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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 2nd Meeting of the Working Party on Manufactured Nanomaterials**

**Berlin, Germany, 25-27 April 2007**

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

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**No. 3**

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

*Tour de Table at the 2nd Meeting of the Working Party on  
Manufactured Nanomaterials  
Berlin, Germany, 25-27 April 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 WPMN had its **2<sup>nd</sup> meeting on 25-27 April 2007 in Berlin, Germany**. 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 such as 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 main objective of the 2<sup>nd</sup> Meeting of the Working Party on Manufactured Nanomaterials (WPMN) was to agree operational plans for six projects agreed at its 1<sup>st</sup> meeting. The purpose of the agenda item 4 (the Tour de Table) is 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 delegations is organised, where possible, under the headings identified below, while recognising that not all delegations are 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 1st meeting of the WPMN (October 2006) 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 1<sup>st</sup> meeting of the WPMN*

- Publication of the findings of a voluntary call for information on uses and quantities of nanomaterials imported or manufactured for industrial uses, including use in cosmetics and personal care products.
- Initiation of a research project to review the ability of Australia's regulatory systems to address potential risks associated with nanotechnology.
- National Nanotechnology Roundtable hosted by the National Health and Medical Research Council.

#### **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 Australian Government is currently developing its response to the paper "Options for a National Nanotechnology Strategy" delivered by its National Nanotechnology Strategy Taskforce to the Australian Industry Minister on 30 June 2006. The report recommends an integrated package of nine elements: (1) establish a dedicated federal office responsible for developing and coordinating the implementation of a national nanotechnology strategy; (2) health, safety and environmental issues (HSE); (3) community awareness and public engagement; (4) metrology and standards; (5) coordination of whole of government activities across Federal and State jurisdictions; (6) international cooperation; (7) industry infrastructure; (8) industry development; and the (9) commercialisation and application of nanotechnology research. The report was released in September 2006 and can be viewed at [www.industry.gov.au/nano](http://www.industry.gov.au/nano) and follow the links.

The Department of Industry, Tourism and Resources in consultation with regulatory and other agencies is undertaking a research project to report on whether Australia's regulatory frameworks are triggered by nanotechnology-based materials, products, applications, and their manufacture, use and handling; and which, if any, groups of nanotechnology-based materials, products and applications are not covered by our existing regulatory frameworks. In addition, the review will assist Government and regulatory agencies to consider whether those groups of materials, products and applications which do not trigger the regulatory frameworks pose significant risk, and if so, how can that risk be managed.

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

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS), the national regulator of industrial chemicals, issued a voluntary call for information to importers and manufacturers of nanomaterials. [http://www.nicnas.gov.au/publications/chemical\\_gazette/pdf/2006feb.pdf](http://www.nicnas.gov.au/publications/chemical_gazette/pdf/2006feb.pdf)

For the purposes of the call for information, NICNAS used the broad definition for nanomaterials as, those materials that have been specifically engineered to have at least one dimension less than 100nm. Industry was asked to provide information on uses and quantities of nanomaterials imported or manufactured for industrial purposes, including use in cosmetics and personal care products. Nanomaterials used exclusively as therapeutic goods, pesticides or food additives do not fall within the scope of NICNAS, and were consequently outside the voluntary call for information. The findings are published on the NICNAS website at [http://www.nicnas.gov.au/Publications/Information\\_Sheets/General\\_Information\\_Sheets/NIS\\_Call\\_for\\_info\\_Nanomaterials.pdf](http://www.nicnas.gov.au/Publications/Information_Sheets/General_Information_Sheets/NIS_Call_for_info_Nanomaterials.pdf)

The information will assist in understanding which nanomaterials are available on the market or close to commercialisation, and help focus our efforts to ensure the adequacy of the regulatory scheme to assess nanomaterials.

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

The Therapeutic Goods Administration (TGA) conducted a review of the scientific literature in relation to the use of nanoparticulate zinc oxide and titanium dioxide in sunscreens. The review can be found at: <http://www.tga.gov.au/npmeds/sunscreen-zotd.htm>

Food Standards Australia New Zealand (FSANZ) has not yet received any applications to consider the regulation of any nanomaterials in the Australia New Zealand Food Standards Code.

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

The Office of the ASCC commissioned a review of the potential OHS implications of nanotechnology. The report, which includes a detailed examination of the potential toxicology of nanoparticles, is derived from a detailed review and analysis of worldwide literature and consultation with nanotechnology stakeholders. The report entitled “A Review of the Potential Occupational Health and Safety Implications of Nanotechnology” has been published and is available on the ASCC website <http://www.ascc.gov.au/ascc/AboutUs/Publications/ResearchReports/AReviewofthePotentialOccupationalHealthandSafetyImplicationsofNanotechnology.htm>

Standards Australia has established a Committee on Nanotechnology (NT-100). This committee provides Australian input to the International Standards Organisation (ISO) for the development of international nanotechnology standards and good practice documents, and is contributing to development of the ISO Technical Report on “Health and safety practices in occupational settings relevant to nanotechnologies”. This Technical Report will provide specific guidance advice for working safely with nanomaterials.

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

In preparation for developing a strategy to address HSE issues, the National Nanotechnology Strategy Taskforce commissioned a report from the National Academies Forum (a coalition of Australia's four learned Academies) on the environmental, health, safety and legal aspects of nanotechnology. It suggests areas of nanotechnology where little risk is present (such as electronics), and suggests further R&D be undertaken in areas where greater risk is possible (such as nanomaterials). The report will be considered as part of the Government's response to the Taskforce report. The National Academies Report can be viewed at [www.industry.gov.au/nano](http://www.industry.gov.au/nano) and follow the links.

A national Nanotechnology Roundtable was hosted by the National Health and Medical Research Council (NHMRC) in December 2006. The Roundtable was attended by representatives from Australian academic institutions, health and environment government departments, regulatory bodies and industry and a representative from the New Zealand Health Research Council. The Chief Executive Officer of the NHMRC is using the outcomes of the Roundtable to inform future directions for the NHMRC with regards to nanotechnology and will establish an Advisory Committee on Health and Nanotechnology.

Australia's research community has established a network called NanoSafe Australia to link together toxicology researchers and assess the potential of nanotechnology to impact on human health, worker safety and the environment. NanoSafe Australia, which brings together nine HSE-related research organisations around Australia, is currently preparing a Position Paper on "Current OH&S best practices for the Australian nanotechnology industry", as well as assessing nanotoxicology skills available in Australia.

Australia's National Measurement Institute is offering a service for calibrating standard reference powders and nanoparticle samples to ensure that nanoparticle measurements are made on a consistent basis throughout Australia and in line with international measurement practices.

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

The Nanotechnology Roundtable, described above, was an important activity that brought together stakeholders and key players with a wide range of experience and expertise to discuss key issues relating to health, safety and environmental impacts of nanotechnology and the development of nanomaterials. The NHMRC plans to consolidate this collaboration with future forums and activities.

**BELGIUM**

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

***Highlight of developments since the 1<sup>st</sup> meeting of the WPMN***

First & Second meeting of the Belgian nanomaterials working group:

- Belgian researchers are now involved in OECD SG1 and SG2
- 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

***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 an 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 during 2007 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 in 2007 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.

During the 2<sup>nd</sup> meeting of the Belgian nanomaterials working group, current Belgian research projects descriptions were collected (see the following table).

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.

#### **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.

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 pollution particles	FWO Vlaanderen G.0165.03N	01/01/03 – 31/12/07	P. Hoet, B. Nemery
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

## **CANADA**

### ***Highlight of Developments since the 1st Meeting of the WPMN***

The following activities have taken place since the 1<sup>st</sup> meeting of the OECD Working Party on Manufactured Nanomaterials in October 2006:

- The Health Portfolio (Health Canada, the Public Health Agency of Canada, and the Canadian Institutes of Health Research) held a workshop to discuss the development of a strategy for nanotechnology with respect to health (See Section 1);
- Industry Canada is conducting some preliminary investigations into the market penetration of nanotechnology in Canada. A report should be available in April 2007 (See Section 2).
- In February 2007, the Council of Canadian Academies was requested by the Government of Canada to undertake an in-depth scientific assessment of the state of knowledge with respect to the environmental, health and safety of nanotechnology. The project will begin in April 2007 and is expected to be completed in 2008.

### **1. Regulatory Developments in Canada**

#### Federal government actions

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. Participants identified concrete needs and objectives for actions under the headings of:

- Safety of health products and foods;
- Consumer products safety including cosmetics and substances under the Canadian Environmental Protection Act; and
- Occupational health and safety.

A Health Portfolio Nanotechnology White Paper will be produced based on a previously developed Health Portfolio Issue Paper and the findings of the workshop.

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.

A Federal Workshop on the Health and Environmental Implications of Nanoproductions (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.

#### Regulatory approach for nanomaterials under the Canadian Environmental Protection Act

A regulatory regime for nanomaterials, targeting mainly industrial substances, is being considered by the New Substances Program of Environment Canada and Health Canada.

The proposed regulatory regime would comprise the following:

- **Phase 1 (fall 2006 – fall 2008)**
  - Inform industry that “new” nanomaterials are subject to notification under the New Substances Notification Regulations.
    - Nanomaterials with unique structures and not listed on Canada's inventory of chemicals currently on the market, the Domestic Substances List, are considered “new”.
    - Notification required if specified trigger volumes are reached.
    - Information to be submitted will be initially the same as for regular chemicals and polymers.
  - Develop a voluntary program to obtain data from industry to build a knowledge base on “new” and “existing” nanomaterials.
  - Work with international partners to develop appropriate property and effects testing methods.
  - Consider amendments to the Canadian Environmental Protection Act to facilitate assessment and management of all nanomaterials if necessary.
- **Phase 2 (fall 2008 – 2010)**
  - Resolution of standard nomenclature and terminology by ISO TC229.
    - The expectation is that a significant number of nomenclature issues will be resolved satisfactorily for regulatory purposes by 2008.
  - Establishment of specific data requirements for nanomaterials under the current notification regulations.

## **2. Developments on Voluntary Schemes in Canada**

A voluntary information submission initiative is being considered. This initiative would 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 “existing” 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 voluntary program include:

- Considering incentives that would encourage notification during the program timeframe.
- Developing consultation documents to engage industry, the public, and other stakeholders.
- Targeting program launch for summer 2007.

