to set research priorities in the field of nanotechnology and health impacts.

#### **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. Additional consultative meetings will be conducted as part of the normal process in the development of a regulatory regime for nanomaterials.

## **DENMARK**

### ***Highlight of developments since the 2nd meeting of the WPMN***

- **Further dialogue between authorities / industry and other stakeholders**
- **Further research initiatives**
- **Future projects regarding information and possible administrative measures**

### ***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 regulation specifically addressing nanomaterials in Denmark.

In Denmark the Ministry of the Interior and Health has in 2006 initiated a survey examining whether the existing regulation in the different sectors (environment-sector; chemical sector, food-sector, pharmaceutical-sector, occupational environment sector, and health sector) would also cover risk related issues in connection with handling and use of nanomaterials. The work is almost completed (expected to be published at the end of 2007). The regulation in the different sectors covers in general situations where nanomaterials are handled or used 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 adjustments in the regulation.

In general there seems to be no need for a new and a broad trans-sector regulation on nanotechnology but rather to focus on identification on areas in the present regulations where updating or adaptations may be required in order to consider specific aspects of nanomaterials.

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](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 March 2007, 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. The bill 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.

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.

The Danish EPA has sent out a call for a project to examine, describe and possibility to develop a declaration guide or standards on 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 project (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 continues its 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 the Danish work in relation to risk assessment and risk management 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](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 claiming 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](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)

Although not fully established yet the Danish EPA consider 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.miljoegsundhed.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****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 Finnish competent authorities in chemicals administration, the Finnish Environment Institute (SYKE) and the National Product Control Agency for Welfare and Health (STTV), under the Ministry of Environment and the Ministry of Social Affairs and Health (STM), respectively, have intensified their networking at different organisational levels, as well as on data collection. SYKE is preparing a survey on environmental effects of nanomaterials.

SYKE and STTV chaired (November 25, 2007) the first Nordic Seminar on Nanomaterial, arranged by the Nordic Chemicals Group under the Nordic Council of Ministries. This seminar was attended by Nordic regulators and related experts. The topics included OECD work (WPMN), German experiences, OECD test guideline work, risk communication, the role of national chemical product registers (including regulatory needs), and discussions on needs of cooperation between Nordic countries. Also the regulatory relevance of the REACH legislation was discussed, and the draft conclusion was that in the current form, without further implementation guidance or additional pieces of legislative instruments, the current legislation, including the REACH regulation, may not be appropriate for nanomaterials.

Finland is actively participating in the OECD test guideline programme and the testing activities, SG3 and SG4 in the WPMN. Recently Jukka Ahtiainen (SYKE) has been appointed to chair a sectiongroup of SG4.

The Department of Occupational Safety and Health in the STM is participating in the European and Nordic discussions on establishing specific occupational limit values for nanosized substances.

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

Various fields of technology and research in small and nanosize particles have been brought together in a national HIUKKASFOORUMI ("Particle Forum") network, based on the 2006 "FINE" technology programme. This forum facilitates data sharing on human exposure, air purification technology, and monitoring/measurement technology, relevant to small and nano size particles. Recently efforts have been made to bring HSE authorities to participate in this network. A recent seminar "Safe Nanotechnologies" was held 1. November 2007.

A survey on nanosafety aspects and needs in Finland is on-going as part of the FinNano Nanoscience and Nanotechnology Programme. This survey covers, in addition to technology companies, several authorities and it is carried out by Gaia Consulting Oy. The first results will be published in December 2007.

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

National Public Health Institute (KTL) and VTT Technical Research Centre participate in the European Nanosafe 2 project. Dr. Hänninen (KTL, Env.Health) will start 2008 in section 4.1 Health at work aspects: reduction of emissions and effluents, with an aim to apply probabilistic modelling techniques in risk assessment.

At the Finnish Institute of Occupational Health a research programme on safety of engineered nanoparticles and nanotechnologies has been initiated. The resources are about 13 person years. The activity is funded by an EU-project with an acronym NANOSH with duration of 36 months and a budget of 2.4 million euros (7 partners from 5 EU-countries). Additionally, another project funded by the Academy of Finland with duration of 36 months and a budget of 782,000 euros has been initiated, also during 2006. Earlier, smaller project on the safety of engineered nanoparticles and nanotechnologies have been carried out by the Finnish Institute (New Technologies and Risks Team). The overall external funding of this activity for next four years is about 3 million euros. Additionally, an EU-application with a duration of 48 months and budget of 11,8 million euros is now being evaluated by the Commission. This last application has 26 partners from 12 EU countries plus one EEA country. The coordinator of all of these projects is the director of the New Technologies and Risks team, Professor Kai Savolainen, MD (email: [kai.savolainen@ttl.fi](mailto:kai.savolainen@ttl.fi))

In addition to these activities, Finnish Institute of Occupational Health organizes an EURONANOSH Conference in Helsinki on December 3-5, 2007 with a predicted number of participants of about 170-200. Co-organizers of the Congress are TEKES (Finnish funding organization for technological innovations, US NIOSH, and the Italian Institute of Occupational Health, ISPESL). The president of the Congress is Professor Harri Vainio, Director General of the Finnish Institute, and Co-President Professor Kai Savolainen.

**FRANCE*****Highlight of developments since the 2nd meeting of the WPMN***

- The Nanoforum being held at the Conservatoire National des Arts et Métiers (CNAM):  
At the government's request, the CNAM has organised a series of regular meetings between the various players concerned (researchers, manufacturers, associations, journalists, government administrations, etc.) focusing on the health, environmental and social aspects of the industrial development of nanotechnologies.

Following the opening session in June 2007, a concrete case – the use of nanoparticle TiO<sub>2</sub> in cements – was discussed by a group of scientists, government officials, citizens, manufacturers and NGOs. The conference held on 6 December 2007 addressed the use of nanomaterials in cosmetic products. The session to be held on 7 February 2008 will deal with nanomaterials in food.

- Proposals developed during the French government's environmental forum (Grenelle de l'environnement):  
The summary of conclusions of the second roundtable – "Health-environment" Programmes: C) Emerging risks: Anticipating the risks of nanomaterials – formulated the following proposals:
  - To hold a public debate on this issue organised by the *Commission Nationale du Débat Public* (National Commission for Public Debate) in 2008
  - To implement mandatory labelling on the presence of nanoparticles in consumer products by 2008
  - To require that cost/benefit analysis be conducted systematically before marketing products containing nanoparticles or nanomaterials by 2008
  - To develop a regulatory framework for products containing nanomaterials
  - To ensure that action is taken to inform and protect employees on the basis of the findings of studies currently being conducted (in particular, by the *Agence Française de Sécurité Sanitaire de l'Environnement et du Travail*, the agency responsible for environmental and occupational health and safety)

***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**
  - 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**
- A group to monitor the health impact of nanotechnologies will be established in January 2008. This expert and advisory group, which is interministerial in scope, will work under the authority of the board of the High-Level Council for Public Health (Haut Conseil de la santé publique). Its mission will be as follows:

- To ensure the scientific monitoring of publications on the health, environmental, social and legal impact of nanomaterials and nanotechnologies and to take stock of on-going research
- To provide analysis and make recommendations to the government on the basis of its findings

**6. Information on any public/ stakeholder consultation**

*Additional Information*

- REACH and nanotechnologies: during the French Presidency of the EU, France might take action to ensure that manufactured nanomaterials are really taken into account in the REACH regulation

**GERMANY*****Highlight of developments since the 2nd 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".

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), Defense (BMVg), Health (BMG) and Commerce and Technology (BMW)). 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 need to be checked again in the future, whether they are sufficient to protect man and environment.

**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](http://www.technikwissen.de/gest/currentarticle.php?data[article_id]=38107&PHPSESSID=45f53091cdd716651169e251e2462e73). An English translation will be available soon.

### **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](http://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. At present it is under revision.

### **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 a fundamental psychological study linked with an opinion poll in the German public. The project aims to analyse appraisal, standard of knowledge and expectations of consumers, to identify psychological factors of perception of nanotechnology and to compile an image of nanotechnology. The BfR conducts this project together with Vierboom & Härten, Business Psychologists and the University of Bonn. First results are expected for December 2007.

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 staged jointly with the University of Muenster and will be finished in June 2008.

**IRELAND*****Highlight of developments since the 2nd meeting of the WPMN***

- In June 2007 the Technical and Scientific Advisory Committee of the Health and Safety Authority agreed to set up an ad-hoc working group on Nanotechnology
- The Health and Safety Authority liaised with Forfás, Enterprise-Ireland, Academia, Irish Industry and Irish Business and Employers Confederation and other Irish departments in the set up of this ad-working group on Nanotechnology
- The Health and Safety Authority proposes to develop a Strategy on the Safe Use of Nanomaterials in the workplace
- The Irish Government has proposed € 31 Million funding to research programmes in the area of nanoscience
- Current call for research proposals in the area of environmental & human health from the Irish EPA
- Projects foreseen under the 7<sup>th</sup> Framework Programme
- Conference: Nanotechnology: implications for human health, the environment and food safety

***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 April 2006 the Health and Safety Authority (HSA) which is the Competent Authority for chemical legislation in Ireland liaised with the National Policy & Advisory Board for Enterprise, Trade, Science, Technology & Innovation (Forfás) and with the governmental agency Enterprise-Ireland responsible for the development of Irish Industry, to discuss future development in relation to the use of nanomaterials.

During 2006 Forfás organized Panel meetings (NanoBio, NanoMaterials and NanoElectronics) (as part of a Technology Assessment process to develop a national approach to the development of Nanotechnology in Ireland) to discuss approaches with stakeholders regarding the nanotechnology development.

Forfás is preparing 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. This is scheduled to be published soon.

It is also hoped that a national policy will be developed with all the key stakeholders following further discussions at national level.

In June 2007 the Technical and Scientific Advisory Committee (TSAC) of the Health and Safety Authority (HSA) agreed to 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. Expressions of interests were received from relevant stakeholders, such as academia, industry and several other Irish departments, to participate in the ad-hoc working group. These were presented to the TSAC for their approval.

The 1<sup>st</sup> ad-hoc working group meeting was held on 1<sup>st</sup> October 2007, where the Terms of Reference was discussed and agreed. The 2<sup>nd</sup> ad-hoc working group meeting is scheduled for the 7<sup>th</sup> December 2007.

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

At present there are no specific initiatives in relation to voluntary or stewardship schemes in Ireland. However, some companies that participated in the HSA nanotechnology internet consultation signaled that they are willing to share further information on current projects. A dialogue with these companies will have to be initiated.

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

Ireland has not yet received a notification of a nanomaterial. Consequently no risk assessment has been carried out.

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

Due to lack of information Ireland is not yet in a position to develop guidance or good practice documents.

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

Ireland does not have an overall specific research programme to address human health and/or environmental safety aspects of nanomaterials. However, Ireland received approval and funding from the EU for a project under the sixth Framework Programme (FP6) search, technical development and demonstration activities. The project NanoInteract focuses on risk assessment of engineered nanoparticles and is led by the University College Dublin (UCD). Several other Irish universities and Irish companies are involved in this project along with UCD.

NanoInteract started on 1<sup>st</sup> January 2007 and will run until 31<sup>st</sup> December 2009.

Enterprise-Ireland has noted a number of risk assessment and health and safety activities under the seventh Framework Programme (FP7) for research, technical development and demonstration activities. The call for FP7 closed on the 4<sup>th</sup> May 2007. It is hoped that some of these projects will be successful in receiving final approval.

In August 2007 the Irish Minister for Education and Science, Mary Hanafin, indicated that the €31 Million funding will be provided to research programmes in the area of nanoscience and will be provided to six universities and two institutes of technology (Ref. Irish Times, 4<sup>th</sup> August 2007). No details are available to date on how much funding will be used in research programmes to address human health and/or environmental safety aspects of nanomaterials.

