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**Series of Safety of Manufactured Nanomaterials**

**No. 20**

**CURRENT DEVELOPEMENT/ACTIVITES ON THE SAFETY OF MANUFACTURED  
NANOMATERIALS - TOUR DE TABLE**

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

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**No. 20**

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

*Tour de Table at the 6th Meeting of the Working Party on  
Manufactured Nanomaterials*

Paris, France 28-30 October 2009

**IOMC**

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INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

A cooperative agreement among **FAO, ILO, UNEP, UNIDO, UNITAR, WHO and OECD**

**Environment Directorate  
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT  
Paris, 2010**

***Also published in the Series of Safety of Manufactured Nanomaterials:***

- No. 1, *Report of the OECD Workshop on the Safety of Manufactured Nanomaterials: Building Co-operation, Co-ordination and Communication (2006)*
- No. 2, *Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 1st Meeting of the Working Party on Manufactured Nanomaterials (2006)*
- No. 3, *Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 2nd Meeting of the Working Party on Manufactured Nanomaterials (2007)*
- No. 4, *Manufactured Nanomaterials: Programme of Work 2006-2008 (2008)*
- No. 5, *Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 3rd Meeting of the Working Party on Manufactured Nanomaterials(2008)*
- No. 6, *List of Manufactured Nanomaterials and List of Endpoints for Phase One of the OECD Testing Programme (2008)*
- No. 7, *Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 4<sup>th</sup> Meeting of the Working Party on Manufactured Nanomaterials(2008)*
- No. 8, *Preliminary Analysis of Exposure Measurement and Exposure Mitigation in Occupational Settings: Manufactured Nanomaterials(2009)*
- No.9, *EHS Research Strategies On Manufactured Nanomaterials: Compilation Of outputs(2009)*
- No.10, *Identification, Compilation and Analysis of Guidance Information for Exposure Measurement and Exposure Mitigation: Manufactured Nanomaterials (2009)*
- No.11, *Emission Assessment for the Identification of Sources and Release of Airborne Manufactured Nanomaterials in the Workplace: Compilation of Existing Guidance (2009)*
- No.12, *Comparison of Guidance on Selection of Skin Protective Equipment and Respirators for Use in the Workplace: Manufactured Nanomaterials (2009)*
- No. 13, *Report of an OECD Workshop on Exposure Assessment and Exposure Mitigation: Manufactured Nanomaterials (2009)*
- No. 14, *Guidance Manual for the Testing of Manufactured Nanomaterials: OECD Sponsorship Programme (2009)*
- No. 15, *Preliminary Review of OECD Test Guidelines for their Applicability to Manufactured Nanomaterials (2009)*

No. 16, *Manufactured Nanomaterials: Work Programme 2009-2012 (2009)*

No. 17, *Current Developments in Delegations and other International Organisations on the Safety of Manufactured Nanomaterials- Tour de Table (2009)*

No. 18, *Manufactured Nanomaterials: Roadmap for Activities during 2009 and 2010 (2009)*

No. 19, *Analysis of Information Gathering Initiative on Manufactured Nanomaterials (2009)*

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

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

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

The Working Party endorsed this document at its 6th Meeting on October 2009. [This document is published under the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology of the OECD.]

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## **EXECUTIVE SUMMARY**

In each meeting of the Working Party on Manufactured Nanomaterials (WPMN), the delegations have an opportunity to provide their developments on the safety of manufactured nanomaterials, so called “Tour de Table.” An earlier version of this document was originally provided to the 5th meeting held 4-6 March 2009 in Paris, France. This document includes an update of the status of the work of the WPMN (Section I) and compiles information provided by member countries and other delegations on current developments on the safety of manufactured nanomaterials (section II) in their countries or organisations. There are also written reports on current activities related to nanotechnologies/ nanomaterials in other International Organisations including the International Organisation for Standardisation, the Food and Agriculture Organisation of the United Nations and the World Health Organisation (section III).

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. This “snapshot” was current at the time of the 6th meeting of the WPMN (October 2009).

## SECTION I: OECD WORK ON THE SAFETY OF MANUFACTURED NANOMATERIALS

This section is intended to summarise the activities related to the WPMN, which includes the current status of the each of the eight projects, co-ordination work with other organisation/bodies as well as recent/upcoming publications information.

The Working Party on Manufactured Nanomaterials (WPMN) was established in 2006 at a time when nanomaterials were becoming more common in products. Its work is intended to ensure that human health and environmental safety aspects of nanotechnology are adequately addressed. A major focus of its work is to ensure that existing instruments (for example, the OECD Test Guidelines) can be reliably applied to nanomaterials. Accordingly, it seeks to promote international co-operation in addressing the human health and environmental safety implications of manufactured nanomaterials.

An important recent element has been OECD's response to the financial and economic crisis. A key element of this response is to foster "green" and innovation-led growth<sup>1</sup>. For its part, the WPMN has aligned its programme of work to support the overall mission and commitment of the organisation and its members. As such, it works closely with other international efforts.