#### 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. First, they are investigating which Canadian firms are directly involved in marketing or producing nanomaterials and nano-enabled products; as of February 2007, 160 firms have been identified. Second, they are surveying known U.S. firms concerning their export activities to Canada. This project will be completed by April 2007.

Current market knowledge points towards several sectors using nanotechnology and/or nanomaterials in Canada. These include:

- Electronics/photonics (*e.g.*, improved performance of electronic devices/microsystems)
- Transportation (*e.g.*, body mouldings on vehicles, ceramic coatings on ships)
- Sports equipment (*e.g.*, tennis rackets, ski waxes)
- Consumer products (*e.g.*, antimicrobial coatings on refrigerators)
- Industrial (*e.g.*, petrochemical catalysts)
- Fashion (*e.g.*, stain and wrinkle-resistant fabric treatments)
- Health and beauty (*e.g.*, moisturizers, makeup, medical imaging)
- Food and food storage (*e.g.*, dietary supplements)

### **3. Risk Assessment Decisions**

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

- Industrial or commercial chemicals
  - No notifications or inquiries to date.
- 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**

Research on human health and environmental impacts in Canada is limited, but interest is growing.

- Environment Canada and Health Canada are supporting research proposals addressing environmental fate of nanomaterials.
- The Natural Sciences and Engineering Research Council (NSERC) and the Canadian Institutes for Health Research (CIHR) are encouraging/requiring the inclusion of health and environmental impacts components for research proposals involving nanotechnology.

#### **6. Public and Stakeholder Consultations**

- Environment Canada has not conducted any public or stakeholder consultations; however, a consultation will be part of the normal process in the development of a regulatory regime for nanomaterials.

***CZECH REPUBLIC***

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

There is only general national regulatory system on human health and environmental safety in the Czech Republic, following the EC regulation. At present the REACH regulation results in thorough adaptation of the chemical legislation.

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

We develop neither voluntary nor 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***

There is little information on the safety of nanotechnology among hundreds of science or making the public familiar articles or monograph on nanotechnology from the Czech authors. Recently, several analytical reviews appear on internet publication Nanotechnologie.cz devoted to social, ethical and health consequences sourcing from the foreign literature.

Number of conference on nanotechnologies realized last years in Czech universities. This year the international conference NANO'07 organized by Technical University in Brno will include the section Nanotechnology: risk for human health.

**DENMARK*****Highlight of developments since the 1<sup>st</sup> meeting of the WPMN***

- Discussion concerning regulation in the Danish Parliament
- Increased public awareness
- Increased research efforts

**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. Although the work is not quite finished yet it seems that the regulation in the different sector would in general cover 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. 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.

Recently (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 specific situations of concern in which the precautionary principle would apply.

**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.

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

There are no specific overall research programmes or strategies in this area, however several governmental research institutions and university institutes have now issued single 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. 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.

The Danish EPA has started a 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 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. Therefore the Danish EPA has initiated a project where the presence of nanomaterials in consumer products in Denmark is identified. This survey will contribute to a better understanding concerning human exposure to nanomaterials in connection with product handling and use.

Furthermore The Danish EPA has initiated 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.

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 is together with industry planning an open conference/workshop in 2007 for stakeholders (e.g. industry and NGOs) concerning issues in relation to use, handling and risk management of nanomaterials.

***Additional Information***

In general there has been an increasing awareness in public; in media and in the political system in DK concerning nanotechnological products and processes in relation to potential environmental and health risks.

In this field 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.

## **FRANCE**

### ***Highlight of developments since the 1<sup>st</sup> meeting of the WPMN***

- Government support for further research on risks [call for research projects by the National Research Agency (ANR), in the wake of work financed in 2005 and 2006].
- Initial approaches to evaluating risks to the general population and consumers.
- Feasibility study for a prospective follow-up of a cohort of exposed workers (including researchers).
- Ongoing establishment of an independent scientific observatory to monitor and issue warnings on health and social risks, and to guide the ANR's calls for projects.
- Under preparation: a standing public forum on health and social risks.
- Opinion of the CNRS Committee on Ethics for the Sciences (COMETS) on the ethical issues relating to nanoscience and nanotechnology.
- Opinion of the National Consultative Ethics Committee for Health and Life Sciences (CCNE) on the ethical issues raised by nanosciences, nanotechnologies and health.
- Communication on "The Development of Nanotechnologies" released by the Council of Ministers of 14 March 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**

Strictly speaking, there have been no regulatory developments to date. However, recommendations have been issued by both the Prevention and Precaution Committee (CPP)<sup>1</sup> and the French Agency for Labour and Environmental Health Safety (AFSSET)<sup>2</sup> regarding the need to take precautionary measures in the workplace and the general environment, to list the nanomaterials produced or imported and to ensure that they are included in the REACH Regulation. The results of the additional AFSSET study covering, in particular, the assessment of professional risks, are expected by year-end 2007.

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

A questionnaire prepared by AFSSET is to be sent out to industrial firms to ascertain the nature of the nanomaterials available on the French market and to compile data on hazards and exposure, as well as categories of use.

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1 . *Nanotechnologies, nanoparticules : quels dangers, quels risques ?*  
[http://www.ecologie.gouv.fr/IMG/pdf/Nanotechnologies\\_juin\\_2006.pdf](http://www.ecologie.gouv.fr/IMG/pdf/Nanotechnologies_juin_2006.pdf)

2 . *Les nanomatériaux, effets sur la santé de l'homme et sur l'environnement.*  
<http://www.afsset.fr/upload/bibliotheque/367611898456453755693572842048/nanomateriaux.pdf>

Changes are to be made to the database on nanomaterials stakeholders in France, which is administered by the Research-Industry Exchange and Collaboration (ECRIN) Association<sup>3</sup> on behalf of the Ministry of Industry's Directorate-General for Enterprise, in order to sharpen the base's focus on nanomaterials and compile information on the nanomaterials produced in or imported to France, and on the uses thereof.

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

At this stage in the development of nanotechnologies, there are no particular requirements in force in France regarding risk assessment for nanomaterials. In theory, however, regulations currently in force in France and throughout the EU on the sale of chemical substances could be used to gather information on the risks posed by manufactured nanomaterials.

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

Preliminary discussions are underway for the preparation of a good practice guide for protecting workers (operators) exposed to nanomaterials.

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

French partners to the integrated European NANOSAFE2 project, which is co-ordinated in France by the Atomic Energy Commission (CEA), are: the National Institute for Industrial Environment and Risks (INERIS), the National Institute for Health and Medical Research (INSERM), the ECRIN Association and the industrial firm Arkema. It should be added that the project includes a segment on societal and regulatory aspects.

The above organisations, but also the National Centre for Scientific Research (CNRS), the National Research and Safety Institute (INRS) and university research teams (from Paris, Toulouse, etc.), are working separately or jointly to develop research programmes to identify and develop the metrology needed to characterise human exposure and enhance knowledge of the toxicity of nanoparticles and nanotubes.

The Health Monitoring Institute (InVS) has also put this on its agenda for 2007.

INERIS has also been asked by the Ministry for Ecology to work on cataloguing the environmental hazards of nanomaterials.

#### **New referrals concerning nanomaterials:**

to **AFSSET**: risks to workers; exposure of consumers and the general population, over the entire lifecycle of nanomaterials, including wear, destruction, waste, recycling – an evaluation that will at first have to be simplified due to measuring difficulties, uncertainties as to the dangers, and the scarcity of knowledge on the linkage between dosage and effect.

to the French Food Safety Agency (**AFSSA**): monitoring of food and drinking water.

to the French Health Products Safety Agency (**AFSSAPS**): monitoring of drugs, medical devices and cosmetics.

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3. <http://www.ecrin.asso.fr>

**Feasibility study for a prospective follow-up of a cohort of exposed workers (including researchers):** the Directorate-General for Health (DGS), working together with the Directorate-General for Labour (DGT), has encouraged epidemiology researchers to explore the idea of a feasibility study for a prospective follow-up of a cohort of exposed workers and researchers (with INSERM, CEA, CNRS and InVS). An initial work session between epidemiologists and scientists was held on 16 February 2007.

**At the OECD:** France is involved in specific projects 3, 4 and 6 of the OECD Working Party on Manufactured Nanomaterials.

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

A lecture/debate was held at the Cité des Sciences et de l'industrie on 19 and 20 March. The event included a summary of discussions to date and constituted the response to the Prime Minister's call for a large nationwide public debate.

### *Other information*

**Seminar:** The interministerial seminar that was held on 19 October 2006 should ultimately enable the government to outline the main thrusts of actions with regard to societal aspects and participatory processes, enhancing scientific knowledge and establishing preventive measures.

**Inter-services group:** This group, which co-ordinates the prevention of nanotechnologies- and nanomaterials-related risks, was set up in the wake of the October 2006 interministerial seminar. It is made up of representatives of the DGS (Directorate-General for Health, Ministry of Health), DGT (Directorate-General for Labour, Ministry of Labour), DPPR (Directorate for Pollution and Risk Prevention, Ministry for Ecology), DGRI (Directorate-General for Research and Innovation, Ministry for Research) and the DGE (Directorate-General for Enterprise, Ministry of Industry). The DGAL (Directorate-General for Food, Ministry of Agriculture) recently became a partner.

**Communication on "The Development of Nanotechnologies" at the Council of Ministers of 14 March 2007:** opening of an interactive French Internet portal on "nanotechnologies"; information and consensus-building initiatives to forge closer ties between the scientific community and society at large; continued efforts to support research and development, requiring all project sponsors to include actions involving workstation safety and product lifecycles, including recycling and risk measurement; participation in standardisation initiatives; creation of an independent scientific watch and warning committee; institution of a platform of research and expertise in toxicology and ecotoxicology.

### **Initiatives involving societal, ethical or legal issues**

**\* Opinion of the CNRS Committee on Ethics for the Sciences (COMETS): "Ethical Issues Relating to Nanoscience and Nanotechnology".** The Committee recommends: promoting ethical vigilance; taking active part in consensus-building among stakeholders (industrial firms, consumer associations, patients' associations, NGOs, etc.); focusing on ethical concerns at multiple levels in researchers' careers (initial and ongoing education, evaluation, research projects, and so on); preparing ethical guidelines for researchers; opening ethics centres in research centres; promoting an interest in nanosciences amongst researchers in the social sciences; instituting procedures for detecting and settling conflicts of interest and for transparency in funding sources for joint CNRS/industry projects; presenting expected benefits without sidestepping possible drawbacks; emphasising the consequences for man without focusing solely on economic and industrial aspects; daring to factor in very long-term considerations and identifying misconceptions; providing forums for dialogue and participating in public discussions.