The Irish EPA has launched a call for research proposals in the area of environmental & human health with a closing date by 23<sup>rd</sup> 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

The Joint Conference: ‘Nanotechnology: Implications for Human Health, the Environment and Food Safety’ was organised by the Dublin Institute of Technology in collaboration with the Food Safety Authority of Ireland and the Irish Society of Toxicology. More than 150 participants from academia, industry, and national regulatory and funding bodies attended the conference. Among the participants were also a number of international delegates from academia in Italy, Germany and Belgium.

## **6. Information on any public/ stakeholder consultation**

In April 2006 the Health and Safety Authority (HSA) developed a questionnaire regarding engineered nanomaterials to address the following objectives:

- Need to gain some information on the nature of nanomaterials, such as:
  - Type of nanomaterials (chemical identity)
  - Type of industry using nanotechnology in Ireland
  - Quantities of nanomaterials used in Ireland
  - Particle sizes of nanomaterials
  - Methods by which nanomaterials are identified
  - Any information available on the potential hazard(s) associated with these nanomaterials
  - Exposure scenarios for nanomaterials in Irish industry
- Need to modify regulations to address the risks of nanotechnology
- Need to share information internationally on nanotechnology
- Need to standardise definitions in respect of nanotechnology
- Guidelines may have to be adapted in respect of nanomaterials
- An alert system containing information on the kind of products involved may have to be created, based on information requirements of regulators

This questionnaire was made publicly available on the HSA website as internet consultation for a period of six weeks (1<sup>st</sup> August to 15<sup>th</sup> September 2006).

Responses were received from companies including the following sectors: electronics, pharmaceutical and medical devices.

## **ITALY**

### ***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**

While at public and private level in Italy there is a general consensus on the need of facing the challenge posed by nanotechnology, the actual situation in the research and regulatory area on health and safety aspects of nanomaterials is characterized by a general scarcity of initiatives at both public and private levels. Policy oriented discussion on the necessary approach for the development of research strategies and programmes to address health and risk implications of manufactured nanomaterials results still very scarce. In the context of the national standardization body (UNI) it has been activated a commission entitled Nanotechnology, which is structured in four working groups: Terminology; Instrumental measurement and characterization; Health and safety aspects; Nanotechnological products and processes. Up to now their activities have been limited to the acquisition of informations from the mirror commissions of ISO and CEN. Their active work is still to be planned.

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

Voluntary or stewardship schemes at institutional or industrial level are still absent and the same happens for the development of good practice guidelines.

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

Regulatory initiatives or decision on testing methods and risk assessment activities are absent at both public and private level.

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

There are no initiatives on this aspect.

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

Specific research studies concerning mainly toxicological experiments *in vitro* on some type of nanomaterials are actually underway in a limited number of small groups of people in some university, research centres, or institutes, but they are conducted with a limited ambition level and poor co-operation/co-ordination among them. Some of these groups participate to the following two research projects funded by the European Commission under the Sixth Framework Program for Research, Technological Development and Demonstration (FP6): “Development of an Integrated Platform for Nanoparticle Analysis” (DIPNA) to verify their possible toxicity and the eco-toxicity, coordinated by Italy (University of Modena and Reggio Emilia), and “Risk Assessment for Particle Exposure” (PARTICLE-RISK) to which cooperate two research centers in Venice, University of Ca’ Foscari and Consortium Venezia Ricerche. In addition at level of initial proposal very recently the National Institute for Occupational, Safety and Prevention (ISPESL) has proposed a project (yet to be approved and financed) to the Ministry of Health on the aspects of occupational exposure to nanomaterials (focused on carbon nanotubes), but the environmental safety aspects are not taken into consideration in this project.

## 6. Information on any public/ stakeholder consultation

Public/stakeholders consultation initiatives result not yet planned or activated.

The only exception which may be considered is an initiative taken by the association AIRI (Italian Association for Industrial Research) and its division NanotecIT (Italian Centre for Nanotechnology) aimed to provide a census of the public and private organizations involved in nanotechnology in Italy ([www.nanotec.it](http://www.nanotec.it)).

The second edition (2006) of the report (first one was published in 2004) gives a general outlook of research activities and initiatives in the country on nanotechnology and provides also a detailed description of the 169 organization having answered the census and doing R&D in the field.

The new census has confirmed the increase of the commitment in nanotechnology in Italy.

The number of structures/organizations (enterprises, research centres, departments, institutes, etc.) active in nanotechnology that answered the census increased, in fact, from 120 in the 1<sup>st</sup> Census to 169: around 60% of them refer to public institutions and around 40% to private enterprises.

The role of public research is still fundamental. All major public research organisations (CNR/INFN, INSTM, INFN, ENEA)<sup>1</sup> and universities are involved. Relevant resources are dedicated to this field and various initiatives have been put in place to improve the effectiveness of the efforts.

In particular seven centre of excellence dedicated to nanotechnology have been established in the last years at various italian universities, while five high technology clusters (structures financed by the government to promote particular technologies in different italian regions), have activities related to nanotechnology; one of them is specifically focused to nanotech.

The new census has also shown that involvement of industry in nanotechnology has also stepped up as indicated by the number of structures linked to private enterprises which have passed from 20 in the 1<sup>st</sup> Census to 65. About one third of these companies are large companies, including widely known national players, while the rest are SMEs, often spin off or start ups.

Both for public and private organizations the research efforts are rather distributed on many thematic areas of research, but, according to the data received, nanomaterials are the field in which the research is more intense.

In the period 2002–2005 the organizations reported in the census have produced about 7000 scientific publications dedicated to nanotechnology, most of them on International journals.

Although the activity in nanotechnology in Italy (as elsewhere) is essentially at research stage, the census has pointed out that more than one third of the public and private organizations considered are working on nano-related products or processes at prototype, pilot or commercial level.

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**CNR:** Consiglio Nazionale delle Ricerche (National Research Council);

**INFN:** Istituto Nazionale di Fisica della Materia (National Institute of the Structure of Matter);

**INSTM:** Consorzio Interuniversitario per la Scienza e Tecnologia dei Materiali (Inter-University Consortium for Materials Science and Technology).

**INFN:** Istituto Nazionale di Fisica Nucleare (National Institute of Nuclear Physics);

**ENEA:** Ente per le Nuove Tecnologie, l'Energia e Ambiente (National Body for New Technologies, Energy and Environment).

***Additional Information/Comments***

A very recent initiative has been announced by industry about the establishment of an European Center for the Sustainable Impact of Nanotechnology (ECSIN). The aim of the center is that of carrying out researches and studies to evaluate whether and which could be the backlash upon human and environment health, due to the exposition to nanoparticles and/or nanomaterials.

ECSIN (<http://www.ecsin.eu>) will be active in three main nanotech sectors, with a multilevel analysis approach:

- Interaction human health / environment
- Public perception and social/ethical policies
- Education for a responsible use

Moreover there are contacts with the Italian Ministry of Health for the creation of a first task force on the potential health risks associated with production and use of nanomaterials.

In conclusion it seems that most of the current research efforts in Italy are more focused on industrial development and application of a variety of nanomaterials than on their potential health and safety implications.

More work remain to be done in the field of health and environmental safety implications of manufactured nanomaterials.

**JAPAN*****Highlight of developments since the 2nd meeting of the WPMN***

- The National Institute of Occupational Safety and Health Japan (JNIOSH) has started a three-year project study on possible health issues related to exposure to manufactured nanomaterials in the workplace since April 2007.
- The National Institute for Environmental Studies (NIES) has installed a nose-exposure chamber to investigate in vivo effects of nanomaterials in a doubly-shielded room. NIES will soon start an inhalation study for in vivo toxicity test for nanomaterials using rats or mice.

***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 the existing regulatory system, the Chemical Substance Control Law obliges manufacturers to notify the government about nanomaterials if they are new chemicals subject to the Law, and some notifications concerning fullerene derivatives have been submitted under the small quantities exemption of the new chemical notification.

The Ministry of Economy, Trade and Industry (METI) has just had a preliminary discussion on the health and environmental safety issues of manufactured nanomaterials as one of the emerging issues to be addressed in the near future within the framework of chemical management in METI's Policy Council on Chemical Issues. However, no proposal regarding concrete measures restricting manufactured nanomaterials has been put on the table yet.

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

The Japanese Government does not have any voluntary reporting scheme on health and environmental safety issues of manufactured nanomaterials at this stage.

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

The Japanese Government does not have any risk assessment decisions regarding manufactured nanomaterials.

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

METI has conducted a preliminary survey on safe handling of nanomaterials at manufacturing sites and research laboratories in fiscal year 2006. Through the survey, METI has reviewed existing good practices both from domestic and overseas sites and has drafted basic guidelines. These draft guidelines are to be reviewed by industry stakeholders for implementation.

Furthermore, METI's programme on safety nanomaterial project "Evaluation of the Potential Risks of Manufactured Nanomaterials based on Toxicity Tests with Precise Characterization" is mentioned hereinafter. It could lead to the development guidance documents relating to good practices for appropriate handling methods of manufactured nanomaterials in the workplace, such as at research institutes and at production sites.

## **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 as a strategic Science and Technology Priorities in the 3<sup>rd</sup> Science and Technology Basic Plan in Japan.

Also, The Cabinet Office has decided to establish a committee that coordinates research and development policy on nanotechnology. Dr. Junko Nakanishi will participate in this committee as a coordinator. One of its targets is to establish the information infrastructure to accelerate innovation, by facilitating research and development of nanotechnology and research for public acceptance of nanotechnology in a focused and strategic manner.

In fiscal year 2005, four national institutes, namely The National Institute of Advanced Industrial Science and Technology (AIST), the National Institute of Health Science (NIHS), the National Institute for Environmental Studies (NIES), the National Institute of Materials Science (NIMS), and some universities have jointly conducted research and surveys to facilitate public acceptance of nanotechnology. They focused on 1) risk assessments of nanomaterials, 2) health issues of nanomaterials, 3) environmental issues of nanomaterials, 4) ethical and societal issues of nanotechnology, and 5) technology assessment for promoting the public acceptance of nanotechnology and its economic effects through funding by the Ministry of Education, Culture, Sports, Science and Technology (MEXT). The survey team has issued a report which contains a series of recommendations to public institutes, the private sector and the government. These survey results may possibly be used as a guide for future national measures by the government. In 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 nanotechnology implication for health, environment and social acceptance.” The additional objective is the establishment of a researchers’ network on the implications of nanotechnology.

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

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

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

Also, MHLW conducted a preliminary project in 2005, and has launched a subsequent three-year project named “Research on the hazard characterization and toxico-kinetic analysis of manufactured

nanomaterials for the establishment of health risk assessment methodology” led by NIHS from 2006. The project has been focusing on detecting 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, MHLW will conduct a survey on nanomaterials used for consumer products. Currently, the details of the survey are under consideration.

The National Institute of Occupational Safety and Health Japan (JNIOSH) has 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.

Last year 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. Recently, a nose-exposure chamber has been installed to investigate in vivo effects of nanomaterials in a doubly-shielded room. NIES will soon start an inhalation study for in vivo toxicity test for nanomaterials using rats or mice.

## **6. Information on any public/ stakeholder consultation**

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

**REPUBLIC OF KOREA**

***Highlight of developments since the 2nd meeting of the WPMN***

- Started a new project on the safety of manufactured nanomaterials in the framework of Ecotechnopia21 project (as elaborated below in #5, worked by MOE).
- Initiated a series of research projects on the toxicity of nanomaterials (as elaborated below in #5, worked by KFDA)

***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. However, MOST (Ministry of Science and Technology) started 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 development related to voluntary or stewardship schemes.

**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.

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

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

**Ministry of Environment (MOE)**

MOE has conducted the Eco-technopia21 project to promote the development of environmental technologies since 2001. MOE started a project on human health and environmental safety of nanomaterials in the framework of Eco-technopia21 from April 2007, which will be continued until 2010. USD 0.5 million per year is invested on this project annually, in total USD 3 million. The ultimate goal of this research is to support the establishment of infrastructure necessary to minimize potential risks derived from the manufacture, distribution and disposal of nanomaterials and nanomaterials-containing products. The research project includes 1) identification of environmental release of manufactured nanomaterials 2) characterization of physico/chemical properties of nanomaterials, 3) development of monitoring methods of nanomaterials in air and waters 4) (eco) toxicological assessment of nanomaterials by systematic molecular biology 5) environment exposure and fate of nanomaterials including LCA, and 6) preparation

of test guideline for the risk management of nanomaterials. The project is designed that results would be used for the supportive data to international cooperation activities of OECD WPMN.