The WPMN work is a science and rules-based approach which is based on information gathering, priority setting, testing and other methodologies to fill data gaps, to facilitate the assessment of hazards, potential exposure, risk assessment and, where needed, risk management measures. By developing the methodologies in OECD to implement this approach and by harmonising their policies and instruments, member countries can reap the benefits of sharing the work among themselves. For this reason, efforts continue to be made in OECD to create, maintain and improve the various parts of a process which guarantees protection of health and environment by addressing issues associated with chemicals production and use, while avoiding inefficiencies caused by duplicative work and creation of non-tariff barriers to trade. This is implemented by the WPMN through a number of projects as outlined below. It should be noted that each of the eight projects is managed by a steering group (SG) comprising delegates to the WPMN.

In addition to delegates from OECD member countries and the European Commission, the WPMN work benefits from the participation of representatives from China, Thailand, South Africa, the Russian Federation, Singapore, as well as other organisations such as FAO, UNITAR, ISO (TC 229), BIAC and Environmental NGOs.

Significant progress in implementing the programme of work has been made to date. The current status of the implementation of each of the projects is summarised below.

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<sup>1</sup> See OECD Strategic Response to the Financial and Economic Crisis: Contributions to the Global Effort [C(2008)191/FINAL], which includes promoting cleaner, climate-friendly alternatives to traditional, polluting energy production, investing in new eco-friendly technologies, diffusing greener technologies and new low-carbon technologies, and supporting R&D in green technologies.

### ***OECD Database on Manufactured Nanomaterials to Inform and Analyse EHS Research Activities***

The Database was publicly launched on 1<sup>st</sup> April 2009. It provides details of completed, current and planned research projects on the safety of manufactured nanomaterials. The research can be searched by the names of nanomaterials, OECD test guidelines and/or by specific endpoints. The link to access the database is provided through the OECD website<sup>2</sup>. As of 1<sup>st</sup> November 2009, there were 732 projects in the database either from OECD member delegations or from non-member economies or organisations.

In addition, the WPMN has conducted a *preliminary evaluation of the database*. This evaluation included: i) examining the user friendliness of the database; ii) identifying gaps in database entries; and iii) conducting a preliminary examination of information in the database that will facilitate analysis of global research activities.

The WPMN project *Development of an OECD Database on Human Health and Environmental Safety Research* and the project *Research Strategies on Manufactured Nanomaterials* were merged into a single project at the 5<sup>th</sup> WPMN. This is because the database contains information on available research projects that will facilitate a detailed analysis of current research efforts in order to determine urgent and medium/long term research needs regarding EHS aspects of manufactured nanomaterials and the joint operational plan was endorsed at the 6<sup>th</sup> WPMN.

### ***Safety Testing of a Representative Set of Manufactured Nanomaterials: The “Sponsorship Programme for Testing Manufactured Nanomaterials”***

This project was launched in November 2007 when delegations agreed to fund and manage the testing of a number of nanomaterials for specific endpoints<sup>3</sup> relevant to human health and environmental safety. Since that time, delegations have been “signing up” to this work. By October 2009, 14 member countries, as well as some non-member economies and other stakeholders<sup>4</sup> have committed to this programme in various capacities<sup>5</sup> in order to pool expertise and to fund the testing.

As part of the sponsorship program, a *Guidance Manual for the Testing of Manufactured Nanomaterials* has been published. This document is meant to be updated as new information becomes available through the sponsorship programme. A document addressing *Alternative methods* has just been finalised and will be included as an annex to the Guidance Manual.

### ***Manufactured Nanomaterials and Test Guidelines***

The unique properties of manufactured nanomaterials have raised the question as to whether existing OECD test guidelines are adequate to address their characterisation and the assessment of their toxicological properties. A Preliminary Review of 115 OECD test guidelines has shown that most tests are suitable but that in some cases, modification will be needed. In addition, it noted the importance of developing *Guidance on Sample Preparation and Dosimetry* because nanomaterials have distinct properties which may be affected by the test medium in which they are used. Accordingly, the WPMN developed *Preliminary Guidance Notes on Sample Preparation and Dosimetry*. These preliminary

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<sup>2</sup> See: [www.oecd.org/env/nanosafety](http://www.oecd.org/env/nanosafety).

<sup>3</sup> See Guidance Manual for the Testing of Manufactured Nanomaterials: OECD’s Sponsorship Programme [ENV/JM/MONO(2009)20]; and List of Manufactured nanomaterials and List of Endpoints for Phase One of the OECD Testing programme [ENV/JM/MONO(2008)13/REV].

<sup>4</sup> The European Commission, the Nordic Council of Ministers, China and BIAC.

<sup>5</sup> Detailed information about the sponsorship program can be available at: [www.oecd.org/env/nanosafety](http://www.oecd.org/env/nanosafety).

guidance notes will be made publicly available, although it is expected that the document will be further developed an update as new information become available.

### ***Co-operation on Voluntary Schemes and Regulatory Programmes***

This project has examined various national voluntary reporting schemes and regulatory programmes to assess the safety of manufactured nanomaterials. One of the outputs of this project is the *Analysis of Information Gathering Initiatives on Manufactured Nanomaterials*, which includes a *Table of Comparison of information gathering schemes*. In addition, the *Report of the Questionnaire on Regulatory Regimes for Manufactured Nanomaterials* has been finalised. Both documents will shortly be publicly available.