**\* Opinion of the CCNE on ethical issues raised by nanosciences, nanotechnologies and health:** We call to attention to this excerpt: “Knowledge is a prerequisite for the exercise of responsibility. This is the very foundation of the concept of free and informed consent. That is why the foremost ethical recommendation would be to demand the development of fundamental research before, and not only after, technical application. Such research must not be limited to the study of possible side effects. It must anticipate research on toxicity related to the nature of nanomaterials in cellular or animal models. In other words, the ethical attitude to nanosciences and nanotechnologies is not to stand in the way of science but on the contrary to ask for more science, more research, more reflection, more soul-searching covering research, transfer, innovation and industrial applications. And less *a priori* expressions of certainty where only the possibly beneficial effects are highlighted while the possibility of adverse effects is denied.”

The CCNE recommends: conducting stringent research before considering taking a product to market; not imposing ethical constraints on fundamental research, although this would also entail making research stakeholders accountable through the formulation of a code of good practice; holding discussions to explore the ethical dimensions of research strategy; specifically developing nanometrology and requiring calls for projects to include primary studies on the impacts on health and the environment, with subsequent evaluation; making health-related nanoproducts subject to bioethics laws and the regulations of French and European agencies; initiating public discussions with panels of trained citizens, researchers and social, economic, medical and environmental experts, and distributing the proceedings very extensively.

**\* At the OECD:** France’s involvement in the Working Party on Nanotechnology of the Committee for Scientific and Technological Policy (CSTP), and strong demand for incorporation of ethical, societal and legal issues.

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*Annex to the French Contribution - INERIS activities on nanomaterials*

INERIS conducts research and makes expert appraisals of the safety of nanomaterials in the following areas:

- Metrology and exposure assessment;
- Ecotoxicology;
- Toxicology;
- Risks of explosion and other accidental risks.

### **Metrology – Exposure assessment**

Development of sampling and control techniques for carbon nanotube manufacturing pilots (in partnership with Groupement de Recherche de Lacq, GRL).

Development of Light-Induced Breakdown Spectroscopy (LIBS) measuring methods as part of the European NANOSAFE2 project for physical and chemical characterisation, so as to ensure the safety of nanoparticle manufacturing processes.

Development of appropriate measuring methods for characterising human exposures and the corresponding public-health risks in partnership with national research programmes (Central Air Quality Monitoring Laboratory – LCSQA, Airparif), with application in the counting of fine particles in an urban environment (Gennevilliers).

Measuring micro-environmental exposures: car interiors, human exposure to indoor airborne ultra-fine particles [AFSSET NANOP Project, with the participation of INERIS, the Scientific and Technical Centre for Building (CSTB), the National Public Health School (ENSP) and the joint INSERM / University of Paris XII Faculty of Medicine team].

Evaluation of risks to human health: enumeration of uses, catalogue of existing research on the general population.

### **Ecotoxicology**

Evaluation of environmental risk (carbon and metal oxides): Study of the penetration of nanoparticles into the brains and lungs of fish and daphnias, establishment of methodologies.

Evaluation of environmental exposures: Release routes, quantities released, target compartments, behaviour in compartments.

### **Toxicology**

*In vitro* work: Study of the cytotoxicity of nanoparticles (European NANOSAFE2 programme). Study of the toxicity of carbon nanotubes on lung cells (ANR NANOTOX programme).

*In vivo* work: Studies on the evolution and effects of nanomaterials on animal models via injection and instillation (rats).

*In silico* modelling work: Development of physiological pharmacokinetic models for extrapolating findings from animals to man.

### **Accidental risks**

Ensuring the safety of nanoparticle production facilities against risks of fire or explosion (European NANOSAFE2 programme).

**GERMANY*****Highlight of developments since the 1<sup>st</sup> meeting of the WPMN***

- As we had reported last time, possible elements of a structured public dialogue about chances and possible risks of nanomaterials and nanoparticles had been discussed last September at a starting conversation between the Federal Minister of Environment and high-level experts of all involved stakeholders. Based on this the “Nanocommission” was established at 24<sup>th</sup> November 2006. This Commission is thought as a strategic board, which will lead in behalf of the German government the NanoDialogue to chances and risks of synthetic nanoparticles for human health and the environment. Therefore it plans also the development of a special communication strategy.
- Furthermore, the commission will accompany and steer the work of three working groups, which have very recently (at 26<sup>th</sup> of March) founded under the roof of the Nanocommission.
- The main tasks of these groups are thought to be:
  - WG 1: Chances for the environment and human health,
  - WG 2: Risks and safety research, and
  - WG 3: guide for a responsible handling of nanomaterials
- A close cooperation with the appropriate OECD SG’s is aspired.

***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 study on regulatory gaps and options undertaken by the Federal Environment Agency (UBA), whose start has been mentioned in our first report, had been finished. This study examined European (REACH) and German chemical and environmental legislation. The final report with conclusions and recommendations has been published on the UBA web page.

**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 elucidate 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 will be published soon.

Further progress is in addition expected from the outcome of the NanoDialogue WG’s (see above)

**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. In course of the year the final version is expected.

Further progress is in addition expected from the outcome of the NanoDialogue WG's (see above)

#### **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 on a one day meeting at November the 30th with stakeholders from industry, science, policy, and NGO's. Under the light of discussion this strategy is under revision and will be provided to OECD WG's. It is also part of the working plan of the German Dialogue WG 2 (see highlights too)

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

A BfR consumer conference on nanotechnology had been held in November last year. The main demands formulated in the vote by the 16 consumers who attended were for comprehensible labelling, clear definitions, terms and standards as well as far more research into the potential risks before nanotechnology is used to a greater degree in consumer products.

The Consumer Conference on Nanotechnology was launched as a pilot project by the Federal Institute for Risk Assessment (BfR) and was jointly staged with the Independent Institute for Environmental Concerns (UfU) and the Institute for Ecological Economic Research (IÖW). It draws on the model of the Danish consensus conference and is being tested by BfR as one possible tool of extended risk communication. The backdrop to BfR's risk communication activities is the dialogue between risk assessors, risk managers and various interest groups from science, politics, industry, associations, public agencies and the public at large. The staging of a consumer conference puts BfR's statutory remit on risk communication into practice by directly involving groups of consumers in the discussions about the risks and benefits prior to the introduction of a broadly based consumer application of this technology. This is the first time that a public agency in Germany has used this tool.

16 people of various ages and occupations were extracted from a cohort of 6,000 randomly selected individuals on the basis of sociodemographic criteria for the Consumer Conference on Nanotechnology. This group took a comprehensive look at this subject at two preparatory weekends, prepared questions on various consumer aspects of this technology and selected experts from science, associations, public agencies and industry to answer them.

**IRELAND*****Highlight of developments since the 1<sup>st</sup> meeting of the WPMN***

- In 2006 the Health and Safety Authority initiated a public internet consultation on engineered nanoparticles addressed at companies in Ireland that research, manufacturer or use nanomaterials.
- The Health and Safety Authority liaised with Forfás and Enterprise-Ireland
- The Health and Safety Authority is planning to develop a national policy on nanotechnology
- Project under the 6<sup>th</sup> Frame Programme and others foreseen under the 7<sup>th</sup> Framework Programme

***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 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 develops a national nanotechnology approach for Ireland and will include the aspiration that Ireland should be the forefront of the debate on Regulation and Safety. This is scheduled to be published soon after the Irish General election (publication of national policy documents is prohibited during election campaigns).

The issue of a National Policy on nanotechnology will have to be discussed further at a national level. However, it is hoped that a national policy will be developed.

**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 internet consultation signaled that they are willing to share further information on current projects. A dialogue with these companies will have to be initiated.

The NanoIreland development may also contribute to this process, until the approval of the recommendations under the NanoIreland umbrella.

**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 a 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). Besides UCD several other Irish universities and Irish companies are involved in this project. NanoInteract started on 1st January 2007 and will run until 31st 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. As the call for FP7 is currently open and will close on the 4<sup>th</sup> May 2007, no numbers can be reported at this stage.

#### **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 six weeks (1<sup>st</sup> August to 15<sup>th</sup> September 2006).

The overall response rate was 33.33% including companies of the following sectors: electronics, pharmaceutical and medical devices.

**ITALY*****Highlight of developments since the 1<sup>st</sup> meeting of the WPMN***

- Nothing specific up to now.

***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.

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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).

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.

***Additional Information/Comments***

In conclusion it seems that most of research efforts in Italy are focused on industrial development and application of a variety of nanomaterials.

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

## **JAPAN**

### ***Highlight of developments since the 1<sup>st</sup> meeting of the WPMN***

- The National Institution of Occupational Safety and Health, Japan (JNIOSH) will start a new research on possible health issues in April 2007, due to exposure to nanomaterials in the workplace. This research on nano-related industries includes measurement methods in the workplace, and toxicology of nanoparticles.
- The Cabinet Office has decided to establish a committee that coordinates research and development policy on nanotechnology. Dr. Junko Nakanishi will participate in this committee as a coordinator. One of its targets is to establish the information infrastructure to accelerate innovation, by facilitating research and development of nanotechnology and research for public acceptance of nanotechnology in a focused and strategic manner.
- METI has conducted a preliminary survey on safe handling of nanomaterials at manufacturing sites and research laboratories in fiscal year 2006. Through the survey, METI has reviewed existing good practices both from domestic and overseas and has drafted basic guidelines. These draft guidelines are to be reviewed by industry stakeholders for implementation.

### ***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 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 develop guidance documents relating to good practices for appropriate handling methods of manufactured nanomaterials in the workplace, such as at research institutes and at sites of production fields.

##### **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 by the funding of the Ministry of Education, Culture, Sports, Science and Technology (MEXT). The survey team has issued a report which contains a series of recommendations to public institutes, the private sector and the government. These survey results may possibly be used as a guide for future national measures by the the government. In fiscal year 2006, by the MEXT funding, the project named "The multidisciplinary experts panel for nanotechnology implication" has started. The project is composed of the above institutes and the university researchers, and focuses on "what are preferential tasks with reference to clarifying the nanotechnology implication for health, environment and social acceptance." The additional objective is establishment of the researchers' network on nanotechnology implication.