#### Ministry of Science and Technology (MOST)

MOST has performed a research project named 'environmental implications assessment of nanomaterials' from 2006. The outputs of the project include 1) the characteristics of nanomaterials 2) the domestic and overseas trends in industrial, social, pharmaceutical, human, and environmental effects on nanomaterial 3) need for research on human health and environmental safety, and 4) a proposal for a new institute to address negative effects of nanomaterials. Besides, MOST is conducting two projects on EHS (Environment, health and Safety) and ELSI (Ethical, Legal, and Social Issue) of nanomaterials, which will be continued for one year from second half of 2006. Those projects will spend USD 200 thousand and USD 100 thousand, respectively.

#### Korea Food & Drug Administration (KFDA)

KFDA is conducting a series of research projects on the toxicity of nanomaterials from 2007 to 2015 aiming for the development of a toxicological assessment system of nanomaterials and establishment of the related guidelines for the area such as food, drug, medical product, and cosmetics. KFDA is spending USD 3 million this year and the budget will be increased upto USD 3 million per year in conducting this project which includes genetic toxicity, inhalation toxicity and *in vitro* study.

#### Korean Agency for Technology and Standards (KATS)

As a Korean representative for ISO, KATS has conducted all works related to ISO/ TC 229. Recently, KATS submitted two standard proposals to ISO/TC 229: 1) for monitoring silver nanoparticles in inhalation exposure chamber for inhalation toxicity testing, and 2) for generation of silver nanoparticles for inhalation toxicity testing.

### **6. Information on any public/ stakeholder consultation**

Korea Nanotechnology Research Society was established by law and is composed of professors and researchers from public and private institutes. Korea Nanotechnology Research Society held a public hearing on environmental implications assessment of nanomaterials in December 2006 where experts from the government, research institutes, universities, and NGOs participated and public opinions on the EHS, ELSI of nanomaterials were collected.

## **THE NETHERLANDS**

### ***Highlight of developments since the 2<sup>nd</sup> meeting of the WPMN***

- In November 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 a document for the Government on the risk strategy by the end of 2007 and an action plan for both applications and risks of nanotechnology in early 2008.
- The first phase of the establishment of a National Observatory dealing with the possible risks of nanoparticles has been completed at the National Institute for Public Health and the Environment (RIVM).
- 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 in early 2008.

#### **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 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**

Recently the VNO/NCW (Business 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. Update is expected before the 4th WPNM meeting in June.

**3. Information on any risk assessment decisions****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 early 2008.

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

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 the spring of 2008.

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

**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 2008.

## **NEW ZEALAND**

### ***Highlight of developments since the 2nd meeting of the WPMN***

- There has been no significant developments in New Zealand since the 2<sup>nd</sup> meeting of the WPMN

### ***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 Code 2007<sup>1</sup>, and the Australia New Zealand Food Standards Code<sup>2</sup>, 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 over the next 18 months or so 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. 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.

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<sup>1</sup> <http://www.nzfsa.govt.nz/policy-law/legislation/food-standards/nz-mrl-fs-2007-consolidation.pdf>

<sup>2</sup> <http://www.foodstandards.gov.au/the-code/foodstandardscode.cfm>

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

Cosmetics containing nanoparticles (other than zinc oxide or titanium dioxide<sup>3</sup>) must be notified to ERMA as a condition of the Cosmetic Products Group Standard<sup>4</sup>. 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.

The Ministry of Research, Science and Technology (MoRST) has published a “Nanoscience & Nanotechnologies Roadmap” on directions for research and policy associated with the responsible development and management of nanoscience and nanotechnologies in New Zealand<sup>5</sup>.

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

There are currently no research programmes underway to address human health and/or environmental safety aspects of nanomaterials.

However, two proposals have been received by the Foundation for Research Science and Technology (FRST) that investigate the plant uptake of quantum dots, and the flow on effects to downstream fauna; and a modelling system that can assess possible environmental exposure scenarios to alleviate the uncertainties associated with nanotechnologies. This may help researchers and regulators predict the environmental risk of nanomaterials when considering the regulatory approval of products containing nanomaterials. These proposals are currently under consideration.

MoRST hosted a successful Symposium on Nanoscience and Nanotechnologies in February. The Symposium enabled policy makers and others to find out more about nanotechnologies and their implications; encouraged collaborations between nanotech and social researchers; identified research questions for social and regulatory issues; and initiated discussion on other required policy work

#### **6. Information on any public/ stakeholder consultation**

No public/stakeholder consultation has been conducted on the safety of nanomaterials, however the MoRST Symposium on Nanoscience and Nanotechnologies in New Zealand provided a forum for useful discussions between policy makers and the nanotechnology industry.

A proposal has been received by FRST for a study into the societal impacts of nanotechnology. If successful, the study will involve a series of public consultation events. The proposal is currently under consideration.

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<sup>3</sup> 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.

<sup>4</sup> <http://www.ermanz.govt.nz/appfiles/orgctrl/pdf/HSR002552Con.pdf>

<sup>5</sup> <http://www.morst.govt.nz/current-work/roadmaps/>

***Additional Information***

MoRST has also established the Navigator Network<sup>6</sup> to identify emerging science trends and innovations, particularly in biotechnology and nanotechnology.

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

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<sup>6</sup> <http://www.navigatornetwork.net.nz/>

**NORWAY*****Highlight of developments since the 2nd meeting of the WPMN***

- The Norwegian Pollution Control Authority has initiated literature review on fate, mobility and ecotoxicity of manufactured nanoparticles.
- Bioforsk has established a national network for health, environment and ethics aspects of nanotechnology.
- A network between authorities responsible for regulating production and uses of nanomaterials has been established.

***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 initiated a literature review on fate, mobility and ecotoxicity of manufactured nanoparticles. The report should be finished at the end of 2007.

**6. Information on any public/ stakeholder consultation.**

The report from the Research Council of Norway has been presented on 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 is has been established at network group between different authorities responsible for the regulation of production and use of nanomaterials

**SPAIN*****Highlight of developments since the 2nd meeting of the WPMN***

- The Spanish REACH Center of Reference has already been set up. This Center has integrated in its portfolio of works the EHS issues related to Manufactured Nanomaterials.
- The R&D+I National Plan 2008-2011 has been approved pointing the Nanoscience and Nanotechnology as a strategic objective horizontal in all areas, counting with specific programs.

***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 yet in Spain. The Spanish REACH Center of Reference (SpRC) has already been set up in Madrid in June 2007 for the implementation of the EC Regulation No 1907/2006. EHS issues related to Manufactured Nanomaterials have been defined among the objectives of the Center. The SpRC collaborate and follows the works of the national standardization group for nanotechnology, AENOR AEN/GET 15, created as a mirror commission of ISO/TC 229 and CEN/TC 352. After the inputs by WPNM, SCENIHR, SCCP, NIOSH, and others, together with the examination of the nanotechnology activity in Spain, SpRC has drafted proposals of coordinated actions. These comprise form the promotion of the public and private awareness, the collaboration with WPMN and AENOR, or the Spanish R&D+I implication in the EHS aspects of NM, to the identification of guidelines, standarization and assessment needs for the parts involved in Spain. In addition, at a more mature stage, this national body will assist in the definition of regulatory frameworks.

**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**

Documents related to good practice are still absent in Spain.

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

While nanoscience and nanotechnology, in general, is becoming a mayor topic of research in Spain, scarce activity is observed related to the heading item. Last September the Ministers Council approved The R&D+I National Plan 2008-2011 with a very significant increase of the budget. The Plan has underlined five strategic objectives horizontal in all areas, with additional specific programs. Nanoscience/Nanotechnology is one of them, and topics related to their potential impact on human health and the environment are among their lines (e.g., nano-ecotoxicity). SpRC will foster the Spanish research in EHS aspects of NM.

**6. Information on any public/ stakeholder consultation**

No public or stakeholder consultations have been conducted yet. However, SpCR is developing a directory of the parts involved in Spain, intended for gathering useful about guidelines, standardization and assessment needs.

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

The Swedish Chemicals Inspectorate has on Commission by the Swedish Government made a compilation on the knowledge available concerning risks for human health and the environment followed by the use of nanotechnology. In addition, proposals for how to fill knowledge gaps were included. The Report is at present only available in Swedish with an English summary.

***In brief, the Swedish Chemicals Agency proposes that the Government:***

- Instruct the Swedish Governmental Agency for Innovation Systems (VINNOVA) to draw up a Swedish strategy for nanotechnological research and development, which includes knowledge about risks to human health and the environment
- Allocate special research funds to the Swedish Research Council for Environment, Agricultural Sciences and Spatial Planning (Formas) for research about the health and environmental risks of nanomaterials
- Instruct the Chemicals Agency to follow developments in the area and propose measures whenever it is justified, and to participate actively in the development of new or modified testing methods within the OECD cooperative framework
- Instruct the Chemicals Agency to produce a deeper analysis of the use of nanomaterials in chemical products and goods after consultation with the trade organisations concerned.
- Instruct the governmental agencies concerned to review the need for complementing existing legislation
- Arrange, in the context of Sweden's EU presidency in 2009, a workshop on how the health and environmental risks of nanotechnology should be dealt with by legislation

Below please find the summary on the report on which the proposals were based:

***The rapid development of new fields of application, and a great lack of knowledge, calls for caution***

The manufacture of nanomaterials is fast-growing industry, both in terms of total volume and the number of manufacturers. Strong growth may furthermore be expected over the next decade in the development of commercial products linked to nanotechnology, according to a number of studies from other countries. Knowledge about the possible health and environmental risks of nanotechnology is scarce. This applies equally to how humans and the environment might be exposed to nanomaterials and to what hazardous characteristics different nanomaterials have. Although there is insufficient evidence today to suggest that the development and use of nanomaterials brings particular health and environment risks, the rapid development in the area and the great lack of knowledge about risks calls for precautionary measures. This applies particularly to nanoparticles, as results from animal tests suggest that certain nanoparticles, when inhaled, could be harmful to human health.

***More research about risks is needed***

There is not enough knowledge about the environmental effects of nanomaterials, e.g. if they are absorbed by organisms in the environment and if they can bioaccumulate. It is furthermore likely to be a major technical challenge to develop methods for detecting nanomaterials in the environment. Humans may be exposed to nanomaterials in their work, as consumers, and via the environment. Since the respiratory system is likely to be the most important exposure route for nanomaterials, research has been mainly in this area. Once inside the respiratory tracts, nanoparticles appear to be capable of spreading to other parts of the

body. There are also studies suggesting that nanoparticles can enter the brain via the olfactory nerve. However, the knowledge about harmful effects is very limited.

It is important that increased resources be allocated in Sweden to research about the health and environmental risks of nanotechnology. A Swedish strategy for nanotechnological development, which also covers research into health and environmental risks, should therefore be drawn up. It is furthermore important that methods for testing the hazardous properties with respect to human health and the environment are developed in international cooperation. Those risk assessments which can be made today are insufficient both due to the lack of data and to the difficulty in interpreting existing data. In risk assessments, it is important to consider the unique physical-chemical characteristics of nanomaterials, as well as new biological activity, new target organs, and unique routes by which nanoparticles can enter the human body and other organisms. A current example of this is that the EU's Scientific Committee on Consumer Products (SCCP) has said in a preliminary finding that it is regarded as necessary to reassess the risks of using the nanoform of titanium dioxide in cosmetic products, due to increased knowledge about nanoparticles, including the IARC's assessment that titanium dioxide could be carcinogenic to humans.