### ***Co-operation on Risk Assessment***

This project is to evaluate risk assessment approaches for manufactured nanomaterials through information exchange and to identify opportunities to strengthen and enhance risk assessment capacity.

The OECD Workshop on Risk Assessment of Manufactured Nanomaterials in Regulatory Context took place on 16–18 September 2009 at Washington D.C., United States. This event was co-hosted by the Business and Industry Advisory Committee to OECD (BIAC) and the Society for Risk Analysis (SRA).

The outcomes of this workshop will allow the completion of the document *Critical Issues in the Risk Assessment of Manufactured Nanomaterials*.

### ***The Role of Alternative Methods in Nanotoxicology***

This project aims at addressing the use of alternative methods and testing strategies for manufactured nanomaterials. Accordingly, the work of this project is implemented in parallel with the *Sponsorship Programme for Testing Manufactured Nanomaterials*.

As a parallel effort, a text on alternative methods was prepared for its inclusion in the *Guidance Manual for the Testing of Manufactured Nanomaterials: OECD's Sponsorship Programme*<sup>6</sup>.

### ***Exposure Measurement and Exposure Mitigation***

Through this project the WPMN is exchanging information on guidance for exposure measurement and exposure mitigation for manufactured nanomaterials. The project covers exposure in occupational settings, consumer exposure, as well as environmental exposure. In addition, a number of case studies on the exposure assessment of manufactured nanomaterials sponsored will be developed.

Finally, through this project leadership, the WPMN will participate as an associated partner with the Aerosol Society Symposium, which will be held in 2010.

### ***Co-operation on the Environmentally Sustainable Use of Nanotechnology***

This is a new project that was recently established by the WPMN. The aim is to investigate potential benefits of applications based on the use of manufactured nanomaterials. As such, it will follow-up on environmental benefits, sustainability and life-cycle related issues. Through this project, the WPMN seek to complement ongoing WPMN work regarding the potential positive and negative impacts on

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<sup>6</sup> Guidance Manual for the Testing of Manufactured Nanomaterials: OECD's Sponsorship Programme

environment and health of certain nano-enabled applications at their different stages of development. The operational plan of this project is under development and it is expected to be finalised by the end of 2009.

### ***OECD Conference on Potential Environmental Benefits of Nanotechnology***

*The OECD Conference on the Potential Environmental Benefits of Nanotechnology: Fostering Innovation-Led Growth* was held on 15-17 July 2009 in OECD's Conference Centre. The event, jointly organised by the WPMN and OECD's Working Party on Nanotechnology (WPN), provided an opportunity for government, academia and industry to consider the state-of-art of nanotechnologies, their potential to bring environmental benefits and any potential human health and environmental safety concerns, while addressing their policy considerations (see: <http://www.oecd.org/nanobenefits/>).

### **Co-ordination and Outreach**

Since its establishment, the WPMN has emphasised the importance of co-ordination with related bodies and organisations. OECD is a Participating Organisation (PO) of the Inter-Organisation Programme for the Sound Management of Chemicals (IOMC), which also includes FAO, ILO, UNEP, UNIDO, UNITAR and WHO (UNDP and the World Bank are observers). OECD has kept these other organisations up to date with the work of the WPMN through the IOMC. In addition, communication has been maintained with the International Organisation for Standardization (ISO), in particular with its Technical Committee 229 on nanotechnologies.

The 2<sup>nd</sup> International Conference on Chemicals Management (ICCM2) was held on 11-15 May 2009 in Geneva, Switzerland. At this Conference nanotechnology and manufactured nanomaterials were identified as one of the important emerging policy. ICCM2 agreed on a resolution regarding nanotechnologies and manufactured nanomaterials, which among other things, invited relevant international organisations, including OECD, to engage in dialogue with stakeholders with a view to gaining further understanding of nanotechnologies and manufactured nanomaterials.

Following the recommendation from the ICCM2, OECD and UNITAR agreed to hold a series of *IOMC/OECD/UNITAR Awareness-Raising Workshops for Developing and Transition Countries on Nanotechnology /Manufactured Nanomaterials* in association with SAICM regional meetings over the course of 2009/2010.

### **Forthcoming events:**

- IOMC/OECD/UNITAR Awareness-Raising Workshop for Developing and Transition Countries on Nanotechnology/Manufactured Nanomaterials
  - 27 November 2009, in Beijing, China
  - 11 December 2009, in Lodz, Poland
  - 26-27 January 2010, in Abidjan, Cote d'Ivoire
  - 12 March 2010, in Kingston, Jamaica
  - 2010 (TBD), in Alexandria, Egypt
- 6<sup>th</sup> Working Party on Nanotechnology, 1-2 December 2009, OECD Conference Centre, Paris
- Nano Thailand, 18-20 November 2010, Convention Centre, Science Park, Thailand

### **Recent Publications on Manufactured Nanomaterials:**

- 📖 Manufactured Nanomaterials: Roadmap for Activities during 2009 and 2010 (2009)
- 📖 Current Developments in Delegations and other International Organizations on the Safety of Manufactured Nanomaterials - Tour de Table (2009)
- 📖 Manufactured Nanomaterials: Work Programme 2009-2012 (2009)