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

- characterization methods/apparatuses and sample preparation protocols for nanomaterials themselves and for organs or cells etc. which contains nanomaterials;
- inhalation test apparatus for nanomaterials;
- non-invasive in vivo imaging protocols and apparatus to measure biological reductive ability;
- biological reaction profiles of in vitro tests;

- methods of evaluation of protective equipment (e.g. mask), and also based on surveillance of amounts and types of nanomaterials released from/inside facilities.

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

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

The National Institution of Occupational Safety and Health, Japan (JNIOSH) will start a new research on possible health issues in April 2007, due to exposure to nanomaterials in the workplace. This research on nano-related industries includes measurement methods in the workplace, and toxicology of nanoparticles.

Last April NIES has started 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) transpulmonary and transpulmonary migration of nanoparticles, (3) in vitro and in vivo toxicity assay of nanomaterials using heat-treated asbestos as reference samples. In addition, NIES has been investigating effects of atmospheric nanoparticles on respiratory and cardiovascular systems for the last 3 years using chronic inhalation chambers for small rodents.

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

The Japanese Government has not implemented public or stakeholder consultation focusing on safety issues of manufactured nanomaterials. However, in the above mentioned survey, a series of workshops in 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.

**KOREA*****Highlight of developments since the 1<sup>st</sup> meeting of the WPMN***

- Start a new project on the safety of manufactured nanomaterials in the framework of Eco-technopia21 project (as elaborated below in #5, worked by MOE)
- Initiate a series of researches projects on the toxicity of nanomaterials (as elaborated below in #5, worked by KFDA)
- Held the third ISO/TC229 conference in Seoul(December 2006)
- Established an inter-ministerial consultation body on the safety of nanomaterials among MOE, KFDA, ATS and MOST(as elaborated below in Additional Information, March 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 Korean government does not have any national regulatory development on human health and environmental safety on manufactured nanomaterials.

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

The Korean government does not have any development related to voluntary or steward schemes.

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

The Korean government initiates a few research projects as elaborated below in #5 this year, which contain risk assessment part, but they are still in the early 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 or 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 of nanomaterials

**Ministry of Environment(MOE)**

MOE has conducted the Eco-technopia21 project to promote the development of environmental technologies since 2001. MOE will start 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 1 million per year will be invested on this project, totally USD 3 million. The ultimate goal of this research is to support the establishment of infrastructure necessary to minimize potential risks derived from the manufacturing, distribution and disposal of nanomaterials and nanomaterials-containing products. The

research project includes 1) measurement methods for nanomaterials 2) (eco) toxicological assessment of nanomaterials 3) environment exposure and fate of nanomaterials, and 4) risk management of nanomaterials

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

MOST performed a research project named “Environmental implications assessment of nanomaterials” in 2006. The outputs of the project include 1) the characteristics of nanomaterials 2) the domestic and overseas trends about industrial, social, pharmaceutical, human, and environmental effect of nanomaterial 3) need of research on human health and environmental safety, and 4) proposal of a new institute to address negative effect of nanomaterials. Besides, MOST is conducting 2 projects on EHS(Environment, Health and Safety) and ELSI(Ethical, Legal, 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 Adimistration(KFDA)

KFDA is planning to conduct a series of research projects on the toxicity of nanomaterials from 2007 to 2015 with the aim of the development of a toxicological assessment system of nanomaterials and establishment of related guidelines for the area such as food, drug, medical product, and cosmetics. KFDA will spend USD 1 million per year in conducting this project, which contains genetic toxicity, inhalation toxicity, *in vitro* toxicity

#### Agency for Technology and Standards(ATS)

As a Korean representative for ISO, ATS has conducted all works related to ISO/TC229. ATS held the third ISO/TC229 conference in Seoul, Korea in December 2006. Recently, ATS submitted 2 standards proposals to ISO/TC229: 1) about monitoring silver nanoparticles in inhalation exposure chamber for inhalation toxicity testing, and 2) about generation of silver nanoparticles for inhalation toxicity testing.

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

Korea Nanotechnology Research Society established by law, being composed of professors and researchers from public and private institutes, held a public hearing on environmental implications assessment of nanomaterials in December 2006, which collected public opinions on the EHS, ELSI of nanomaterials. Experts from government, research institutes, universities, and NGO participated in the public hearing.

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

MOE will hold an international seminar on the safety of nanomaterials on April 13 in 2007. US EPA, Japan NIES, Korea MOE, KFDA, ATS will make a presentation about policy or research trends on the safety of nanomaterials.

For harmonizing the policy on the safety of nanomaterials in Korea, MOE, MOST, KFDA, and ATS established an inter-ministerial consultation body on the safety of nanomaterials in March 2007. The consultation body will play an important role in order to perform effective research and harmonious policy development in the area of nanosafety.

**NETHERLANDS*****Highlight of developments since the 1<sup>st</sup> meeting of the WPMN (26-27 Oct 2006, London)***

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 an action plan for the Government this year.
- 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.

**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 on Intend to enter into a voluntary agreement with the Dutch government. Update is expected before the 3 WPNM meeting in november.

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

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

The SER (Dutch Socio Economic Council = existing of bussines rep. Union rep. and independent Academia) will be asked to advice on good practice on workplace exposure start forseen in oct-nov 2007.

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

A working group of the Ministries of Argiculture (food) Health (consumer goods, medicine), Labour (working conditions) and Environment (substances) will prepare a paper which addresses the risk management strategy on nanotechnologies (focusing first on nanoparticles). This paper will than be discussed with stakeholders (Business, NGO's United Trade Unions) amended and sent to parliament by the fall of 2007.

A national research agenda including a "risks section" is being drafted by the Netherlands Nanotechnolgy 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 in September 2007.

**NEW ZEALAND*****Highlight of developments since the 1<sup>st</sup> meeting of the WPMN***

- Ministry of Research Science and Technology (MoRST) Symposium on Nanoscience and Nanotechnologies in New Zealand
- Launch of MoRST Nanoscience & Nanotechnologies Roadmap document

***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.

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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>

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

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

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

Cosmetics containing nanoparticles (other than zinc oxide or titanium dioxide<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. The Foundation for Research Science and Technology has called for research proposals in its “Creating Opportunities Through New Physical Technologies” portfolio<sup>6</sup> that investigate the environmental and socio-economic uncertainties associated with nanotechnologies.

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.

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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/>

<sup>6</sup> <http://www.frst.govt.nz/research/NPT.cfm>

***Additional Information***

MoRST has also established the Navigator Network<sup>7</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>7</sup> <http://www.navigatornetwork.net.nz/>

## **NORWAY**

### ***Highlight of developments since the 1<sup>st</sup> meeting of the WPMN***

- A national strategy for nanoscience and nanotechnology has been adopted by The Research Council and forward to the Minister of Education and Research.

### ***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 EC.

#### **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.

#### **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.

**SPAIN*****Highlight of developments since the 1<sup>st</sup> meeting of the WPMN***

- Spanish government is launching a National Consortium intended to adopt the REACH regulations. It includes a division devoted to EHS issues of Manufactured Nanomaterials (MN), and will observe the SCENIHR opinion on risk assessment methodologies for MN.
- Strategic Action in Nanoscience and Nanotechnology will be renewed this year and is expected to increase the funding support for EHS issues related to MN.
- Several existing Agencies, Networks, Platforms and Foundations based on Nanoscience and Nanotechnology have been identified.
- Public awareness has increased.

***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 Spain, and only the generic legislation framework is applicable. As a member of the EU and in order to accomplish the implementation of the coming up REACH regulation, Spain is at the first phase to establish an inter-ministerial national body (Ministries of Environment, Health, Industry, Agriculture and Science and Education), which will integrate research experts from institutes, universities, industry and authorities from the administration. Concerned with the knowledge gaps associated to the potential risks of MN, the consortium decided the creation of a division to coordinate the aspect related to any EHS issue of nanomaterials. The division will carefully follow the EU SCENIHR opinion about the appropriateness of existing risk assessment methodologies for nanomaterials, and is intended to be closely linked to Spanish research Agencies and Foundations such as those described below (5<sup>th</sup> heading).

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

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

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

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

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

Documents related to good practice have not been developed yet in Spain. However, the Spanish Association for Standardization and Certification (AENOR), observing the Standard Code UNE 166006:2006 EX (R&D+I management: Technological Watch System), has recently launched a commission for Nanotechnology.

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

In terms of Government efforts in general nanotechnology, an initiative was the Strategic Action in Nanoscience and Nanotechnology (2004-07) under the umbrella of the R&D+I Agenda of the Ministry of Science and Education (MEC). Afterwards, Agencies and Foundations promoting interdisciplinary R&D+I activities, coorganizing important international meetings (Trends in Nanotechnology) and national workshops, and identifying research needs, have been established. For instance:

- a. PHANTOMS Foundation ([www.phantomsnet.net/Foundation/index.php?project=1&intra=1](http://www.phantomsnet.net/Foundation/index.php?project=1&intra=1)), and excellence platform of nanotechnology funded by EU and MEC
- b. NANOSPAIN ([www.nanospain.org/nanospain\\_English.htm](http://www.nanospain.org/nanospain_English.htm)) a network coordinating about 210 national research groups and companies (1200 researchers), funded by MEC.
- c. M<sup>4</sup>NANO ([www.m4nano.com/m4nanoc\\_m4/index.php](http://www.m4nano.com/m4nanoc_m4/index.php)) or “Modelling for Nanotechnology”, a WEB-based initiative led by Spanish Institutions including universities and the Phantoms Foundation.
- d. NANOMED Spain Platform ([www.nanomedspain.net](http://www.nanomedspain.net)) an action to integrate researchers, industry, hospitals, and experts from the administration, devoted to the development of a common strategy in the field of nanomedicine, which includes a *Toxicity and Regulation* working party.

Other individual inputs made by regional administrations have led to the foundation of the Nanotechnological Center of Aragon (Zaragoza), the Nanotechnological Platform in Oviedo, the NanoGalicia and Nanobiocal (Catalonia) Networks, or a section of Saretek (Vasque Country), among others.

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

No public or stakeholder consultations have been conducted yet.

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

There has been an increasing awareness in general public, in media and in the political bodies in Spain concerning nanotechnological products and processes in relation to potential environmental and health risks. In this field the Spanish authorities support and acknowledge the work and the strategic approach by the OECD.