***Companies are responsible for ensuring that human health and the environment are not damaged***

Legislation places the same responsibility on companies with regard to nanomaterials as it does for chemical substances, chemical products and goods. However, the scientific limitations that exist today in assessing the risks imply that companies should apply special precautions in the development and use of nanomaterials in order to limit exposure to humans and the environment. This applies particularly to risks from the inhalation of nanoparticles.

Companies are obliged to classify substances themselves based on available information. In those cases where there is no information on a substance's health or environmental hazards, existing EU classification of health and environmental hazards for the substance at a larger scale shall apply for the nanoform as well.

***Legislation needs to be extended***

Although current legislation covers nanomaterials, regulations need to be made clearer as nanomaterials imply particular problems both in risk assessment and risk management. The rapid development of the area in combination with the great lack of knowledge about health and environmental risks call for precautionary measures. This is likely to involve complementing the EU regulatory framework with rules for nanomaterials, including rules about the way in and extent to which companies must test nanomaterials' health and environmental hazards. Affected government agencies will need to set up a working collaboration in order to provide the Government with a basis for upcoming reviews of EU rules.

**UNITED KINGDOM****Summary of UK Work on Health and Environmental Safety Aspects of Manufactured Nanomaterials**

In May 2007, Defra published the results of a study looking at environmentally beneficial applications of nanotechnologies. Oakdene Hollins Limited, the contracted research team, were tasked to identify and examine nanotechnology applications which could contribute to the reduction of greenhouse gas emissions. The study considered issues of feasibility, along with any obstacles which might impede adoption, and made policy recommendations designed to foster further advance and implementation where appropriate.

“Environmentally Beneficial Nanotechnologies: Barriers and Opportunities” provides a detailed examination of current and foreseen applications of nanoscience in the areas of photovoltaics, insulation, electricity storage, engine efficiency and hydrogen use. The report is available at: <http://www.defra.gov.uk/environment/nanotech/policy/index.htm>

**Developments in the UK’s Voluntary Reporting Scheme (VRS) for Manufactured Nanomaterials**

The UK’s Voluntary Reporting Scheme (VRS) for Manufactured Nanomaterials reached its first anniversary on 22<sup>nd</sup> September 2007. A total of 9 submissions have been received since the scheme’s launch, 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. A data reporting form has been provided.

In late July 2007, the UK government’s Advisory Committee on Hazardous Substances (ACHS) carried out a review of the VRS to assess (a) if the scheme’s aims and context were being clearly articulated and; (b) whether any changes to the scheme were appropriate at this point. While fully endorsing the objectives of the VRS and encouraging further submissions from companies involved in nanotechnologies, the Committee considered that improvements to the scheme’s guidance were needed in order to increase participation levels and enhance the quality and relevance of data submitted. These changes will be introduced shortly.

The UK government remains committed to the VRS and has worked with the Research Councils and the nanotechnology industries’ representative bodies to encourage participation. We know from our discussions with these groups that there remain a number of areas of uncertainty, which we are working to resolve. These include the use of commercially confidential information within the VRS and concerns over how scheme data may be used to assist in the international research effort. These issues are being explored within WPMN Steering Group 5 (Reporting Schemes and Regulatory Programmes).

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

Three ‘Good Practice Guides’ are being developed by the British Standards Institution (BSI) for publication in 2007 to meet immediate UK industry needs regarding health & safety issues around nanotechnologies:

- Guide to Safe Handling and Disposal of Free engineered Nanomaterials
- Guide to Specifying Nanomaterials

- Good Practice Guide for Labelling of nanoparticles and products containing nanoparticles (PAS)

The BSI is also nearing completion of its work to develop six new terminology documents, to be published in December as Publicly Available Specifications (PAS). These are:

- Terminology for Medical, Health and Personal Care Applications of Nanotechnologies
- Terminology for the Bio-Nano Interface
- Terminology for Common Nanoscale Measurement Terms Including Instrumentation
- Terminology for Carbon nanostructures
- Terminology for Nanofabrication
- Terminology for Nanomaterials

The three guides and six terminology documents will be made freely available on the www in January 2008. Further information is available at [www.bsi-global.com/nano](http://www.bsi-global.com/nano)

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

Two studies have recently been completed to identify exposure and hazard data needs for addressing the risks presented by nanoparticles and nanotubes. The reports have been used to identify research needs to find out more about the potential risks associated with free engineered nanoparticles to the environment and human health:

- ‘A scoping study to identify exposure data needs for addressing the risks presented by nanoparticles and nanotubes’, published by the UK Health and Safety Laboratory (report available at <http://www.defra.gov.uk/environment/nanotech/research/pdf/hazarddata-scoping.pdf>).
- ‘REFNANO: Reference Materials for Engineered Nanoparticle Toxicology and Metrology’ published by the UK Institute of Occupational Medicine (report available at <http://www.safenano.org/Uploads/REFNANOREport.pdf>). This report provides a priority list of candidates and a development schedule for their inclusion in a set of reference materials to support measurement, toxicology and risk assessment of engineered nanoparticles.

A further study has been carried out by Watts & Crane Associates, which looks at whether current standard ecotoxicity methods are appropriate to nanomaterials. The objectives of this study were:

- To assess current ecohazard test strategies and associated methods.
- To review studies that have characterised the hazard of nanomaterials, summarising and appraising key issues and challenges arising from these.
- To use this information to identify which elements of test strategies and associated methods for hazard assessment are not fit for purpose, giving reasons.
- To propose variants on current tests based on the information gathered.
- To propose an experimental programme to empirically test variants on the standard methodologies.

**UNITED STATES****Highlights**

- EPA issues draft inventory document relevant to determining whether nanomaterials are “new” or “existing” chemicals under TSCA
- EPA issues draft stewardship program concept paper
- FDA issues task force report
- NEHI issues interim report on prioritizing EHS research needs for engineered nanomaterials
- NIEHS and NIBIB/NIH jointly propose NanoHealth Enterprise
- EPA is developing a nanomaterial research strategy
- NTP initiates nanomaterial testing program
- EPA begins nanomaterial risk assessment case studies
- EPA holds public meetings on stewardship program, on materials characterization and on pollution prevention through nanotechnology

**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 Environmental Protection Agency (EPA) released for public comment guidance under the Toxic Substances Control Act (TSCA) in order for manufacturers of nanoscale materials to make the distinction between “new” and “existing” chemicals on the TSCA Inventory. EPA is reviewing comments and will announce a final version in early 2008.

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;**

For new products using nanotechnology, USG agencies have encouraged manufacturers to enter into discussions with the appropriate review authority early in the product development process, prior to submitting an application or notice for regulatory decision, so that potential issues of regulatory uncertainty or information needs can be identified and where possible addressed. These discussions are ongoing for a number of products that use manufactured nanomaterials.

On July 12 EPA announced in the Federal Register the availability of the documents for public review and comment. These documents included a Concept Paper for the Nanoscale Materials Stewardship Program, a TSCA Inventory Status of Nanoscale Materials - General Approach, and an Information Collection Request for the program that included a proposed optional reporting form. EPA is developing the final program based on public input and expects to announce the program early in 2008. Key goals of the Program are to assemble and encourage the development of scientific information on hazards, exposure, risks, and risk mitigation practices to provide a sound scientific foundation to inform industry and EPA. The program would complement EPA’s regulatory authorities and ensure the responsible development and commercial use of nanoscale materials.

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

EPA has assessed a number of new chemical notices for potential nanoscale materials under TSCA.

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

None.

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

On August 16, 2007 the Nanotechnology Environmental and Health Implications Working Group of the National Science and Technology Council released an interim report for comment entitled "Prioritization of Environmental, Health and Safety Research Needs for Engineered Nanoscale Materials" ([http://www.nano.gov/Prioritization\\_EHS\\_Research\\_Needs\\_Engineered\\_Nanoscale\\_Materials.pdf](http://www.nano.gov/Prioritization_EHS_Research_Needs_Engineered_Nanoscale_Materials.pdf))

The National Institutes of Environmental Health Sciences and the National Institute of Biomedical Imaging and Bioengineering at the National Institutes of Health are proposing an integrated, interdisciplinary initiative that will employ state-of-the-art technologies to examine the fundamental physical and chemical interactions of engineered nanomaterials with biological systems at the molecular, cellular, and organ level. This initiative, called the NanoHealth Enterprise, proposes a partnership with private industry, other federal agencies, international partners, public health advocates, and academia to address critical research needs for the safe development of nanoscale materials and devices.

The US Food and Drug Administration (FDA) issued a Nanotechnology Task Force Report dated July 25, 2007. The report offers the Task Force's initial findings and recommendations to the FDA Commissioner and includes:

- A synopsis of the state of the science for biological interactions of nanoscale materials;
- Analysis and recommendations for science issues; and,
- Analysis and recommendations for regulatory policy issues.

US EPA is developing a Nanomaterial Research Strategy (NRS) that identifies a research program that will be coordinated with research conducted by other US agencies. The NRS will undergo external peer review in November 2007 and will be published in the *Federal Register* for comment. The NRS covers fiscal years 2007-2012 and is focused on addressing EPA's programmatic needs within four research themes:

- Sources, Fate, Transport, and Exposure
- Human Health and Ecological Research to Inform Risk Assessment and Test Methods
- Risk Assessment Methods and Case Studies
- Preventing and Mitigating Risks

The National Toxicology Program (NTP) is designing and/or conducting studies on the following nanomaterials:

- Cadmium selenide based Quantum dots
- Titanium dioxide
- Fullerene-C60
- Multiwalled carbon nanotubes
- Ceric oxide
- Gold
- Silver

EPA is developing a series of case studies of selected nanomaterials as a means to identify what is known and what needs to be known to be able to assess the potential environmental and health implications of these materials. In the present context, the term case study should be understood to mean an illustration of issues, rather than a fully developed assessment. The draft case studies will be developed and released for invited review in 2007 and 2008. We intend to have a number of cases, each being a type of application from two classes of nanomaterials: nanoscale titanium dioxide and single-walled carbon nanotubes.

#### **6. Information on any public/ stakeholder consultation.**

On August 2 EPA held a general public meeting to receive further public input and comment on the stewardship program.

EPA's Office of Pollution Prevention and Toxics (OPPT) held a scientific peer consultation September 6-7, 2007 on material characterization pertaining to nanoscale materials to support development of the stewardship program it is considering.

On September 25-26, 2007 EPA sponsored a conference on pollution prevention through nanotechnology. The purpose of the P2 conference was to exchange information and ideas on the potential environmental and pollution prevention benefits of innovative nanotechnologies and nanomaterials. A second area of concentration was to identify and promote stewardship opportunities associated with applications of nanotechnology.

## **EUROPEAN COMMISSION**

### ***Highlight of developments since the 2<sup>nd</sup> meeting of the WPMN***

- The European Commission adopted the Communication "*Nanosciences and Nanotechnologies: An Action plan for Europe 2005-2009. First implementation report 2005-2007*" in September 2007. [http://ec.europa.eu/nanotechnology/policies\\_en.html](http://ec.europa.eu/nanotechnology/policies_en.html).
- REACH (regulation (EC) No 1907/2006) came into force 1 June 2007. The European Chemicals Agency (ECHA) was opened in Helsinki. A draft Regulation proposal on the classification and labelling of chemicals based on the Global Harmonised System was adopted by the Commission on 27 June 2007 and is now examined by the Council and Parliament.
- The EC is planning to adopt a review of regulations relevant for nanomaterials early 2008.
- 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" [http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihr/docs/scenihr\\_o\\_010.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_010.pdf)
- The EU Scientific Committee on Consumer Products has approved an opinion on "Safety of Nanomaterials in Cosmetic Products" for public consultation. After evaluation of the comments, the adopted opinion will be published at: [http://ec.europa.eu/health/ph\\_risk/committees/04\\_sccp/docs/sccp\\_o\\_123.pdf](http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_123.pdf)
- The first calls for proposals in the 7th EU Research Framework Programme (FP7) have been published on 22 December 2006. The proposals received in these topics have been evaluated and the research projects will begin in 2008. Calls for proposals for 2008 relevant for environment and health aspects have been published on 30 November 2007 with deadline for application 06 March 2008. In particular one large scale project will address development and validation of test methods. Additional information can be found at the website <http://cordis.europa.eu/fp7/dc/index.cfm?fuseaction=UserSite.FP7CallsPage>
- Recent updates on research projects funded by the European Commission can be found at <http://cordis.europa.eu/nanotechnology/src/safety.htm>
- A "Code of Conduct for Responsible Nanosciences and Nanotechnologies Research" is planned for early next year, including input from a public consultation in 2007.