- 📖 Preliminary Review of OECD Test Guidelines for their Applicability to Manufactured Nanomaterials (2009)
- 📖 Guidance Manual for the Testing of Manufactured Nanomaterials: OECD Sponsorship Programme (2009)
- 📖 Report of an OECD Workshop on Exposure Assessment and Exposure Mitigation: Manufactured Nanomaterials (2009)
- 📖 Comparison of Guidance on Selection of Skin Protective Equipment and Respirators for Use in the Workplace: Manufactured Nanomaterials (2009)
- 📖 Emission Assessment for the Identification of Sources and Release of Airborne Manufactured Nanomaterials in the Workplace: Compilation of Existing Guidance (2009)
- 📖 Identification, Compilation and Analysis of Guidance Information for Exposure Measurement and Exposure Mitigation: Manufactured Nanomaterials (2009)
- 📖 EHS Research Strategies On Manufactured Nanomaterials: Compilation Of Outputs (2009)
- 📖 Preliminary Analysis of Exposure Measurement and Exposure Mitigation in Occupational Settings: Manufactured Nanomaterials (2009)
- 📖 Analysis Information Gathering Initiatives on Manufactured Nanomaterials (2009)

**Upcoming Publications:**

- 📖 Preliminary Guidance Notes on Sample Preparation and Dosimetry
- 📖 Alternative Methods: Annex to the Guidance Manual for the Testing of Manufactured Nanomaterials: OECD's Sponsorship Programme
- 📖 Critical Issues in the Risk Assessment of Manufactured Nanomaterials
- 📖 Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 6th Meeting of the Working Party on Manufactured Nanomaterials

## **SECTION II: RECENT AND PLANNED NATIONAL ACTIVITIES IN CHEMICALS REGULATORY AREA ON HEALTH AND ENVIRONMENTAL SAFETY ASPECTS OF MANUFACTURED NANOMATERIALS**

### **Background**

The purpose of this document (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 nanomaterials. This will facilitate the implementation of the projects of the Working Party on Manufactured Nanomaterials (WPMN) by allowing delegations to share their experiences and preoccupations with respect to safety, and will identify opportunities for future co-operation and co-ordination.

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

### **Headings for the Tour de Table**

In considering the Tour de Table, each delegation was invited to prepare a short written paper. It was recommended that the information in these papers be organised, where possible, under the headings identified below, while recognising that not all delegations would be able to supply information under each heading. Those delegations who made submissions for 5<sup>th</sup> meeting of the WPMN (March 2009) might wish to simply review their previous submission and update it as needed. Information submitted could be supported by any supplementary information, or supporting documentation, especially if it was available in electronic form including links to website.

1) Firstly, please provide a list of the latest developments in your country and organisation since the 5th meeting of the WPMN (March 2009) as highlights to appear at the top of your document (see example below):

Example:

***Highlight of developments since the 5th meeting of the WPMN***

- Request for information on nanomaterials issued on..... (Day/Months/2009)

-

2) Identify work completed, underway or planned in your country or organisation, which relates to activities on health and environmental safety aspects of manufactured nanomaterials (focusing on the chemicals sector).

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

2. Developments related to voluntary or stewardship schemes;

3. Information on any risk assessment decisions;

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

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

6. Information on any public/ stakeholder consultation.

*Additional Information*

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

## RESPONSES FROM DELEGATIONS

### AUSTRALIA

#### *Highlight of developments since the 5<sup>th</sup> meeting of the WPMN*

- The Australian Government announced a four year, National Enabling Technologies Strategy (NETS) in May 2009.
- Extensive public awareness and community engagement activities have been undertaken in 2009.
- The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) has developed and will be consulting on a strategy for oversight of industrial nanomaterials. Public consultation will occur later this year.
- Safe Work Australia (SWA) is currently in the process of revising the Code of Practice for Safety Data Sheets (SDS), proposing the addition of a number of non-mandatory parameters, specifically relevant to engineered nanomaterials in physicochemical sections.
- A Nanotechnology OHS Program, managed by SWA, is being implemented.
- Food Standards Australia New Zealand (FSANZ) requirement for new Applications to amend the *Australian New Zealand Food Standards Code* to contain information on particle size, size distribution and morphology.
- Participation in the joint FAO/WHO Expert Consultation on Nanotechnology relating to food safety implications of nanotechnology in food.
- Completion of a review by the Food Standards Australia New Zealand (FSANZ) of the scientific literature relevant to oral bioavailability, as a determinant of potential toxicological novelty, of nanomaterials.

#### *Work completed, underway or planned*

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

The Australian National Nanotechnology Strategy (NNS) ceased on 30 June 2009. In May 2009, the Government announced a four year, National Enabling Technologies Strategy (NETS) to provide a framework for the responsible development of enabling technologies such as biotechnology, nanotechnology and other new technologies as they emerge in Australia. The Strategy will build on the work of the earlier National Biotechnology Strategy (NBS) and NNS, and it specifically supports a whole

of government approach to policy development, regulation, public engagement and coordinated involvement in international efforts to address health and safety issues. NETS also provides funding for new and enhanced biotechnology and nanotechnology measurement laboratories and research so that measurement standards can be established for regulators and industry (through Australia's National Measurement Institute).