**SWEDEN****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 are no regulations specifically addressing nanomaterials in Sweden. Sweden is a member of the EU and accordingly follows the EU regulation.

On Commission by the Government, Swedish Chemicals Inspectorate will review available knowledge on risks related to nanotechnology. The work also includes identification of data-gaps and proposals on how to fill the gaps.

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

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

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

No risk assessment on specific nanomaterials has been conducted in Sweden.

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

There is no good practice documents developed in Sweden at this stage.

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

There are no specific research programs or strategies in this area

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

Ongoing:

- *Network on Risk assessment of Nanomaterials*, organized by Swedish Chemicals Inspectorate
- *Network on Standards for Nanomaterials*, organized by Swedish Standards Institute

## **UNITED KINGDOM**

### ***Highlights since the 1st Working Party on Manufactured Nanomaterials***

- Publication of a study: "An Overview of the Framework of Current (UK) Regulation Affecting the Development and Marketing of Nanomaterials"
- Publication of an analysis of the environmental benefits of nanotechnologies
- Publication of the UK Nanotechnology Research Coordination Group's (NRCG) first progress report
- First 6 monthly review of the UK's Voluntary Reporting Scheme for engineered nanoscale materials
- Publication of a review by the Council for Science and Technology of the UK Government's progress with actions for the responsible development of nanotechnologies.
- Funding of the first round of successful proposals under the Environmental Nanoscience Initiative investigating environmental fate, behaviour and ecotoxicology.
- Funding for three research contracts on reference materials, environmental exposure of nanomaterials and the use of environmental hazard assessment methods for nanomaterials commenced

### **1. National regulatory developments on human health and environmental safety**

On 21 December 2006 the findings of a study "An Overview of the Framework of Current (UK) Regulation Affecting the Development and Marketing of Nanomaterials" were published<sup>1</sup>. This report provided an analysis of the potential gaps in the regulation of the development, manufacture, supply and use and end of life of free engineered nanoparticles.

Many of the gaps identified in the report arise from the lack of data on the potential effects of nanomaterials on human health and the environment, rather than any major regulatory oversight. There are uncertainties which relate both to the potential for adverse effects and to the level at which these effects might occur. The report also highlighted the current lack of technical capacity to monitor and sample relevant media.

The report also identified potential for regulatory gaps for the following reasons:

- Thresholds: Where thresholds set within regulations may be inappropriate for nanomaterials;
- Equivalence to existing substances: Where the regulation of nano-substances placed upon the market depends upon their equivalence to substances already regulated and understood, this may be inappropriate for some nanomaterials;

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<sup>1</sup> See: <http://www.dti.gov.uk/files/file36167.pdf>

- Limited scope of existing regulations: Where some regulations appear too narrow in scope and interpretation to prevent, restrict or control harm to the environment due to the presence of nanomaterials;
- Prescribed substances: Where regulation chooses as its primary method the prescription of certain listed substances so that their handling, use or disposal might be controlled, little attention is likely to be given to nano-substances.

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

The UK Government's Voluntary Reporting Scheme (VRS) for engineered nanoscale materials<sup>2</sup> was introduced on 22 September 2006. The VRS is run by Defra and will run to September 2008. To date 6 submissions have been received under the VRS.

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.

The VRS has been proactively promoted by the UK's Nanotechnologies Industry Association (NIA), who have offered to assist their members in completing data submissions. The chairperson of the NIA has made personal visits to their members, during the course of which she has discussed the VRS. Companies have given various reasons for failing to submit data, including (a) lack of time/resource; (b) uncertainty as to when in the development/manufacturing cycle a submission should be made; and (c) worries over becoming the subject of adverse publicity. To counter this last concern, the European Nanotechnology Trade Alliance have offered to act as a confidential intermediary, enabling anonymised VRS data to be submitted. Defra and the NIA are continuing to engage and discuss concerns with industry and remain optimistic that there will be an increase in the level of submissions made during the remaining 18 months of the scheme.

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

We have not conducted any risk assessments or taken any risk assessment decisions.

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

Three 'Good Practice Guides' are being developed by the British Standards Institute (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)

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<sup>2</sup> See: <http://www.defra.gov.uk/environment/nanotech/policy/index.htm#voluntary>

The BSI has also commenced work on the following new Publicly Available Specifications (PAS) which will be submitted to ISO/TC 229 and made freely available on the www before the end of 2007:

- 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

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

The UK Nanotechnology Research Coordination Group (NRCG) was established in 2005 to develop and oversee the implementation of a cross-Government research programme on the potential human health and environmental risks posed by free engineered nanoscale materials. The NRCG works to a programme of nineteen research objectives which aim to characterise the potential risks posed by free engineered nanoscale materials. The NRCG published its first progress report on 19 October 2006<sup>3</sup>.

The Environmental Hazard and Risk Assessment Task Force commissioned the Environmental Nanoscience Initiative<sup>4</sup> during 2006 and closed a call for research proposals into the environmental effects of manufactured nanomaterials in November. Funding was allocated in April 2007 to 11 successful grantees, covering, environmental fate, behaviour and ecotoxicology in soil, aquatic and marine environments.

Defra is currently funding three underpinning research contracts on nanomaterials. One is looking into the development of reference nanomaterials, the second is studying current and future environmental exposure to nanomaterials and the third is reviewing the potential of existing methods for evaluating environmental hazards of chemicals for use with materials at the nanoscale. These are due to report in summer 2007 and will be made available to the OECD WPMN.

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

The UK Government's programme of public engagement<sup>5</sup> on nanotechnologies is centred on three projects – Nanodialogues, the Nanotechnology Engagement Group (NEG), and Small Talk – which aim to elicit and understand people's aspirations and concerns around the development of these technologies. Small Talk concluded in 2006 and Nanodialogues and NEG will produce final reports this summer. The Government will consider the outcome of these projects before making decisions about future activities.

We have additionally established a Nanotechnologies Stakeholder Forum, which enables key stakeholders from industry, academia and civil society organisations to learn about and discuss each other's views, as well as Government activities, on appropriate controls and research.

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<sup>3</sup> See: <http://www.defra.gov.uk/environment/nanotech/research/reports/progress-report061019.pdf>

<sup>4</sup> See: [www.nerc.ac.uk/research/programmes/nanoscience](http://www.nerc.ac.uk/research/programmes/nanoscience)

<sup>5</sup> See: <http://www.dti.gov.uk/files/file27705.pdf>

***Additional information***

The UK Government has commissioned a study to analyse the potential environmental benefits of nanotechnologies with regard to its key policy challenges, including climate change and sustainable energy. The project will additionally identify potential barriers to the development and realisation of environmentally beneficial nanotechnologies, including how Government can help in this respect. A report of this study will be published during April/May 2007.

The Council for Science and Technology, the UK Government's top level advisory body on strategic science and technology policy, has been reviewing the Government's progress with actions for the responsible development of nanotechnologies (in response to the 2004 Royal Society and Royal Academy of Engineering report on nanoscience and nanotechnologies). It published its report on 27 March 2007<sup>6</sup>.

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<sup>6</sup> See: <http://www2.cst.gov.uk/cst/business/nanoreview.shtml>

## **UNITED STATES**

### **Highlights**

- EPA publicly released a White Paper on Nanotechnology, 15 February 2007
- NIOSH released “Progress Toward Safe Nanotechnology in the Workplace,” February 2007
- NSET/NEHI held a public meeting on an EHS research strategy, 4 January 2007
- EPA held a scientific peer consultation on risk management practices, 19-20 October 2007

### **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 Nanoscale Science, Engineering, and Technology (NSET) Subcommittee's Nanotechnology Environmental and Health Implications (NEHI) Working Group provides for exchange of information among agencies that support nanotechnology research and those responsible for regulation of nanotechnology-related products. The Working Group also seeks to facilitate research and other activities that support responsible development of nanotechnology.

The NSET Subcommittee member agencies are active participants in national and international standards development activities, including those of ISO Technical Committee on Nanotechnologies (TC 229), American National Standards Institute- Nanotechnology Standards Panel and ASTM International's Nanotechnology Committee (E56).

The Food and Drug Administration (FDA) has initiated an internal Task Force on Nanotechnology that will, among other considerations, examine regulatory approaches to manufactured nanomaterials.

The Environmental Protection Agency (EPA) is developing 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 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 (including EPA, NIOSH, and FDA) 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.

EPA has established an Agency-wide workgroup to develop a stewardship program under TSCA that could complement EPA's regulatory authorities and to ensure the responsible development and commercial use of nanoscale materials. A key goal of the Program is 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.

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

The National Institute for Occupational Safety and Health (NIOSH) has drafted and released for public review Current Intelligence Bulletin: Evaluation of Health Hazard and Recommendations for Occupational Exposure to Titanium Dioxide (<http://www.cdc.gov/niosh/review/public/tio2/>).

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;**

In August NIOSH released a second edition of its best practices document for working with nanomaterials “Approaches to Safe Nanotechnology: An Information Exchange with NIOSH” (<http://www.cdc.gov/niosh/topics/nanotech/safenano/>).

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

The NSET Subcommittee’s NEHI Working Group has released a document entitled “Environmental, Health, and Safety Research Needs of Engineered Nanoscale Materials” that identifies EHS research needed to enable risk assessment and risk management of nanoscale materials ([http://www.nano.gov/NNI\\_EHS\\_research\\_needs.pdf](http://www.nano.gov/NNI_EHS_research_needs.pdf)). The NEHI is performing a gap analysis and developing a prioritized research strategy to address EHS research needs.

The U.S. National Institutes of Health (NIH), U.S. Department of Health and Human Services, established a “Health Implications Working Group” to consider unintentional exposures to manufactured nanomaterials and intentional exposures to nanodiagnosics and therapeutics, as part of a larger Tran-NIH Nanotechnology Task Force. Currently, several million dollars of the NIH annual total expenditure of about \$170 million on nanotechnology research is devoted to assessing health affects of manufactured nanotechnologies (see Annex A).