### ***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 Commission is performing a regulatory inventory, covering EU regulatory frameworks that are applicable to nanomaterials (chemicals, worker protection, environmental legislation, product specific legislation etc.). The purpose of this inventory is to "examine and, where appropriate, propose adaptations of EU regulations in relevant sectors" as expressed in Action 6d) of the Commission Action Plan.

Preliminary findings indicate that the regulatory frameworks in principle give a good coverage; different aspects of production and products are at the same time subject to various Community provisions. Implementation is facilitated by different types of documents, adopted within this regulatory framework, such as implementing legislation, European standards, regulatory and technical guidance documents that may have to be adapted in order to cover HSE risks in relation to nanomaterials. However, many of the knowledge gaps (toxicity thresholds, test schemes etc) will need to be addressed to ensure implementation and adaptation of 'supporting documents'. Those knowledge gaps are in line with the ones earlier identified by EC and others and reported to the OECD. The Commission's report therefore will also indicate initiatives undertaken (e.g. Research Framework Programmes, activities of Joint Research Center, cooperation within OECD, standardisation, Scientific Committees) in order to improve knowledge levels, so as to allow a proper implementation of the EU regulatory framework.

In the chemicals regulatory area, EU competent authorities (CAs) have decided that:

- a. The decisive criterion whether a nanomaterial is a new or existing substances is the same as for all other substances, i.e. whether or not the substance is on EINECS. When a nanomaterial is derived from an existing substance, article 7.1 of the Existing Substances Regulation 793/93 (ESR) on the updating of reported information applies.
- b. Nanomaterials having specific properties may require a different classification and labelling compared to the bulk material, also when the nanoform is derived from a bulk substance.
- c. They invite industry to provide a number of dossiers on different representative nanomaterials, to show what kind of data is available, how risk assessment is being performed and how the risks are controlled.
- d. For the longer term, a review of the applicability of testing methods and risk assessment methods should be carried out. This should be done at international level (e.g. within the OECD chemicals programme) with active input from industry and contributions from the EU.

REACH (regulation (EC) No 1907/2006) was adopted on the 18 December 2006 and published in the Official Journal of the European Union on 30.12.2006. REACH will gradually revoke and replace several of the existing EU legislation on chemicals. REACH entered into force on 1<sup>st</sup> June 2007. The European Chemical Agency ECHA in charge of following-up the registration, the evaluation and the authorisation process under REACH, was opened on the same day in Helsinki. Nanomaterials are covered by the provisions of this Regulation.

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

The EC has not developed any voluntary or stewardship schemes at this stage. Issues regarding information on nanomaterials will be discussed in the chemicals CAs working group, also as a follow-up to 1.c. above.

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

In relation to nanomaterials in chemicals legislation, risk assessment and management is implemented at this moment as for other chemicals in the framework of the current legislation on new and existing chemicals (see 1.a. above). More specific guidance and information may be required in the future.

The EU Scientific Committee on Emerging and Newly Identified health Risks (SCENHIR) has produced two Opinions in relation to nanomaterials risk assessment, respectively on 10 March 2006, and on 21-22 March 2007. In its first opinion, SCENHIR concluded that the existing toxicological and ecotoxicological methods are appropriate to assess many of the hazards associated with the products and processes involving nanoparticles, but that they may not be sufficient to address all the hazards. Therefore the risk assessment needs to be done on a case-by-case basis. The assays may need to be supplemented by additional tests, or replaced by modified tests, as it cannot be assumed that current scientific knowledge has elucidated all the potential adverse effects of nanoparticles. Specifically, attention needs to be given to the mode of delivery of the nanoparticles to the test system to ensure that it reflects the relevant exposure scenarios.

For exposure, SCENHIR also expressed that the use of mass concentration data alone to express dose is insufficient, and the number concentration and/or surface area would need to be used as well. Equipment that enables routine measurements for exposure to free nanoparticles is not yet available. In particular, existing methods used for environmental exposure assessment may not necessarily be appropriate for determining the environmental fate of nanomaterials. Consequently, current risk assessment procedures may require modification for nanoparticles both regarding test methods for hazard identification and exposure assessment.

The SCENHIR suggested that there is insufficient knowledge and data concerning nanoparticle characterisation, their detection and measurement, the fate (and especially the persistence) of nanoparticles in humans and in the environment, and all aspects of toxicology and environmental toxicology related to nanoparticles, to allow for satisfactory risk assessments for humans and ecosystems to be performed.

In its second opinion, dealing particularly with the appropriateness of the risk assessment methodology in accordance with the Technical Guidance Documents (“TGD”) for new and existing (chemical) substances for assessing the risks of nanomaterials, the SCENHIR concluded that current methodologies described in the TGDs are likely to identify certain hazards, but modifications are required for the assessment of risks to human health and the environment. Furthermore, the opinion highlights needs to determine appropriateness of current test procedures for the prediction of human health hazards and estimation of risks for all types of nanoparticles. In particular, the SCENHIR focussed on the potential of nanomaterials to reach new target organs in the body, when administered in similar ways than bulk chemicals (translocation). This observation would lead to additional requirements of test methods to demonstrate potential new hazards.

On 19 June 2007, the Scientific Committee for Consumer Products (SCCP) adopted an Opinion for public consultation in June 2007 on safety of nanomaterials in cosmetic products. For labile particles, conventional risk assessment methodologies based on mass metrics may be adequate, whereas for the insoluble and slowly soluble particles other metrics, such as the number of particles, and their surface area as well as their distribution are also required. It is crucial when assessing possible risks associated with nanoparticles to consider their uptake. It is primarily for the insoluble and slowly soluble particles that health concerns related to possible uptake arise. Should they become systemically available, translocation/transportation and eventual accumulation in secondary target organs may occur. The Committee also identifies a number of knowledge gaps. More particularly as regards the ban on animal testing with respect to cosmetics, the Committee takes note that at present no methodology has been validated for nanomaterials. Finally, the Committee states that review of the safety of the nanomaterials presently used in cosmetics is required.

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

The Commission is closely following the work in ISO and CEN. Both nanotechnology related Technical Committees in ISO (TC 229) and in CEN (TC 352) are currently working on the nomenclature and hence on the definition aspects. In ISO/TC 229, the working group on Health, Safety and Environment is proposing a Technical Report on "Current Safe Practices in Occupational Settings Relevant to Nanotechnologies". In addition, in ISO/TC 146 on Air Quality, the SC2 subcommittee on Workplace atmospheres has released a technical report ISO/TR 27628:2007 "Ultrafine nanoparticles and nanostructured aerosols – Inhalation exposure characterization and assessment". In ISO/TC 24/SC4 (Sizing by methods other than sieving), the particular issue of nanoparticle size measurements and the required reference materials is considered with more care

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

As stated in Action Plan on Nanosciences and Nanotechnologies (N&N), the European Commission aims at reinforcing N&N research and development in the seventh framework programme for research, technological development and demonstration activities (FP7) and has proposed a significant increase of the budget compared to FP6.

It has also committed itself to boost support for collaborative R&D into the potential impact of N&N on human health and the environment via toxicological and ecotoxicological studies as well as developing appropriate methodologies and instrumentation for monitoring and minimising exposure in the workplace.

Activities in FP7 have been started: In the first call for proposals, several topics were launched specifically addressing the safety of nanomaterials. The proposals received in these topics have all now been evaluated and the research projects will begin by the start of 2008 (except for one that has already started).

NMP-2007-1.3- 1 (Large scale integrating projects)	Specific, easy-to-use portable devices for measurement and analysis
NMP-2007-1.3- 2 (Small or medium-scale focused research projects)	Impact of engineered nanoparticles on health and environment
NMP-2007-1.3- 3 (Coordination and support actions)	Critical review on the data and studies on the potential impact on environment and health of nanoparticles
NMP-2007-1.3- 4 (Coordination and support actions - only one database and support action will be funded)	Creation of a critical and commented database on the impact of nanoparticles

NMP-2007-1.3- 5 (Coordination and support actions)	Coordination in studying the environmental and health impact of nanoparticles and nanotechnology based materials and products
HEALTH-2007-1.3- 4 (Small or medium-scale focused research projects) Call coordinated with NMP-2007-4.1.3-2/4.4-4	Alternative testing strategies for the assessment of the toxicological profile of nanoparticles used in medical diagnostics

Dedicated calls are foreseen among the next actions of the FP7, in particular the second calls launched on 30 November 2007, with two dedicated topics:

- NMP-2008-1.3-1 Validation, adaptation and/or development of risk assessment methodology for engineered nano-particles
- NMP-2008-1.3-2 Impact of engineered nanoparticles on health and the environment

Additionally, the European Commission has supported a nano-related pilot projects under the umbrella of “Transatlantic methods for handling global challenges”. The objective of the pilot project is to fund innovative ventures between European and US policy makers that cannot be pursued under existing EU-US instruments of cooperation, and to promote mutual learning amongst EU and US policy researchers and policymakers on more effective transatlantic approaches to challenges with a global dimension.

With this background, a Call for Proposals was launched to identify eligible projects in a variety of areas, among them, in particular

- Safety of nanotechnologies. Building on experience from the EU’s 6th Research Framework Programme, promote closer international cooperation with economically advanced countries in nanoscience and nanotechnologies in order to share knowledge and reap the benefits of critical mass.

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 nano-metrology 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

On 18 July 2007, the European Commission announced a public consultation on a Recommendation on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research. The consultation, that

was open until 21 September, will provide input for a Recommendation on governance of this emerging area of science, which the Commission will put forward later this year. Contributions were received from a broad cross-section of European society, including the scientific community, industry, civil society, policy-makers, media and the general public.

The European Commission also open a Open Consultation on the Strategy on communication outreach in nanotechnology; The public and other stakeholders were invited to comment on the report and results from a workshop held by the European Commission in Brussels, February 6th 2007. This paper shaped operative recommendations for future European funding on appropriate communication and innovative approaches to engage the European civil society into a dialogue on nanotechnology. Experts in the field of science communication share success, best practices and challenge stories, to give to different audiences a "voice" in the policy making process. As a result, a set of recommended activities for Europe were outlined, which could be commented

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

Several conferences on nanotechnology have been organised by different organisations throughout the EU and by recent EU Presidencies. The Finnish Presidency of the EU organized a conference on "Nanotechnologies: Safety for Success" in September 2006. In October 2007 the European Commission organised the another stakeholder dialogue related to consumer products.

### ***Additional Information***

The European Group on Ethics in Science and New Technologies (EGE) is a high-level group of independent experts on ethics appointed by President Barroso. The EGE advises the Commission on ethical issues related to science and technology or other relevant EU policies. The Group adopted an Opinion on ethical aspects of Nanomedicine in January 2007 ([http://ec.europa.eu/european\\_group\\_ethics/index\\_en.htm](http://ec.europa.eu/european_group_ethics/index_en.htm)).

Several research projects funded by the European Commission are related to innovation, ethical aspects and societal implications of nanotechnology. Additional information can be found at <http://cordis.europa.eu/nanotechnology/>. Linked to the European Technology Platform on Sustainable Chemistry, several documents are becoming available such as a code of conduct on nanotechnology; a guide on safe manufacturing and for activities involving nanoparticles at workplaces; and detailed information on the characterisation of nanomaterials. Moreover, the recent Nanosafety Hub event organised by the European Technology Platform on Industrial Safety (ETPIS) on the 23<sup>rd</sup> March 2007 in Brussels, BE provided an overview of progress on the development of detection and monitoring technologies and the state-of-the-art in the fields of toxicity of nanoparticles, secured integrated processes as well as workplace health, safety and environmental safety all linked to nanomaterials (more information are available on <http://www.industrialsafety-tp.org> & [http://euvri.risk-technologies.com/events/event\\_3/default.htm](http://euvri.risk-technologies.com/events/event_3/default.htm)).