A Health, Safety and Environment Working Group (HSE WG) established under the National Nanotechnology Strategy (NNS) continues to maintain consultation across the Australian Government to build a uniform, whole of government approach to regulation of nanomaterials. Regular meetings and workshops support communication between departments.

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) has developed a strategy for oversight of industrial nanomaterials to protect the health of the Australian public, workers and the environment. The proposed package was developed in consultation with NICNAS's external Nanotechnology Advisory Group (NAG) in response to the *Review of the Possible Impacts of Nanotechnology on Australia's Regulatory Framework* (also called the Monash Report) published in 2008. In developing the strategy, NICNAS reviewed its existing regulatory framework and administrative processes in light of the unique challenges posed by these novel materials. It provides for the use of best available scientific evidence in NICNAS's risk assessment and the ability to review decisions as new information becomes available. Overall the strategy will ensure safe and sustainable use of these substances through appropriate regulatory oversight, industry cooperation and community confidence and will be supported by comprehensive communication/outreach activities.

NICNAS also issued a 2<sup>nd</sup> voluntary Call for Information in 2008 (closed 23 January 2009) to gauge the extent of nanomaterial introduction into Australia, aiming to ascertain what categories of physicochemical and toxicological data are held on each nanomaterial. The outcomes of the 2008 Call have been validated and results will be published shortly.

The Australian Pesticides and Veterinary Medicines Authority (APVMA) also published a Call for Information (closed 12 December 2008) and results indicate that specifically engineered nanomaterials were not used in agricultural or veterinary chemicals or chemical products in Australia during that year, and that nanomaterials were not being considered for inclusion in agricultural or veterinary chemical formulations in the immediate future. APVMA intends to create a special permit for substances containing nanomaterials for research use and to revise relevant registration forms to identify the presence of nanoscale substances in agricultural and veterinary chemicals and products. This will be complemented by the development of an electronic search facility for nanoscale product applications and approvals during 2009.

Safe Work Australia is currently in the process of revising the Code of Practice for Safety Data Sheets (SDS). In the section which lists physicochemical parameters for which information on chemicals should be provided, Safe Work Australia is proposing the addition of a number of non-mandatory parameters, specifically relevant to engineered nanomaterials (but also relevant for some other chemicals). This document has been available for public comment. A paper on this matter has also been prepared for the Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (UNSCEGHS) meeting in December 2009. Safe Work Australia is also considering the addition of a small number of advisory notes relating to nanotechnologies to other relevant OHS regulatory documents, for example: *Note: Manufactured nanomaterials may require a different classification and hazard communication elements (labelling and SDS) compared to the macro-form of the same material.*

Food Standards Australia New Zealand (FSANZ) has undertaken a review of its regulatory preparedness in relation to nanotechnology in food. As an outcome of this assessment FSANZ has

amended its *Application Handbook* an Australian legislative instrument, which sets out the essential information required to make an application to vary the *Australia New Zealand Food Standards Code* (the Code). In relation to nanotechnology the Application Handbook has been amended to include the requirement of information on particle size, size distribution and morphology where substances are particulate in nature and will remain so in the final food. This amendment is a requirement for food additives, processing aids, novel foods, contaminants and nutritive substances. Applications which do not contain this information will not be accepted by FSANZ for assessment.

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

No developments since the 5th meeting of the WPMN.

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

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

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

- NT-001 contributed to development of the ISO Technical Report on "Health and safety practices in occupational settings relevant to nanotechnologies", and was represented on the ISO Steering Group for this project. This Technical Report provides advice relating to health and safety issues when working specifically with nanomaterials.
- NT-001 is also represented on the ISO TC229 HSE Working Group, which coordinates the development of international HSE related nanotechnology standards, and on 4 project groups:
  - Development of safe handling and disposal guide for manufactured nanomaterials
  - Occupational risk management approach for manufactured nanomaterials based on control banding
  - Nanomaterials risk evaluation process
  - Preparation of SDS for nanomaterials

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

FSANZ has completed a review of the scientific literature relevant to oral bioavailability, as a determinant of potential toxicological novelty, of nanomaterials. This review consolidates current available scientific and technical information on the assessment of nanotechnology in this area as it relates to food safety. FSANZ has also contributed staff, resources and chaired the joint FAO/WHO Expert Consultation on Nanotechnology. This international workshop considered the food safety implications of the application of nanotechnology in food and was driven by FSANZ, FAO and WHO.