The U.S. National Institutes of Health (NIH), with co-sponsorship with other U.S. agencies (NIOSH and EPA), announced on 29 September 2006 a request for applications (RFA) on a research program on the physico-chemical properties of manufactured nanotechnologies. Further information on this RFA is at: <http://grants.nih.gov/grants/guide/rfa-files/RFA-ES-06-008.html>. The research that will be supported seeks to characterize the physical and chemical properties of nanomaterials and determine the interaction of these properties with a relevant biological system at the cellular, molecular and systemic levels. NIH’s National Institute for Environmental Health Sciences (NIEHS) is leading this multi-institute/multiagency program to investigate the effects of manufactured nanotechnologies on human health. NIH intends to broadly share research results.

Also under the aegis of NIH/NIEHS, and in collaboration with the U.S. Food and Drug Administration and the Centers for Disease Control’s (CDC) National Institute for Occupational Health and Safety (NIOSH), the National Toxicology Program’s Nanotechnology Safety Initiative is undertaking toxicological evaluations of specific engineered nanoscale materials. The U.S. Consumer Product Safety Commission (CPSC), EPA and the U.S. Occupational Safety and Health Administration (OSHA) are also active participants in this initiative.

EPA’s Science Policy Council released its “Nanotechnology White Paper” (EPA/100/B-07/001, February 15, 2007) (<http://www.epa.gov/osa/nanotech.htm>) describing the science issues that EPA is addressing now, and will address in the future, regarding the potential environmental benefits and impacts of nanotechnology.

FDA has initiated research, in collaboration with NIST, to characterize certain particles used widely in commerce that are also used in drug products.

EPA is developing a nanotechnology research framework for 2007-2012. In fiscal years 2007 and 2008, EPA will focus on the following high-priority areas: environmental fate, transport, transformation, and exposure; and monitoring and detection methods. Resulting data will be used to inform and develop effects and exposure assessment methods and identify important points of releases for potential management.

NIOSH Nanotechnology Research program (<http://www.cdc.gov/niosh/topics/nanotech/research.html>) addresses health hazard and safety aspects of nanotechnology in occupational settings.

In February 2007, NIOSH's Nanotechnology Research Center (NCTR) released the nanotechnology progress report "Progress Toward Safe Nanotechnology in the Workplace" (NIOSH Publication No. 2007-123) available on-line at <http://www.cdc.gov/niosh/docs/2007-123/>. This new report details the advancements made by the NIOSH, through the NCTR, in advancing the scientific knowledge in understanding the occupational safety and health implications of engineered nanoparticles. The document also identifies 10 critical topic areas important for understanding the potential work-related health risks of nanotechnology products and developing and disseminating recommendations for mitigating these risks; it further suggests potential areas where future research could expand this knowledge.

NIOSH's Interdisciplinary Field Team of nanotechnology researchers partners with nanotechnology companies to assess exposures to nanomaterials in the workplace and the effectiveness of engineering controls and personal protective equipment in reducing such exposures.

EPA, the National Science Foundation (NSF), NIOSH, and NIH plan an expanded joint extramural research program addressing potential EHS implications of nanotechnology for human health and the environment.

NIOSH is supporting focused research on nanotechnology issues associated with worker safety and health as outlined in the NIOSH Nanotechnology Strategic Plan (available at [www.cdc.gov/niosh/topics/nanotech/strat\\_plan.html](http://www.cdc.gov/niosh/topics/nanotech/strat_plan.html)) through intramural and extramural programs and international collaborations.

The NIH National Cancer Institute's Alliance for Nanotechnology Characterization Lab is developing a characterization cascade for use in preclinical evaluations of nanomaterials intended for cancer therapeutics.

NSF supports basic research directed at environmental, health, and safety impacts of nanotechnology development. NSF has funded hundreds of grants for such study to individual researchers, environmental centers and interdisciplinary groups.

See Annex A for a Chart summarizing research programs in the USG directed at environmental, health, and safety impacts of nanotech.

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

The NSET Subcommittee sponsored a workshop in May 2006, with support from the EPA, on Public Participation in Nanotechnology. On January 4, 2007, NSET and NEHI held a public meeting to receive comments on the document "Environmental, Health, and Safety Research Needs of Engineered Nanoscale Materials" (described in Section 5) and next steps in developing an EHS research strategy. Additional

public comments were collected through the end of January. The NEHI Working group is considering this input as part of its effort to further prioritize the needs discussed in the document.

EPA's Office of Solid Waste and Emergency Response hosted a symposium on July 12 -13, 2006 about nanotechnology and its influence in waste management practices.

FDA held a public meeting October 10, 2006 to consult with the public about the kinds of new

nanotechnology material products under development and whether there are new or emerging scientific issues that should be brought to FDA's attention, including issues related to the safety of nanotechnology materials.

EPA's Office of Pollution Prevention and Toxics (OPPT) is held a scientific peer consultation October 19-20, 2007 on risk management practices pertaining to nanoscale materials to support development of the stewardship program it is considering. A second peer consultation on materials characterization is being planned for summer, 2007 in conjunction with a public meeting to receive input on the stewardship program.

OPPT is also planning a pollution prevention conference for summer 2007 to provide a forum to exchange information and ideas on the potential environmental and pollution prevention benefits of innovative nanotechnologies and nanomaterials.

NIOSH invites public comments on its nanotechnology-related documents posted on NIOSH

nanotechnology web-page (<http://www.cdc.gov/niosh/topics/nanotech/>), such as .Approaches to Safe Nanotechnology: An Information Exchange with NIOSH.

(<http://www.cdc.gov/niosh/topics/nanotech/safenano/>).

NIOSH sponsored a workshop on nanotechnology and occupational safety and health hosted by the RAND Corporation on October 17, 2005. The workshop focused on policy and planning issues (as opposed to scientific issues) that are key to understanding the options available to NIOSH in formulating and implementing its strategic objectives to protect the safety and health of workers exposed to nanoscale materials ([http://www.rand.org/pubs/conf\\_proceedings/CF227/](http://www.rand.org/pubs/conf_proceedings/CF227/)).

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### *Annex A*

Research programs directed at environmental, health, and safety (EHS) impacts of nanotechnology development, and risk assessment of such impacts are a growing component of the U.S. National Nanotechnology Initiative. R&D leading to a detailed understanding of the health and safety impacts of nanotechnology for researchers, workers, consumers, and the public is a strategic priority within the NNI's Societal Dimensions Program Component Area, and is reported by agency in the table below. Note that the funding indicated in this table does not include R&D within other NNI Program Component Areas that is highly relevant to EHS implications but not primarily directed at those implications, such as fundamental studies of the interactions between engineered nanoscale materials and biological systems, development of improved instrumentation for measuring the properties of engineered nanoscale materials, or applications oriented work that also produces information related to potential toxicity of nanoscale or nanostructured materials.

U.S. National Nanotechnology Initiative Budget for Environmental, Health, and Safety R&D, 2006-2008 (in millions of U.S. Dollars)			
	<b>2006 Actual</b>	<b>2007 Estimate*</b>	<b>2008 Proposed</b>
NSF	21.0	25.7	28.8
DOD	1.0	1.0	1.0
DOE	0.5	0.0	3.0
DHHS (NIH)	5.2	4.6	5.7
DOC (NIST)	2.4	1.8	5.8
NASA	0.0	0.0	0.0
EPA	3.7	8.0	9.6
USDA (CSREES)	0.1	0.1	0.1
DHHS (NIOSH)	3.8	4.6	4.6
USDA/FS	0.0	0.0	0.0
DHS	0.0	0.0	0.0
DOJ	0.0	0.0	0.0
DOT (FHWA)	0.0	0.0	0.0
<b>TOTAL</b>	<b>37.7</b>	<b>45.8</b>	<b>58.6</b>

\* The 2007 Estimates reflect 2007 Budget levels, except for the Departments of Defense and Homeland Security, which are the enacted levels. Several agencies have updated their 2007 Budget levels since the release of the 2007 NNI Budget Supplement.

**EUROPEAN COMMISSION*****Highlight of developments since the 1<sup>st</sup> meeting of the WPMN***

- 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 is an overhaul of the current chemicals legislations in the EU. A European Chemicals Agency will be set up in Helsinki in spring 2007.
- The EU Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) approved end of March 2007 for public consultation 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. The final opinion is expected for June 2007. SCENIHR continues its work with a scientific review of definitions related to the products of nanotechnology/ nanomaterials.
- The EU Scientific Committee on Consumer Products is finalising an Opinion on the Safety of Nanomaterials in Cosmetic Products. It will be submitted for public consultation in due course.
- The first calls for proposals in the 7<sup>th</sup> EU Research Framework Programme (FP7) have been published on 22 December 2006 including several topics related to potential impacts of nanoparticles on human health and the environment. Recent updates on research projects funded by the European Commission can be found at <http://cordis.europa.eu/nanotechnology/>.
- The European Group on Ethics of science and new technologies (EGE), the independent advisory body to the President of the EC, has issued 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)). The opinion addresses several issues related to ethical, legal and social implications of nanomedicine.

***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:

1. 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.
2. 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.
3. 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.
4. 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.

## **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 EC Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) adopted an opinion on “The appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies” in March 2006 after the public consultation of the first version adopted in September 2005<sup>1</sup>. In essence, the SCENIHR scientific opinion states that “given [...] uncertainties [concerning respectively hazard and exposure], the current risk assessment procedures require modification for nanoparticles.”

Three new scientific opinions related to risk assessment of nanomaterials are foreseen from the EC Scientific Committees during the first half of 2007, namely:

- a scientific opinion from the SCENIHR 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”<sup>2</sup>.
- a scientific opinion from the Scientific Committee on Consumer Products on the safety of “nanomaterials in cosmetic products”<sup>3</sup>;
- a scientific opinion from the SCENIHR on "the scientific review of existing and proposed definitions related to products of nanotechnology/nanomaterials"

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<sup>1</sup> [http://ec.europa.eu/comm/health/ph\\_risk/committees/04\\_scenihr/docs/scenihr\\_o\\_003.pdf](http://ec.europa.eu/comm/health/ph_risk/committees/04_scenihr/docs/scenihr_o_003.pdf) (p. 60)

<sup>2</sup> [http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihr/docs/scenihr\\_q\\_008.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_q_008.pdf)

<sup>3</sup> [http://ec.europa.eu/health/ph\\_risk/committees/04\\_sccp/docs/sccp\\_nano\\_en.pdf](http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_nano_en.pdf)

#### **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 nano-structured 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.