A standardization mandate is currently in consultation with Member States to formally convey priorities to the European standards bodies and to request feedback on their activities. The European standards bodies are invited to forward a program of activities to the European Commission and Member States that subsequently can be endorsed by Commission and national authorities. The mandate states that European standardisation efforts will preferably be elaborated in cooperation with the international standards bodies.

## **BRAZIL**

### ***Highlight of developments since the 2nd meeting of the WPMN***

Activities since January, 2007:

- International Seminar "Nanotechnology, Agricultural Commodities and Minerals" (on May 28<sup>th</sup>)
- Debates "Public Engagement in Nanotechnology Project" involving the scientific community and society (on May 5<sup>th</sup> and on June 22<sup>th</sup>)
- IV SEMINANOSOMA (6 - 8, August)
- Seminar on "Nanotechnology, Health Workers, Food and Impact on Society and the Environment" (3-4, October)

### ***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 regulation specifically addressing nanomaterials in Brazil. There is only general national regulatory system on human health and environmental safety in Brazil.

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

There are no voluntary or stewardship schemes.

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

No risk assessment on specific nanomaterials has been conducted in Brazil and no risk assessment decisions have been taken.

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

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

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

### **Current research**

RENANOSOMA - *Public Engagement in Nanotechnology*  
(<http://nanotecnologia.iv.fapesp.br/portal>)

Start: December, 2006

Goal: make nanotechnology also a subject of research of human sciences and disseminate the discussion of nanotechnology in the various segments of Brazilian society. RENANOSOMA inform and discuss nanotechnology with the public, not specialists.

Budget 2007 and 2008: R\$ 120.000.00

FUNDACENTRO -*Preliminary Survey of the Impact of Nanotechnology on the Health of Workers*

Start: January, 2007.

Goal: identify the main areas where they are in application techniques with nanoparticles in Brazil. Identifying the priority areas for further studies of the recognition and control of risk. Propose projects specific to certain areas, according to the team that can be formed.

Budget 2007: R\$ 29.124.00

The first initiative was made by Brazilian Research Network in Nanotechnology, Society and Environment – RENANOSOMA - that realized two International Nanotechnology, Society and Environment Seminar – SEMINANOSOMA - when was discussed the impacts of nanotechnology in environment, society, economy, agriculture, ethic and regulation.

The third - SEMINANOSOMA – was made together with the I International Seminar “*Nanotechnology and The Workers*” (São Paulo, November 8-10, 2006). This is the start point of official discussion of nanotechnology and occupational health in Brazil and in FUNDACENTRO. After that a research group was constitute by FUNDACENTRO and Dra. Arline Arcuri is the coordinator.

The first action of this research group was to integrate the project “*Public Engagement in Nanotechnology*” that is coordinated by Dr. Paulo Martins – RENANOSOMA’s coordinator. It aims to disseminate information and discusses nanotechnology with people not specialized in nanotechnology, particularly with the workers and the staff of trade unions.

#### ACTIVITIES SINCE JANUARY, 2007:

On May 28<sup>th</sup>, the International Seminar "*Nanotechnology, Agricultural Commodities and Minerals*" was held in São Paulo by the project in partnership with RENANOSOMA and FUNDACENTRO program.<sup>1</sup>

The FUNDACENTRO and RENANOSOMA done in partnership debates “Public Engagement in Nanotechnology Project” involving the scientific community and society: May 5 in Recife/Pernambuco and June 22 in Rio de Janeiro/Rio de Janeiro.

Implementation of lectures<sup>1</sup> by the coordinator of FUNDACENTRO’s protect, Dr. Arline Arcuri, in other forums, such as: Brazilian Society for the Progress of Science-SBPC, The Office of work “*Pharmaceutical Industry and Risk for Health of Workers*” and Birthday of DIESAT<sup>2</sup>.

On October 3<sup>rd</sup> and 4<sup>th</sup>, the Seminar on “*Nanotechnology, Health Workers, Food and Impact on Society and the Environment*” was held in São Paulo, in FUNDACENTRO. The programme and the presentations are also available in Portuguese on the site <http://blog.iiep.org.br/nanotecnologia/>. During the seminar two publications prepared by the IIEP were distributed and reproduced in 500 copies each for FUNDACENTRO for workers. A CD was also reproduced. The content of this CD and the two publications in full are available in the site <http://blog.iiep.org.br/nanotecnologia/>.

The planning and organization of the seminar were held with the 7 institutions and committees: FUNDACENTRO, RENANOSOMA, IIEP<sup>3</sup>, DIESAT<sup>2</sup>, DIEESE<sup>4</sup>, INCRA<sup>5</sup>, ORIT<sup>6</sup>, planning through

<sup>1</sup> Programs, content, files available in Portuguese in the site <http://blog.iiep.org.br/nanotecnologia/fundacentro/>

<sup>2</sup> DIESAT - Inter Department of Studies and Research of Health and the Working Environment

<sup>3</sup> IIEP - Interchange, Information, Studies and Research

<sup>4</sup> DIEESE - Inter-Union Department of Statistics and Socio-Economic Studies

<sup>5</sup> INCRA - The National Institute of Colonization and Agrarian Reform

<sup>6</sup> ORIT - The Inter Regional Organization of Workers

various meetings. The concern was not limited to the impacts on the health of workers, but social, economic and ethical aspects. After the seminar a meeting was held for evaluation of activities and establishment of strategies. The meeting had 25 participants, mostly trade unionists, and the researchers of FUNDACENTRO and Environmental NGOs.

One of the activities of the RENANOSOMA is realizing debates three times a week, where researchers and experts are invited to discuss with the public (not expert) on various aspects of nanotechnology.

Researchers of FUNDACENTRO have participated in the RENANOSOMA's debate, also granting interview (files available in Portuguese on <http://chat.ipt.br/renanosoma/index.php?agenda>).

A questionnaire to be applied to research institutions and industries that use nanotechnology in Brazil is being prepared in order to identify the applications and current practices in risk prevention.

Some researchers from several institutions are including in their research toxicological, ecotoxicological and metrological aspects on nanotechnology, but there is no official network for these areas.

## **6. Information on any public/ stakeholder consultation**

No public or stakeholder consultations have been conducted in Brazil.

### ***Additional Information***

On September 12<sup>th</sup> and 13<sup>th</sup> a meeting happened between the coordinator of Renanossoma, Dr. Paulo Martins, and members of the Ministry of Science and Technology, which established a term of reference for developing guidelines for the future public network of research in social environmental risks of manufactured nanomaterials.

**CHINA****Abstract**

*In our report we collected information on the following initiatives related to the safety of nanomaterials in China after the first meeting of the WPMN:*

1. *Concerning nanometer biological material class medical devices product classification adjustment notice;*
2. *Published and implemented China Standards of nanotechnologies;*
3. *Research on the social implications of nanotechnology.*

### **1. The adjustment of government regulation concerning product classification for medical devices made with nanometer biological materials**

The State Food and Drug Administration of China (SFDA) announced a notice (document number 146, 2006) for all of its sub national bureaus to inform the issue on the adjustment of product classification for medical devices made with nanometer biological materials, as follows:

In 2004, the National Bureau of the State Food and Drug Administration (SFDA) issued the regulation to classify the “nanometer silver antibiotic device for women’s use” - a product produced using nanometer level metal silver material – as a Class II medical device. Currently, there are some 10 products made with nanometer level metal materials that have been registered and sold in the market as Class II medical devices. In view of the special characteristics of the nanometer level materials, it is decided, from the date of issuance of this regulation, that medical devices made with nanometer biological materials (for example medical instruments made with nanometer metal silver material) will be classified as Class III medical devices, and be subject to the administration of the relevant regulations of Class III medical devices. Nanometer biological material products that have been granted product license as Class II medical devices before the issuance of this regulation can continue their production within the validity of their product licenses. The produces of these registered products may be sold within the validity of the produced products. When the validity of the current product license has expired, the product should be re-registered as a Class III medical device in accordance with this regulation. For products that the SFDA has accepted the applications for license, but has not yet granted the license, they will be treated as Class III medical devices in the continued process of examination and registration. <http://www.casmed.net/hm/apa/35.htm>

### **2. Published and implemented China Standards of nanotechnologies**

Up to date China standards for nanotechnologies as following:

- (1) GB/T 18735-2002 General specification of nanometer thin standard specimen for analytical transmission electron microscopy (AEM/EDS)  
(Published: 2002-5-22; implemented: 2002-12-1)
- (2) GB/T 19345-2003 Amorphous and nanocrystalline soft magnetic alloy strips  
(Published: 2003-01-01; implemented: 2004-05-01)
- (3) GB/T 19619-2004 Terminology for nanomaterials  
(Published: 2004-12-27; implemented: 2005-04-01)
- (4) GB/T 13221-2004 Nanometer power-Determination of particle size distribution-Small angle X-ray scattering method(ISO/TS 13762:2001,MOD)  
(Published: 2004-12-27; implemented: 2005-04-01)
- (5) GB/T 19587-2004 Determination of the specific surface area of solids by gas adsorption using the BET method(ISO 9277:1995,NEQ)  
(Published: 2004-12-27; implemented: 2005-04-01)
- (6) GB/T 19588-2004 Nano-nickel powder (Published: 2004-12-27; implemented: 2005-04-01)

- (7) GB/T 19589-2004 Nano-zinc powder (Published: 2004-12-27; implemented: 2005-04-01)
- (8) GB/T 19590-2004 Nano-calcium carbonate (Published: 2004-12-27; implemented: 2005-04-01)
- (9) GB/T 19591-2004 Nano-titanium dioxide (Published: 2004-12-27; implemented: 2005-04-01)
- (10) GB/T 19627-2005 Particle size analysis-Photon correlation spectroscopy (ISO 13321:1996,IDT) (Published:2005-01-13; implemented: 2005-08-01)
- (11) GB/T 15445.4-2006 Representation of results of particle size analysis—Part 2:Characterization of a classification process (ISO 9276—4 : 2001,IDT) (Published: 2006-02-05; implemented: 2006-08-01)
- (12) GB/T 20307-2006 General rules for nanometer-scale length measurement by SEM (Published: 2006-07-19; implemented: 2007-02-01)
- (13) GB/T 20099-2006 Sample preparation dispersing procedures for powders in liquids ISO 14887 : 2000,IDT) (Published: 2006-2-5 implemented: 2006-8-1)

Other Chinese Standards related to Nanotechnology as following:

- (1) GB 11847-1989 Determination of specific surface area of uranium dioxide powder by multipoint BET method (Published: 1989-10-21 implemented: 1990-08-01)
- (2) GB/T 13390-1992 Metallic powder—Determination of the specific surface area—Method of nitrogen adsorption (Published: 1992-02-19 implemented: 1992-10-01)
- (3) GB/T 17507-1998 General specification of thin biological standards for X-ray EDS microanalysis in electron microscope (Published: 1998-10-16 implemented: 1999-07-01)
- (4) GB/T 12334-2001 Metallic and other inorganic coatings--Definitions and conventions concerning the measurement of thickness idt ISO 2064 : 1996 (Published: 2001-01-02 implemented: 2002-06-01)
- (5) GB/T 18873-2002 General specification of transmission electron microscope(TEM)-X-ray energy dispersive spectrum(EDS) quantitative microanalysis for thin biological specimens 100nm-300nm (Published: 2001-01-02 implemented: 2002-06-01)
- (6) GB/T 18907-2002 Method of selected area electron diffraction for transmission electron microscopes (Published: 2001-01-02 implemented: 2002-06-01)
- (7) GB/T 10722-2003 Carbon black—Determination of total and external surface area by nitrogen adsorption (Published: 2003-10-11 implemented: 2004-05-01)
- (8) GB/T 19077.1-2003 Particle size analysis-Laser diffraction method ISO 13320-1:1999,MOD
- (9) GB/T 19921-2005 Test method of particles on silicon wafer surfaces (Published: 2005-09-19 implemented: 2006-04-01)
- (10) GB/T 19922-2005 Standard test methods for measuring site flatness on silicon wafers by noncontact scanning (Published: 2005-09-19 implemented: 2006-04-01) (Published: 2003-04-01 implemented: 2003-09-01)
- (11) GB/T 20725-2006 Electron probe microanalysis guidelines for qualitative point analysis by wavelength dispersive X-ray spectrometry ISO 17470:2004, IDT (Published: 2007-03-26 implemented: 2007-08-01)
- (12) GB/T 6524-2003 Metallic powders—Determination of particle size distribution by gravitational sedimentation in a liquid and attenuation measurement (ISO 10076:1991,IDT) (Published: 1986-06-02 implemented: 2004-05-01) (Substitute GB/T 6524-1986 Determination of particle size distribution of metallic powders by method of photosedimentation, ASTM B430-1979 NEQ)
- (13) GB/T 20170.1-2006 Test methods for physical characters of rare earth metals and their compounds--Determination for particle size distribution of rare earth compounds (Published: 2006-04-13 implemented: 2006-10-01)
- (14) GB/T 20170.2-2006 Test method of physical characters of rare earth metals and compounds—Determination on specific surface area of rare earth compounds

(Published: 2006-04-13 implemented: 2006-10-01)

Recently, the Ministry of Science and Technology (MOST) started to support standardization activities in nanotechnology including health, safety and environment.