NICNAS has developed a comprehensive technical strategy to complement regulatory developments (described under Regulatory Developments section). Technical activities are aligned as appropriate with national and international developments in this area, and include:

- Developing risk assessment and modelling capabilities;
- building scientific capability in relation to six particular nanomaterials of relevance to Australian industry. These are titanium dioxide, zinc oxide, cerium oxide, fullerenes, carbon nanotubes and nano silver;
- reviewing data requirements for NICNAS assessments and benchmarking risk assessment methodology for nanomaterials that meet international best practice;
- leveraging linkages between national and international agencies that are working in the same area to maximise efficiency of research;
- continue to lead the OECD WPMN project on a database of environment, health and safety (EHS) research into manufactured nanomaterials;
- continuing participation in ISO TC229, through the Standards Australia Nanotechnology Committee (NT-001) to facilitate reliable characterisation and testing of nanomaterials;
- developing information products for use by industry and community on nanomaterials.

NICNAS is also facilitating the Australian consortium to participating in the OECD WPMN Sponsorship Program for the safety testing of cerium oxide, zinc oxide and silver nano-particles. The Commonwealth Scientific and Industrial Research Organisation (CSIRO) leads this consortium with the National Measurement Institute and the Royal Melbourne Institute for Technology. CSIRO also is in the process of establishing a new research program into the health, safety and environmental effects of nanotechnology (Theme 5 - Nanosafety) as part of its Niche Future Manufacturing Flagship.

NICNAS continues to proactively engage with industry by publishing advice that introducers of industrial nanomaterials should contact NICNAS to ensure that any nanomaterial they wish to introduce is either on the Australian Inventory of Chemical Substance (AICS) inventory or if a new chemical that they wish to introduce under exemption categories, that the new chemical poses ‘no unreasonable risk to health and safety and the environment’. Instances that have been received in relation to possible non-compliance have been investigated. This work is being supported by the previously detailed technical strategy, to build best practice risk assessment methodologies and practices for industrial nanomaterials in Australia.

Australia’s national medical research funding agency, The National Health and Medical Research Council (NHMRC), has included “Nanotechnology and Health” research relating to health safety, new diagnostics, and novel nanotechnology treatments in its 2009 Strategic Plan Initiatives. Any research supported by the NHMRC to increase the knowledge on health hazards and risk assessment, as well as exposure and monitoring tools, will be complementary to, and may inform, regulatory regimes.

The Department of the Environment, Water, Heritage and the Arts (DEHWA) has completed a technical review on the environmental fate of manufactured nanomaterials to inform its risk assessment methodologies and provide scientific advice to regulatory agencies. To address some of the research needs identified in the review, a laboratory research study on the analysis and partitioning of nanoparticles in soil and waste streams was commissioned by DEHWA and recently completed.

A Nanotechnology OHS Program, managed by Safe Work Australia, is being implemented. The program is Australia-focused, and also contributes to global efforts on nanotechnology OHS. The program has been designed to address a number of key areas:

- OHS Regulatory Framework - This includes identifying the specific information and knowledge requirements to ensure the framework operates effectively
- Classification - Identifying the hazardous properties associated with different engineered nanomaterials
- Measurement Capability - Development of nanomaterials exposure measurement capability
- Workplace Controls - Evaluating the effectiveness of workplace controls for preventing exposure to engineered nanoparticles
- Business Support - OHS support for Australian nanotechnology businesses and research organizations

Eleven projects have been commissioned by Safe Work Australia to progress work in these key areas. Research reports will shortly be published.

The work program is supported by two reference groups:

- Nanotechnology OHS Reference Group. The role of the group is to provide support for a coordinated national approach to the management of nanotechnology OHS. Members are employee and employer representatives, OHS regulators, and representatives of other Australian Government agencies.
- Nanotechnology OHS Measurement Reference Group. The role of the group is to help ensure the safe development and use of nanotechnology in Australian workplaces, by facilitating the development of suitable methods for assessing emissions of nanoparticles, and exposure levels in workplaces. Members are nanoparticle measurement experts, occupational hygienists, nanotechnology risk managers and OHS regulators.

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

As part of the development of the National Enabling Technologies Strategy, the Department for Innovation, Industry, Science and Research has undertaken consultations with a range of stakeholders including industry, Government, NGOs, researchers and universities. The outcomes have contributed to the development of advice to the Federal Minister for Innovation, Industry, Science and Research on the detail of the Strategy. An announcement on the detail of the Strategy is expected later in the year. The department also hosted a Second Roundtable on Nanotechnology in September 2009 with representatives of the research, industry, union and civil society communities. It is planned that another event will be held in 2010. More non-HSE specific consultation by the Department for Innovation, Industry, Science and Research is detailed in Attachment 1.

NICNAS continues to engage with stakeholders on industrial nanomaterials through periodically updated website, newsletter and fact sheets. It has also been in active consultation with Nanotechnology Advisory Group in developing its proposed regulatory strategy and is planning broader inclusive and transparent consultation to ensure a positive and efficient outcome for the community, industry and research sectors. This is expected to take place in late 2009-early 2010 and will be conducted according to community engagement principles established by NICNAS's [Community Engagement Forum](#).

FSANZ continues to receive and respond to enquiries relevant to nanotechnology in food. FSANZ has produced a fact sheet ([Small particles, Nanotechnology and Food](#)) which provides general information on

nanotechnology, the application of nanotechnology in food and current regulations around the use of nanotechnology in food.

APVMA has published three papers relating to nanotechnology on its website, including the [APVMA strategies](#) for improving the regulation of agvet chemicals and chemical products containing nanomaterials.