Future activities in FP7 are being drafted have taken into consideration external and internal inputs. The data gathered in an informal collection of inputs on (eco)toxicology provide valuable information to prioritise research on health and safety aspects of nanotechnology-based products. Additional information such as priorities identified in the SCENIHR opinion, external stakeholders comments (such as representatives from the Member States and the Advisory group on Nanotechnologies and Nanosciences as well as internal discussions between different Commission services have also been taken into consideration when drafting the work programme for the first years. Based on the regulatory inventory work, additional detailed and prioritized research needs were identified. Dedicated calls are foreseen among the first actions of the FP7.

The Commission has dedicated up to now around 25 million € to nanotechnology research projects particularly focused on safety aspects (additional funds have been made available within nanotechnology projects with targets not specifically related to safety) and intends to continue rising the funds available for risk-related research activities.

The first calls for proposals in the FP7 have been published on 22 December 2006. Amongst others, nanotechnology related calls can currently be found in the Cooperation Programme under following Themes:

- The NMP Theme: Most calls for proposal directly addressing safety of nanomaterials can be found in the NMP theme, mainly in chapter 4.1 (nano and converging sciences and technologies; health, safety and environmental impacts) of the NMP work programme. Four calls have been published for 2007: Large Research projects (LARGE): FP7-NMP-2007-LARGE-1, Small research Projects (SMALL): FP7-NMP-2007-SMALL-1 and Coordination and Support Actions (CSAs): FP7-NMP-2007-CSA-1.

- Other nano-related calls are in the HEALTH Theme (related to nanomedicine), the KBBE Theme (related to nanotechnology in food and agriculture and to nanobiotechnology), the ICT Theme (related to nanoelectronics), the ENERGY Theme (related to nanotechnological solutions for energy) and the Transport Theme related to nanomaterials for transport) can be found in FP7-AAT-2007-RTD-1.

These are the calls directly related to safety of nanomaterials are:

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

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

As with previous framework programs, FP7 is open to the participation of virtually all countries in the world. The possibility of coordinated calls with third countries and other specific actions is foreseen.

## 6. Information on any public/ stakeholder consultation

As mentioned under 5), a collection of inputs on (eco)toxicology took place as input to shaping the future activities within FP7. The SCENIHR first opinion on nanotechnology was slightly modified after the

comments received from a public consultation via Internet. The public consultation of the SCENIHR opinion on Nanomaterials in TGDs of the chemicals' legislation started on 11 April 2007 and lasts until 23 May 2007, while the public consultation of the opinion of the Scientific Committee on Consumer Products (SCCP) is planned for June-July 2007.

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 to examine how to promote the safe, integrated, and responsible development of nanotechnologies. The conference confirmed safety as a prerequisite to the success of nanotechnologies, the need for stronger coordination and a clear road map as well as the usefulness of a sustained dialogue between stakeholders.

### ***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.

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.

## **CHINA**

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/htm/apa/35.htm>

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

Up to date China standards for nanotechnologies as following:

1. GB/T 19619-2004 Terminology for nanomaterials (Published: 2004-12-27; implemented: 2005-04-01)
2. 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)
3. 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)
4. GB/T 19588-2004 Nano-nickel powder (Published: 2004-12-27; implemented: 2005-04-01)
5. GB/T 19589-2004 Nano-zinc powder (Published: 2004-12-27; implemented: 2005-04-01)
6. GB/T 19590-2004 Nano-calcium carbonate (Published: 2004-12-27; implemented: 2005-04-01)

7. GB/T 19591-2004 Nano-titanium dioxide (Published: 2004-12-27; implemented: 2005-04-01)
8. GB/T 19627-2005 Particle size analysis-Photon correlation spectroscopy (ISO 13321:1996,IDT) (Published:2005-01-13; implemented: 2005-08-01)
9. GB/T 15445.2-2006 Representation of results of particle size analysis—Part 2:Calculation of average particle sizes/diameters and moments from particle size distributions (ISO 9276—2: 2001,IDT) (Published: 2006-02-05; implemented: 2006-08-01)
10. 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)
11. GB/T 20307-2006 General rules for nanometer-scale length measurement by SEM (Published: 2006-07-19; implemented: 2007-02-01)
12. GB/T 20099-2006 Sample preparation dispersing procedures for powders in liquids ( ISO 14887: 2000,IDT) (Published: 2006-2-5 implemented: 2006-8-1)

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.

**THAILAND*****Highlight of developments since the 1st meeting of the WPMN:***

- Contact persons have been appointed to take part in WPMN Steering Groups: Dr.Nuttapun Supaka and Dr.Rawiwan Maniratanachote for SG2 (research strategies); Dr.Nuttapun Supaka, Dr.Rawiwan Maniratanachote and Dr. Lerson Tanasugarn for SG3 (safety testing of representative manufactured nanomaterials); Dr.Noppawan Tanpipat for SG4 (manufactured nanomaterial test guidelines); and Dr. Sirasak Tepakum for SG6 (risk assessment/ exposure measurement).
- The Nanosafety/ Nanoethics Guideline Drafting Project 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.
- Chulalongkorn University has formed a nanosafety forum 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).

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 nano-devices. 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 is 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). So far no concrete development has been reported.

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. Initially, NANOTEC expected to commission Chulalongkorn University to draft the nanosafety and nanoethics 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).

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

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**

### **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 2006, the American Bar Association Section of Environment, Energy and Resources prepared and made available a series of white papers reviewing the adequacy of six US environmental laws, and provided a seventh paper on innovative management systems. The six papers review each of the core domestic environmental laws and consider how each can be effective to address issues regarding nanomaterials and nanotechnology. The papers are available at <http://www.abanet.org/environ/nanotech>.

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

BIAC supports the actions being taken by the US Environmental Protection Agency (EPA) and the UK Department for Environment, Food and Rural Affairs (Defra) to establish a voluntary reporting system as a means of building an evidence base to allow for more informed discussion and decisions about appropriate regulatory controls. BIAC believes that existing laws provide the competent authorities with full authority to address environmental, health and safety implications of nanotechnology (TSCA Authority White Paper, March 2006).

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

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

The German Chemical Industry Association (VCI) has finalized a position on the legal coverage of nanoparticles and nanoscale substances together with recommendations on the safe handling in February 2006. In spring 2006 VCI started a survey in cooperation with the German Federal Institute for Occupational Safety and Health (BAuA) to determine the use of nanomaterials within the German chemical industry and to gather information on the exposure scenarios and safety measures applied. The results will be presented at a workshop on 19 April 2007. From the results of that survey, VCI and BAuA have jointly developed a best practice guideline for handling and use of nanomaterials at the workplace. The guideline will also be discussed with stakeholders on April 19.

In order to support the development of globally harmonized data requirements for carrying out risk assessments, VCI has published in September 2006 a proposal for a tiered data gathering as basis for further discussion on risk assessment with the authorities. The activities of the chemical industry are directed to safeguard the fulfilment of current and future legal provisions. The German mirror group of the ISO Technical Committee 229 Nanotechnologies has prepared an issue sheet to sketch the SHE relevant issues in analytic procedures and analytical conditions for nanotechnologies standardization.

Furthermore VCI will work out several New Work Item Proposals (NWIP) for the ISO TC 229 WG3 (HSE) on standards for exposition measurement, analytic procedures and analytical conditions for toxicity testing strategies referring to specific exposition scenarios.

The US Technical Advisory Group (TAG) to ISO TC 229 is preparing a NWIP on "Guidance on physico-chemical characterization of engineered nanoscale materials for toxicologic assessment".

In the US, guidelines are being collected as a web-based resource by the ORC Task Force on Nanotechnology. The Task Force provides a forum for private sector nanotechnology experts to share

current work practices and strategies, and is made up of both members of ORC Worldwide's Occupational Safety and Health and Environmental Networks and non-ORC member participants. The Guidelines are considered a living document that is being updated as new information becomes available. It addresses nine broad areas applicable to nanotechnology health safety and environment concerns: Assessing Hazard Characteristics; Assessing Worker Exposure; Assessing Process Safety Considerations; Assessing Environmental Emissions & Fate; Performing HS&E Risk Assessment; Implementing HS&E Risk Control; Medical Monitoring; Communication & Training; Assessing Transportation Needs. Under each of these headings, it provides or aims to provide links to specific materials, tools, and peer reviews. Anyone can submit materials for inclusion after review by the ORC peer review process. The location is: <http://www.orc-dc.com/Nano.Guidelines.Matrix.htm> .

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

The Nanoparticles Occupational Safety & Health Consortium (NOSH) consists of international companies, government agencies from the US and UK and NGOs with the purpose of developing methods to generate consistently nanoscale materials and to well characterize the aerosol, to develop portable prototype equipment that can monitor nanomaterials in occupational settings, and to measure barrier efficiency of filter media to specific engineered nanoparticles. The Consortium has published some of its work and more publications are under development.

Policy in Japan (METI) includes:

A. Government will collect safety information data about Nanotechnology (Nano Tech) as follows:

1. Need for standardization of measurement technology etc. as a base of safety investigation.
2. Collect updated safety information about Nano Tech without any specific regulation.
3. Many of the test methods for existing chemical substances can be applied.
4. The actual circumstances of Nanomaterials should be researched as quickly as possible, such as existing circumstances and exposure volume.

B. Industries are expected to conduct self risk assessment of Nanomaterials.

1. Industries are needed to conduct risk assessment of their own Nanomaterials because they fall under the regulations dealing with safe handling of chemicals
2. Industries are also expected to do aggressive safety research of Nanotechnology from the standpoint of CSR.

VCI and Dechema have collected a list of research activities concerning exposure, characterization methods and toxicological testing of nanomaterials. Together with scientists from universities and applied research institutes a joint Working Group "Responsible Production and Use of Nanomaterials" of the German Society for Chemical Engineering and Biotechnology (DECHEMA) and German Chemical Industry Association (VCI) has listed and prioritized research needs for a roadmap and link with the 7th European R&D Framework Programme that has been disseminated to authorities on national and European level. Most of the highest priority issues are meanwhile covered by several research projects of the chemical industry and institutes - especially by the project "NanoCare" dealing with methodology, toxicology, hazard evaluation and exposure assessment. NanoCare is jointly federal and industry funded and coordinates industry and academia activities.

The German chemical industry will propose "Guidance Documents" to conduct toxicological and ecotoxicological tests. These guidance documents may partly be derived from the German project "NanoCare" that will be presented at the 2<sup>nd</sup> OECD WPMN meeting 25 – 27 April 2007 in Berlin.