### **3. Research on the social implications of nanotechnology**

In China, about 1000 enterprises are involved in nanotechnology, the commercialization of which is gradually increasing. The main nano products in China are still nanoscale powders of oxides, metals, carbon nanotubes, fullerenes, their diverse derivatives, and applications of them such as those for coatings, fibers, fabric, papers, ceramics, catalysts, and nanomedicine, etc. But, most of the enterprises are still small. With the rapid development of application fields of nanotechnology, as has happened in many other countries, the issue of nanotechnology safety has given rise to serious public and governmental concern. Researchers from the Chinese Academy of Sciences (CAS) initiated activities to study the environmental and toxicological impacts of manufactured nanomaterials in 2001, including recognition, identification and quantification of the biological and environmental hazards resulting from exposure to diverse nanomaterials/ nanoparticles. In 2003, a formal research “Lab for Bio-Environmental Health Sciences of Nanoscale Materials” was established at the Institute of High Energy Physics, CAS. In this laboratory, researchers from nanoscience, biological, toxicological, environmental sciences and chemical fields work together to explore the biological and environmental (including both the positive and negative) effects of nanoscale materials. The research activities include not only ways to identify the possibly adverse effects of nanomaterials, but also ways to recover or reduce the release of nanoparticles in manufacturing processes, how to eliminate nanotoxicity, how to reverse-utilize nanotoxicity in clinical diagnoses and therapy by assimilating knowledge and techniques of nanoscience, toxicology, medicine, life sciences, chemistry and physics, etc.

In 2004, the highest-level scientific meeting organized by Chinese government, (a joint symposium organized by the Ministry of Science and Technology (MOST), the National Natural Science Foundation of China (NSFC), the Ministry of Education (MOE) and CAS etc) was held in Beijing Fragrant Hill, focusing on the issues of "Nanosafety: Biological, Environmental and Toxicological Effects of Nanoscale Materials/Particles". Researchers from more than 20 universities and institutes, government officials and policy makers attended the symposium, presented their research data and exchanged ideas. Currently, more than 30 research organizations in China have initiated their research activities studying the toxicological and environmental effects of nanomaterials/ nanoparticles, and techniques of recovering nanoparticles from manufacturing processes.

Educational activities aiming at introducing nanotechnology to the public in China have thus far been few. Recently, China's Science Press established an editorial board to edit and publish a series of Nano-books for the public. Prof. Chunli Bai, the most famous nano-scientist in China, and the Executive President of CAS, has been invited to be the Editor-in-Chief. They plan to publish at least two books per year, and this publication plan will continue into the future. Every year, a “science week” is held in local areas in different parts of China, where introductory lectures on nanotechnology are given to a public audience.

In 2006, NCNST decided to establish the Nanosafety Lab focusing on the economic, environmental and social aspects of the research, standardization, regulations, etc. being done in connection with nanotechnology, and then signed an agreement with the Institute of High Energy Physics (IHEP), CAS, to co-build the China “Lab for the Bio-Environmental Effects of Nanomaterials & Nanosafety”. This Lab was opened in August 2006, and includes two branches, one located at IHEP, CAS, and the other at NCNST. The missions of the China Nanosafety Lab mainly include, (1) Doing methodological and metrological studies of nanoparticle detection; (2) Identification and quantification of nano-hazards to humans and the

environment; (3) Exploring the behaviors of nanoparticles in the environment (air, water, soil, and other parts including foods and nanodrugs, etc.), and their health impacts; (4) Accumulating experimental data on nanotoxicology and nano-ecology; (5) Drafting regulatory frameworks for research and industrial activities on nanotechnology; (6) Establishing standard procedures for safety assessment of nanoproducts for nano-industries/ enterprises including assessment methods, and identifying the toxicity classes of nanomaterials.

## ***RUSSIAN FEDERATION***

### ***Highlight of developments***

1. Participation of Russia in the work of ISO/TC 229.
2. Support of a number of R&T projects on impacts of nanotechnologies on health and environment 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 2002-2006”. Studies on the physico-chemical properties of nanomaterials (in particular, nanoparticles) carried out by a number of Institutes of Russian Academy of Sciences (RAS) and Universities. The main scientific results were published in the scientific journals worldwide.
3. More and more studies on impacts of nanomaterials on health and environment have been presented during the scientific conferences, workshops, exhibitions, i.e.:
  - The International Symposium «EU-Russia Co-operation in Biotechnology, Agriculture, Forestry and Food”. Suzdal, 30 August – 2 September 2007 (<http://www.fp7-bio.ru/>);
  - The Fourth International Conference on “Science and Business”: “NanoBio and Related New and Perspective Biotechnologies”. Biological Center of RAS, Pushchino, Moscow Region, October 15 - 17, 2007 (<http://www.cerbrd.ru/nanoE.htm>).
4. Regulation № 54 concerning the inspection of new products containing nanomaterials, issued by the Federal Consumer Rights and Human well being Department (Rospotrebnadzor, the head Mr. G. Onischenko) on 23-d of July 2007: (<http://www.kadis.ru/texts/index.phtml?id=21973>)
5. The structure of specialized working groups with focus on development of different aspects of nanosafety is currently elaborating by different Ministries and other governmental structures in Russia.
6. 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 been established on behalf of the Ministry of Education and Science of Russian Federation.

### ***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**

Regulation № 54 concerning the inspection of new products containing nanomaterials was issued by the Federal consumer rights and human well being department (Rospotrebnadzor, the head Mr. G. Onischenko) on 23-d of July 2007: <http://www.kadis.ru/texts/index.phtml?id=21973>

This document contains recommendations to list the nanomaterials produced in/imported to Russia and to ensure the inspection of manufactured nanomaterials.

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

- The expert analytical group at Saint-Petersburg State Polytechnic University is working at Questionnaire to be sent to research institutes and universities; industrial firms; small and middle enterprises. The aim of this initiative is the identification of “existing” nanomaterials, gathering information on nanomaterials available on Russian market and building a comprehensive knowledge base on this. Also, the bulletin:

“Nanorisks and nanosafety” was drafted by this group. - The Regulation № 54 contains recommendations:

- To establish the information analytical center for studies of nanosafety and to compile the information on nanomaterials.
- To develop the guidance on appropriate testing to identify potential health and environmental impacts of nanomaterials.

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

A number of research projects containing risk assessment part, have been carried out within Federal Target Programme for R&D (2002-2007) and the Programmes of RAS

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

The expert analytical Group at Saint-Petersburg State Polytechnic University is going to publish a booklet on potential risks of nanotechnologies for human health and environment encompassing the international experience in this area.

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

- New Federal Targeted R&T Programme for 2007-2012 in Russia.
- Nanotechnology Action Plan for Russia - 2015 will contain the special subprogramme covering nanosafety and potential impacts of nanomaterials on health and environment. It's planned to establish a special Working Group at the Ministry of Education and Science of Russia aiming at assistance to the international collaboration of Russia in the field of nanosafety (including OECD).

### **6. Information on any public/ stakeholder consultation.**

- Presentation of international experience on nanosafety at different conferences/ workshops;
- Round table on nanorisks for human health and environment (The National conference for Crystal Growth, October, Moscow, 24, 2006).

#### ***Additional Information***

- The special event for nanosafety, organized by Open Economy Foundation (Moscow, December 2007);
- The 2-d International Conference on NanoBioTechnologies ([www.spbcas.ru/nanobio](http://www.spbcas.ru/nanobio)), Saint-Petersburg, June 16-20, 2008;
- NATO Advanced Research Workshop on Biological and Invironmental Risks of Nanotechnology, Nanobionics and Hybrid Organic-Silicon Devices (Silicon vs. Carbon), Saint-Petersburg, June, 2007.

**THAILAND**

## Status and point of contact:

- The Project of Thailand Nanosafety and Ethics Guideline has been split into 3 phases: (1) International status and trend. This phase has already started since the beginning of April 2007. (2) Local status and trend, and (3) Guideline drafting. It is expected to be completed by the year 2008.
- Chulalongkorn University has formed a forum of nanosafety with the objective of sharing information among interested faculty members & researchers. This activity is supported in part by a grant from the Thailand Research Fund (TRF), with core research personnel on loan from the university's Nanotechnology Center. The forum is coordinated by Dr. Varapan Danutra, National Center for Environmental and Hazardous Waste Management, Chulalongkorn University.
- Thailand has sent a delegation to participate in the Observational Study Mission on Strategic Industries in Member Countries: Nanotechnology, organized by the Asian Productivity Organization (APO) in Seoul, Republic of Korea, from 10-13 April 2007. (One session was about potential collaboration in nanosafety and nanoethics).
- The public hearing in nanosafety and toxicity in nanomaterials had been arranged and organized in October 2007. The participants are composed of researchers, public and government sector.
- Contact persons have been appointed to Dr. Lerson Tanasugarn and Dr. Sirasak Tepakum.

Following the US National Nanotechnology Initiative (NNI) in 2000, the Royal Thai Government established the National Nanotechnology Center (NANOTEC) three years later under the umbrella of the National Science and Technology Development Agency (NSTDA), a non-government public institution. NANOTEC has a mandate to formulate a National Nanotechnology Strategic Plan (2004 – 2013) for Thailand as well as to establish nanotechnology operational plans and the guidelines. However, NANOTEC's main objectives are:

- To conduct and promote nanotechnology research in order to improve the competitiveness of Thai industries.
- To develop well trained human resources in the field of nanotechnology
- To establish networks and collaborations with other research centers, academics, industrial sectors national and internationally
- To promote public awareness and understanding of nanotechnology

Therefore, NANOTEC has become a central for R&D funding, conducting nanotechnology research, and driving national policy plans. Moreover, NANOTEC provides state-of-the-art nano-measurement testing services both physical- and biological test for private and government sectors.

During the past three years, NANOTEC has initiated and supported various projects in the fields of semiconductor and optical devices, nanocomposite, nanoscale surface coating, and nanoencapsulation of active ingredients.

NANOTEC, however, has currently been more focus in R&D by concentrating on 3 essential platform technologies; nano-coating, nano-encapsulation, and functional nano-structures. With these 3 platforms, they will be applied mostly by 3 major industrial clusters; Textiles, Cosmeceutical, and Food.