## ATTACHMENT 1

### *Information on any public/ stakeholder consultation in Australia – non-HSE specific*

The Department of Innovation, Industry, Science and Research undertook a range of public awareness and community engagement activities in 2009. A DVD of the 2007-08 series of public forums on nanotechnology, held in all major Australian capital cities, was distributed to key stakeholders in early 2009. Podcasts of most speaker presentations from these forums were made available on the website [www.nanotechnology.gov.au](http://www.nanotechnology.gov.au). A report on the 1 December 2008 workshop held in Canberra to discuss differing community views on social inclusion and engagement matters for nanotechnology was also made available on the website.

Presentations on science communication and nanotechnology issues were provided to various university workshops, industry days and community events throughout 2009. A range of complementary engagement activities were also held, including booths at public shows, discussions with scientists at community club meetings, and online forums. For example, in August, an exhibition at the Brisbane Royal Show to engage members of the community in matters concerning nanotechnology. Similar engagement activities were conducted in other Australian states and territories and the Gene and NanoTechnology Information Service (GNTIS). Publications on scientists working in nanotechnology and specific nanoscience matters were distributed to the general public and placed online. Public engagement meetings were held with nanotechnology scientists to assess how the community might respond differently to uses of technology when it is framed in terms of applications and when members of the public have an opportunity to engage directly with scientists.

In May 2009 the Australian Government released a literature review on the [Social and Economic Impacts of Nanotechnologies](#)<sup>7</sup>. The report provides an overview of trends in the Social and Economic Impacts of Nanotechnologies that are covered in national and international literature (particularly focussed on socio-economic literature, rather than scientific literature). It identifies gaps in the literature and will inform any further work on social and economic impacts of nanotechnologies conducted by the Department of Innovation, Industry, Science and Research.

The July 2008–June 2009 report on in-depth quantitative and qualitative media analysis in Australia of nanotechnology matters was published in August 2009. This survey was commissioned to assess the Australian media's coverage and analysis of issues concerning nanoscience and nanotechnology in Australian newspapers, radio and television. Among other key findings, the report indicates that suburban newspaper coverage was the most favourable source of nanotechnology articles with an average favourability of 57.8 per cent (extremely favourable). The two lead topics in unfavourable coverage were regulation and labelling and safety. The key risks discussed were the potential health affects of nanotechnology exposure through food, recycled sewage water, nanotechnology and cosmetics, and health in the workplace.

A one-day workshop with government, industry and researchers stakeholders to discuss various aspects on nanotechnology issues was held in Canberra on 9 July 2009. The participants were asked to

<sup>7</sup> Available at [http://www.innovation.gov.au/Section/Innovation/Documents/Literature\\_Review.pdf](http://www.innovation.gov.au/Section/Innovation/Documents/Literature_Review.pdf)

outline their 2009 program on enabling technology issues. The workshop identified engagement gaps which it considers need addressing and identified follow-on events to involve key stakeholders in community development activities. In addition, a public attitude survey was conducted to determine what issues are most pressing in the general public's minds to guide ongoing engagement activities. As part of this market research activity, stakeholder consultations on nanotechnology matters were conducted in early October. The results were fed into the qualitative surveys conducted on attitudes towards nanotechnology in the Australian community.

A national online nanotechnology school resource for secondary schools called AccessNano was further developed by the science communications group Bridge8 in consultation with the Australian Science Teachers Association in 2009. AccessNano promoted nanotechnology issues to secondary school teachers nationwide through online and printed science and education resources. The feedback received was used to improve AccessNano's website to cover more topics relevant to its stakeholders.

## AUSTRIA

### *Highlight of developments since the 5th meeting of the WPMN*

➤ The draft of the **National Austrian Action Plan on Nanotechnology** including measures to minimize potential risks as well as to enhance the utilization of potential benefits has been completed. Lead-managed by the Federal Ministry of Agriculture, Forestry, Environment and Water Management (BMLFUW) relevant stakeholders (ministries, agencies, NGOs, occupational health organisations, the Austrian Chamber of Commerce (WKO) and research institutions were included to address potential risks and benefits and define measures to minimize potential risks as well as to enhance the utilization of potential benefits.

The development of the National Action Plan has been performed by four Working Groups:

- WG for general and occupational health (lead by the Federal Ministry of Health, Family and Youth and the Federal Ministry of Labour Occupational Health, Social Affairs and Consumer Protection)
- WG for environmental issues (lead by Federal Ministry of Agriculture, Forestry, Environment and Water Management and the Austrian Umweltbundesamt)
- WG for economic issues (lead by the Austrian Chamber of Commerce (WKO))
- WG for research and science (lead by Federal Ministry for Transport, Innovation and Technology and the Federal Ministry for Science and Research)

In this national Austrian Action Plan on nanotechnology specific recommended actions and measures are compiled, which should be implemented by Austrian stakeholders on national, EU – and international level. One of these recommendations is the national pooling of resources regarding nanosafety-research.

After a public consultation phase, in which the Austrian Action Plan on Nanotechnology was published on several websites, the National Action Plan is going to be revised by including comments of this consultation phase. As a next step the Austrian Action Plan on Nanotechnology will be presented to the Austrian council of ministers.