Furthermore the German chemical industry will work out and propose requirements for the identifications of toxicological endpoints and the toxicological relevant solubility.

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

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

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

**Summary of the status of ISO/TC 229, 23.03.2007**  
**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. To date it has held three meetings - November 05 in London, June 06 in Tokyo and December 06 in Seoul. The next meeting will be in Berlin in June. The committee currently has 37 members - 28 "P" and 9 "O". The TC structure consists of 3 working groups - Terminology and Nomenclature (WG1, convened by Canada), Measurement and Characterization (WG2, convened by Japan) and Health, Safety and Environment (WG3, convened by USA). There are currently 3 work items in development: an ISO/TS (technical specification) - terminology and definitions for nanoparticles (led by Dr Mark Gee from NPL, UK), which will be submitted for Committee Draft ballot before the next plenary in June; an ISO/TR (technical report) - health and safety practices in occupational settings relevant to nanotechnologies (led by Dr. Vladimir Murashov from NIOSH, USA), which should be published later this year; and an ISO/IS (international standard) - endotoxin test on nanomaterial samples for in vitro systems (led by Dr Kawasaki from AIST, Japan), which will be ready for publication in late 2009 or early 2010. The committee has recently received 7 new work item proposals – five in the area of characterization of carbon nanotubes and two associated with toxicological testing of nanoparticle silver, which have ballot deadlines of April/May. The TC is expecting further new work item proposals before the next meeting.

The TC works closely with the CEN TC in the area (TC 352 – Nanotechnologies, also chaired by UK), using the Vienna agreement where appropriate, and with the newly formed IEC (International Electrotechnical Committee) TC 113 - “Nanotechnology standardization for electrical and electronic products and systems” chaired by the US, with Germany providing the secretariat. ISO/TC 229 and IEC/TC 113 are in the process of establishing two joint working groups (JWG) – in Terminology and Nomenclature (ISO/TC 229 WG1) and in Measurement and Characterization (TC 229/WG2) - both led by ISO. Close contact will be maintained in the area of activity of TC 229/WG3 – HS&E – though it is not currently planned to establish a JWG for this. The two Technical Committees plan to hold joint plenary meetings starting in December 2007. Liaisons have also been established with 15 other ISO TC's, with the OECD (Working Party on Manufactured Nanomaterials, with which a coordination agreement is being developed), 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 WG2, 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 Berlin meeting.

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.

The originator of the new work item proposal shall

- make every effort to provide a first working draft for discussion, or shall at least provide an outline of such a working draft;
- nominate a project leader.

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, i.e. to make an effective contribution at the preparatory stage, by nominating technical experts and by commenting on working drafts;
- b) approval of the work item by a simple majority of the P-members of the technical committee or subcommittee voting.

ISO/TC 229 is not the only ISO TC with an interest in nanotechnologies but maintains responsibility for the development of “horizontal” standards in the area and those not more appropriately developed in other TCs.

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.

**WOODROW WILSON INTERNATIONAL CENTER FOR SCHOLARS*****Highlight of developments since the 1st meeting of the WPMN***

- Andrew D. Maynard, et al, "Safe handling of nanotechnology," *Nature* 444(16): 267-269 (16 November 2006)
- Andrew D. Maynard, Comments on Public Meeting on Research Needs and Priorities Related to the Environmental, Health, and Safety Aspects of Engineered Nanoscale Materials (4 January 2007)
- Mark Greenwood, Thinking Big About Things Small: Creating an Effective Oversight System for Nanotechnology (14 March 2007)
- Dan M. Kahan, et al, Nanotechnology Risk Perceptions: The Influence of Affect and Values (7 March 2007)
- Project grant renewal by The Pew Charitable Trusts, \$3 million over 2 years (15 March 2007)
- Barbara Karn, Pilar Aguar, and Per Martin Schmidt, et al, Nanotechnology and Life Cycle Assessment: A Systems Approach to Nanotechnology and the Environment (20 March 2007).
- Pending: Karen F. Schmidt, NanoFrontiers: Visions for the Future of Nanotechnology (23 April 2007)
- Pending: Karen F. Schmidt, Green Nanotechnology: It's Easier Than You Think (26 April 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 Project on Emerging Nanotechnologies is an initiative launched by the Woodrow Wilson International Center for Scholars and The Pew Charitable Trusts in 2005. It is dedicated to helping business, government and the public anticipate and manage the possible health and environmental implications of nanotechnology. As part of the Wilson Center, the Project on Emerging Nanotechnologies is a non-partisan, non-advocacy organization that collaborates with researchers, government, industry, non-governmental organizations (NGOs), and others concerned with the safe applications and utilization of nanotechnology. In March 2007, the Project received an additional \$3 million investment from Pew to continue and expands its work over the next two year.

The Project on Emerging Nanotechnologies has been instrumental in facilitating the process of evaluating the current U.S. government EH&S risk research portfolio, identifying gaps in ongoing EH&S research, prioritizing future research needs and developing effective oversight and risk research management options for government and industry. For example, Project Director David Rejeski testified before the Food and Drug Administration on the need for a coherent framework for nanotechnology oversight. Additionally, the Project has published numerous reports that analyze the effectiveness of existing regulatory systems and recommendations for new laws and guidance materials, including Michael

R. Taylor, *Regulating the Products of Nanotechnology: Does FDA Have the Tools It Needs?* (October 2006) and Mark Greenwood report referenced above.

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

Andrew D. Maynard presented testimony before the U.S. House of Representatives Committee on Science hearing entitled “Research on Environmental and Safety Impacts of Nanotechnology: What are the Federal Agencies Doing?” on September 21, 2006. Dr. Maynard suggested mechanisms to support an internationally focused, joint government-industry funded, cooperative science organization, similar to the Health Effects Institute, with a five-year plan to systematically address the human health impacts of engineered nanomaterials through independent, targeted risk-related research. The Project is continuing to explore the possibility of creating such an organization (available at [http://www.nanotechproject.org/file\\_download/100](http://www.nanotechproject.org/file_download/100)).

The Project has worked on establishing a variety of voluntary and stewardship schemes. In March 2007, the Project released a proceedings report, in conjunction with the European Commission, on the need for and potential application of life cycle assessment (LCA) for nanomaterials. Moreover, for the past three years, the Project has helped support work by Environmental Defense and Dupont, which recently resulted in the announcement of a Nano Risk Framework ([www.environmentaldefense.org/go/nano](http://www.environmentaldefense.org/go/nano)). In addition, we are working with a small nanotechnology firm in Virginia (Luna Innovations) to help widely propagate an Environmental Management System (EMS) that the firm has developed. Finally, we have an ongoing project with the Environmental Protection Agency’s voluntary Performance Track Program, which rewards excellent facility performance in firms (<http://www.epa.gov/performancetrack/>), and an Ohio company Nanofilm ([www.nanofilmtechnology.com](http://www.nanofilmtechnology.com)). The goal is the development of a nanotechnology-relevant environmental management system that will allow Nanofilm to qualify for inclusion in EPA’s program.

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

Late in 2005, the Project created, and continues to maintain, the first publicly available, web-based, and fully searchable Inventory of Nanotechnology Environment, Health and Safety Research, which contains investigator, funding and categorization details on over 200 research projects from eight countries or regions around the world. According to data in the inventory, the U.S. government invested an estimated \$11 million in 2005 in highly relevant risk research dedicated to addressing the potential impacts of engineered nanomaterials (available at <http://www.nanotechproject.org/18/esh-inventory>).

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

The Project published the report *Nanotechnology: A Research Strategy for Addressing Risk*, by Andrew Dr. Maynard, in July 2006. This report proposes detailed EH&S risk research priorities—including identifying and measuring nanomaterials exposure and environmental release, evaluating nanomaterial toxicity, controlling the release of and exposure to nanomaterials and developing “best practices” for working safely with nanomaterials—and offers short-, medium- and long-term timeframes for such investigation (available at [http://www.nanotechproject.org/file\\_download/77](http://www.nanotechproject.org/file_download/77)).

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

Under the lead authorship of Andrew D. Maynard, the Project provided a forum for the release of the article “Safe handling of nanotechnology” in the November 16, 2006 edition of *Nature*. Authored by 14 internationally renowned scientists who have identified, prioritized and mapped Five Grand Challenges for targeted research on nanotechnology’s potential EH&S risks, the article addresses central challenges aimed

at focusing attention on key components of a strategic research agenda that must be met if the technology is to reach its potential (available at <http://www.nature.com/nature/journal/v444/n7117/full/444267a.html>). The Five Grand Challenges include:

1. Developing instrumentation to measure nanoparticles in air and water,
2. Evaluating the hazard of new nanomaterials,
3. Predicting the toxicity of emerging nanomaterials with models,
4. Assessing the possible impact of nanotechnologies across their lifetime, and
5. Developing strategic programs to enable risk-focused research.

These five challenges do not in themselves constitute a robust strategic research plan. However, they do lay a foundation for developing such a plan, and are beginning to be reflected in emerging research agendas, such as the European Union Framework Seven Research Agenda. The fifth challenge of creating a strategic research framework is particularly pertinent to today's meeting addressing research priorities. As the OECD and federal governments begin to consider research priorities, they should be encouraged to use these challenges as a framework on which to build a strong and relevant strategic research program.

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

The Project continues to place increased importance on continued public dialogue and outreach. In particular, the Project has supported numerous research projects into tracking and addressing nanotechnology public perception and trust in government, including Peter D. Hart Research Associate, Inc., *Attitudes Toward Nanotechnology and Federal Regulatory Agencies* (September 2006) and the Dan M. Kahan report referenced above. Additionally, these reports complement the Project's work in tracking the commercialization of nanotechnology consumer products. Through the development of our Nanotechnology Consumer Product Inventory, we found that there are a wide variety of products—over 380 from 17 different countries—claiming to contain and use nanomaterials already on the market. This means that researchers, workers, consumers and ecosystems are already being exposed to these substances, despite, in many cases, uncertainty over the potential risks they may present (available at <http://www.nanotechproject.org/consumerproducts>). The Project also supports the development of more novel and more creative methods for interacting with the public. For example, the Project on Emerging Nanotechnologies is planning to develop a series of downloadable audio podcasts on the future of nanotechnology and expects to hold a series of web dialogues over the coming months to encourage participation by broader segments of the population, such as women, the elderly, and minorities, to contribute ideas about nanotechnology governance.