Owing to the global publicity of nanotechnology and the marketing success of the locally manufactured nano-fabrics/ apparel and nano-encapsulated cosmetics, Thai consumers have slowly entered the age of nano-hypes. The general public was led to believe that a product manufactured using

nanotechnology must possess a superior quality over a normal product, regardless to any possible health risk. Possible adverse effects of nanotechnology and nanoparticles in the environment are virtually unheard of. Therefore, the regulation of Thai nano-products might be required. NANOTEC with the collaboration of the Office of the Consumer Protection Board will develop nano-label (or nanomark) to verify properties and improvement on a nanoproduct. In addition, researches on nano-toxicity and the effects of nanoparticles in the environment are on-going.

**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 draft the nano-safety and nano-ethics guideline that covered nanotechnology research, development, manufacturing, transport, usage, consumption, and the treatment/ disposal of wastes arising from any of the mentioned activities, the drafting would commence at the beginning of 2007 and run for 9 months with a budget of approximately \$100,000 as reported at the 1<sup>st</sup> WPMN. Due to bureaucracy red tape stemming from governmental changes and budgeting cuts, however, the project was divided into 3 phases with the first one starting in April 2007.

The main objective of the first phase is 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**

No information

**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<sub>2</sub>) coated fish tanks were tested for toxicity to fish. Skin creams containing titanium dioxide nanoparticles were also tested for skin penetration through mode (pig) skins. Safety data should be availableS through NANOTEC after the research works are completed. Nevertheless, there has never been a research program specifically designed to address human health and/ or environmental safety aspects of nanomaterials as such.

It is expected that the policy recommendations in the third phase of the project mentioned in Item 1 will address nanosafety strategy at the national level.

## **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 13<sup>th</sup>, 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 nanotechnology thus enhancing Thailand's competitiveness, (5) disseminate knowledge and transfer nanotechnology 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.

**BIAC**

***Contribution by selected BIAC members***

***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**

- Environment Canada published an interpretation that nanoforms of materials listed on its Domestic Substances List (DSL) are also considered to be existing chemicals under CEPA. However, CEPA's five year review is scheduled for 2008, and this existing interpretation may be re-evaluated during that review.
- The US Food and Drug Administration stated that existing reviews of food, drugs, and medical devices are sufficient to address nanoscale materials. The approach on cosmetics is still being evaluated, and additional guidance is expected on this issue.
- The cities of Berkeley, CA (enacted) and Cambridge, MA (considering) within the US are addressing the registration by firms producing or handling manufactured nanomaterials within these jurisdictions.
- EPA circulated on 12 July 2007 its TSCA inventory interpretation paper as part of the NMSP information.

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

- The US Environmental Protection Agency introduced its Nanomaterials Stewardship Program (NMSP). The program is scheduled to be implemented in early 2008.
- The American Chemistry Council Nanotechnology Panel conducted a survey of its members addressing product stewardship practices. Results of the survey may be viewed at: [www.americanchemistry.com/nanotechnology](http://www.americanchemistry.com/nanotechnology)
- Environment Canada and Health Canada held a stakeholder meeting on voluntary and regulatory options for managing manufactured nanomaterials.
- UK DEFRA VRS undergoing one-year review.

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

- Related Information- NIOSH in the US noted that existing personal protective equipment (PPE) appears to be effective in protecting workers handling manufactured nanomaterials.

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

- ISO TC 229 is working on evaluating and developing standards for a number of activities related to nanomaterials including definitions, physical properties that need to be considered for toxicological evaluations, and numerous other issues, and is embarking on a nomenclature system for nanomaterials.
- June 2007 issuance of ED and DuPont NanoRisk Framework  
<http://nanoriskframework.com/page.cfm?tagID=1095>.

- A multistakeholder working party, led by the Royal Society, Insight Investment, the UK Nanotechnology KTN and the Nanotechnology Industries Association (NIA) has launched the Consultation Draft of a proposed *Responsible NanoCode* (i.e. voluntary Code of Conduct for organisations working with nanotechnology); the draft will be open to public comments until middle of December 2007. <http://www.responsiblenanocode.org/>

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

- The US National Nanotechnology Initiative recently issued a revised report on EHS research priorities. Additional prioritization work will be needed.
- NIST recently held a workshop to identify if reference materials are needed to help address EHS impacts related to nanomaterials.
- EC progress report on nanoscience policy making/funding initiatives from 2005-2009 (<http://cprdis.europa.eu/nanotechnology/actionplan.htm>).
- EPA Board of Scientific Counselors recommendation to EPA that EPA strengthen its coordination with other research agencies and improve its research on nano health and exposure issues. <http://www.epa.gov/osp/bosc/pdf/sp2072307.pdf>.

#### **6. Information on any public/ stakeholder consultation**

- EC consultation: 'Towards a Code of Conduct for responsible Nanosciences and nanotechnologies Research' (July 2007 – September 2007)

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

### ***INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO)***

#### **ISO/TC 229 - Nanotechnologies**

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 four meetings to date - November 05 in London, June 06 in Tokyo, December 06 in Seoul and June 07 in Berlin. The next meeting will be in Singapore in December. The committee currently has 39 members - 29 "P" and 10 "O".

The TC structure consists of 3 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); and Health, Safety and Environment (WG3, convened by USA). The work programme at the start of November 2007 contained 17 work items – 4 in JWG1, 8 in JWG2 and 5 in WG3 (Annex 1), with a further 4 New Work Item Proposals out for ballot. Of the current work items, the most relevant to the Working Party are those in WG3, though both the terminology work, in JWG1, and the measurement and characterization work, in JWG2, could impact the work of the WPMN.

The TC works closely with the IEC (International Electrotechnical Committee) TC 113, chaired by the US, with Germany providing the secretariat. The two Technical Committees plan to hold joint plenary meetings 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 material specification, and 18 relevant to other ISO TCs. The information gathered is being used to prepare road maps for both the individual working groups and for the TC. These roadmaps are expected to be available for the Singapore meeting.

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 is being planned for February 2007 to identify needs and to provide a forum for discussions on harmonization and coordination issues (see Annex 2).

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 1: ISO/TC 229 Work Programme at 1 November 2007**

JWG1

- *ISO/TS: Terminology and definitions for nanoparticles*
- *ISO/TR: Terminology and nomenclature for nanotechnologies — Framework and core terms*
- *ISO/TS: Outline of Nanomaterials classification ("Nano tree")*
- *ISO/TS: Terminology and definitions for carbon nanomaterials*

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*

WG3

- *ISO/TR: Safe Practices in Occupational Settings Relevant to Nanotechnologies*
- *ISO/IS: Endotoxin test on nanomaterial samples for in vitro systems*
- *ISO/IS: Generation of silver nanoparticles for inhalation toxicity testing*
- *ISO/IS: Monitoring of silver nanoparticles in inhalation exposure chambers for inhalation toxicity testing*
- *ISO/TR Guidance on physico-chemical characterization of engineered nanoscale materials for toxicologic assessment*

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

## **Annex 2: International workshop on measurement and characterization for nanotechnologies (DRAFT 2)**

### **Partner organizations** (to be confirmed):

ISO, IEC, NIST and OECD

### **Contributors:**

The objective is to involve a comprehensive and balanced representation of the main organizations active in standardization in those fields covered by the workshop – including the leaders of technical groups from the partner organizations<sup>14</sup>.

An advisory group responsible for the development of the workshop programme will be composed by senior representatives of the partner organizations.

### **Purpose:**

The high global interest in the field of nanotechnologies has increased pressure on standards makers to develop deliverables to support commercial and regulatory needs. Standardization activities in the field are developing at the international level and in many countries, involving a broad variety of interests and organizations.

Given the large number and diversity of standardizers and stakeholders actively participating in the field, it is clear that exchange of information and cooperation among the key players in nanotechnologies standardization needs to be intensified and promoted, with a view to supporting the emergence of high-quality, globally relevant International Standards for the field.

The workshop is designed to promote a dialogue among the organizations most active in nanotechnologies standardization, to foster better understanding among the key players and to capture input and recommendations on relevant matters, which will be channelled for consideration to the existing technical bodies.

### **Focus:**

The area of measurement and characterization has a fundamental supporting role to virtually all other standards, requiring special and early attention. In particular, there is a pressing need for the development, validation and approval of standardized methods for physico-chemical characterization of manufactured nanomaterials to support human and eco-toxicology testing.

The workshop is designed to cover this area in detail, with a view to:

- identifying and exchanging information on existing standards, deliverables expected in the short-term, standardization programmes, and emerging needs in the field of measurement and characterization for nanotechnologies, including pre- and co-normative research (PNR and CNR), certified reference materials, etc.
- providing a framework to analyze and propose mechanisms for improving coordination and harmonization of, and cooperation on standardization activities in the selected field

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<sup>14</sup> See attachement

Expected outputs from the workshop will include reports detailing the above, draft proposals concerning mechanisms and agreements supporting coordination and collaboration, and a shared vision of the evolution of international standards to meet the needs and opportunities identified.

**Benefits of attendance:**

It is expected that all participating organizations will benefit from enhanced awareness of international activities in the area and from the development of improved mechanisms for coordination, collaboration and harmonization, as will International Standardization in general.

**Draft workshop structure:**

All participating organizations will be asked to prepare presentations detailing their existing standards portfolios and current and planned activities relevant to nanotechnologies, and any needs they can identify that are not, to their knowledge, being met. These presentations will occupy much of the first day and will set the scene for the remainder of the workshop.

The next two half day sessions will be devoted to facilitated breakout sessions on specific aspects of measurement and characterization, e.g. nanoparticles, carbon and other nanotubes, physico-chemical properties, dosimetry, support for toxicology, etc, and will address the needs and challenges of standardization in these different areas, focusing particularly on the challenges posed by limitations in existing equipment and calibration procedures, experimental techniques, e.g. sample preparation, and fundamental understanding.

Each breakout session will be followed by a feedback period to capture relevant details. The next session will be devoted to facilitated road-mapping exercises to draft a number of roadmaps for the most important areas for standardization, and an overall roadmap for the field will be developed after the end of the workshop. The final session will bring together all participants to consider how future coordination can be achieved to ensure stakeholder needs are met, particularly in the areas of human and eco-toxicology and risk assessment.

**Setting:**

National Institute of Standards and Technology, Gaithersburg, MD 20899-8443, USA

**Date and Duration :**

The 3 day workshop will take place during the last week of February 2008

**Attendees:**

There are expected to be some 70 individually invited participants that are appropriate representatives (e.g. chairmen and relevant working group convenors/project leaders) of the various committees identified and any other groups deemed to be appropriate.

## ATTCHMENT

### Draft list of Organizations to be invited

Currently a number of ISO Technical Committees and other organisations have an active interest in the development of measurement and characterization standards and other instruments, whilst significantly more will benefit from their development by being able to apply them to their own area of activity. The committees and other organisations identified as having an active involvement are:

- ISO TC 24 - Sieves, sieving and other sizing methods
- ISO TC 146 – air quality
- ISO TC 147 – water quality
- ISO TC 194 - Biological evaluation of medical devices
- ISO TC 201 – Surface chemical analysis
- ISO TC 202 – microbeam analysis
- ISO TC 209 – clean rooms and associated controlled environments
- ISO TC 213 - Dimensional and geometrical product specifications and verification
- ISO TC 229 - Nanotechnologies
- ISO Remco (Committee on reference materials)
- ASTM E56 – Nanotechnology
- CEN TC 352 – Nanotechnologies
- IEC TC 113 - Nanotechnology standardization for electrical and electronic products and systems
- IEEE Nanotechnology council
- OECD Working Party on Manufactured Nanomaterials (WPMN)  
(*OECD other groups?*)
- VAMAS (Versailles project on Advanced Materials and Standards)

The National Standards Bodies member of ISO will also be informed of the initiative and, if they have a special interest in the field, will have the possibility to participate (through a qualified representative).

Where two or more ISO or IEC Technical Committees have a mutual interest in some aspects of a subject it is normal practice for them to establish a liaison, which facilitates the sharing of information and, where appropriate, resources. However, given the number of organisations involved, the speed of development of nanotechnologies and the consequent need for international standards, a more efficient and effective mechanism would seem to be required than the one-to-one sharing of information implied by a formal liaison.