➤ A project investigating nano-workplaces to get preliminary overview on different uses and risk management applied, is currently conducted by Federal Ministry of Labour Occupational Health, Social

Affairs and Consumer Protection

➤ A brochure for “**Assessment of Toxicological Effects by in-vitro and in-vivo Assays and open flow microperfusion**” was released by the national platform EURO-NanoTOX, which is co-ordinated by the BioNanoNet Forschungsgesellschaft mbH. See [http://www.euro-nanotox.at/images/stories/folder\\_euronanotox\\_webversion.pdf](http://www.euro-nanotox.at/images/stories/folder_euronanotox_webversion.pdf)

➤ A **consumer brochure** on nanotechnology was compiled by the Austrian Environmental NGO “GLOBAL 2000” and funded by Federal Ministry of Agriculture, Forestry, Environment and Water Management (BMLFUW): <http://umwelt.lebensministerium.at/article/articleview/77864/1/1467>

➤ The **3rd international Authorities Dialogue** for German speaking countries was held in Vienna the 9.-10. November 2009. Participants from Austria, Germany, Liechtenstein and Switzerland, discussed communication regarding nanotechnologies. The dialogue was organized by the Austrian Federal Ministry of Agriculture, Forestry, Environment and Water Management (BMLFUW) and “the innovation society” from Switzerland.

➤ The **3rd NanoTrust Autumn Conference** with the topic "Possible health effects of manufactured nanomaterials" was held on September 24th, 2009 in Vienna: see <http://nanotrust.ac.at/nano09/>

➤ An **OECD-WPN-Roundtable** regarding "Communicating knowledge - communicating uncertainty regulatory requirements for science" took place in September 25th, 2009 in Vienna.

➤ The **4th International Conference on the Environmental Effects of Nanoparticles and Nanomaterials** was held at the University of Vienna, from Sun 6th- Wed 9<sup>th</sup> September 2009. The conference was hosted by the Department of Environmental Geosciences (contact person: Frank van der Kammer; Department for Environmental Geosciences, Vienna University). See also <http://nano2009.univie.ac.at/>

➤ A **Conference on Nano-Safety** was organised with WPMN support from 22-24. April 2009 in Ljubljana, Slovenia, as part of the Twinning project "Chemical Safety 3", which is led by the Austrian Umweltbundesamt and the Chemicals Office of the Ministry of Health of the Republic of Slovenia.

### *Work completed, underway or planned*

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

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

A **platform (“Österreichische Nanotechnologie-Plattform”)** of relevant ministries, agencies, NGOs, occupational health organisations, the Austrian Chamber of Commerce (WKO) and research institutions lead-managed by the Federal Ministry of Agriculture, Forestry, Environment and Water Management (BMLFUW) was established in autumn 2007. Its main purpose is the exchange of information as well as the discussion and planning of possible activities with a focus on risk assessment and risk management of nanomaterials as well as information for the public.

## 2. Developments related to voluntary or stewardship schemes

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

## 3. Information on any risk assessment decisions

No information provided

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

No information provided

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

The project **NanoTrust**, funded by the Austrian Federal Ministry for Transport, Innovation and Technology (BMVIT), is a research project to continually survey, analyse and summarise the state of knowledge regarding potential health and environmental risks of nanotechnology. Research gaps will be identified and differing assessments will be made transparent. Dossiers on specific nano-related topics are released.

**EURO-NanoTOX** is an open virtual centre and national platform which is co-ordinated by the BioNanoNet Forschungsgesellschaft mbH. It will elaborate strategies to conduct standardised toxicological in-vitro as well as in-vivo methods on nano-structured material. The main focus is human Nanotoxicology and human risk assessment. Comparative studies will be organised. See: <http://www.euro-nanotox.at/>

At the Centre for Medical Research of Medical University of Graz, **nanotoxicology studies** regarding **SiO<sub>2</sub>** and **polystyrene** are performed (contact: Eleonore Fröhlich).

A scientific study regarding „**Sustainability assessment of nano-products**“ is conducted in cooperation of the Austrian Umweltbundesamt and the University of Applied Sciences, Technikum Wien (contact: Jana Bolldorf)

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

A multi-parameter cell chip for **high-sensitive nanotoxicology assays** is currently developed by Austrian Research Centres GmbH ARC, Nano-Systems-Technologies “

Toxicological Investigation of Nanoparticles - Effects On Human Cells” by Austrian Research Centres GmbH – ARC Life Sciences: The aim was the establishment of an in-vitro test system to reveal the potential risk to human health of **nanoparticles at the workplace**.

Together with the Department of Freshwater Ecology, the Department for Environmental Geosciences University Vienna conducted a research project dealing with the behaviour, fate and effects of different TiO<sub>2</sub> nanoparticles in the aquatic environment.

## EU-projects with Austrian participation within FP6:

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

**NANOCAP:** Nanotechnology capacity building NGOs,

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

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

**POLYSOA:** Polymers in Secondary Organic Aerosols (NEST Insight activity): Austrian partner: Technical University of Vienna, Hans Puxbaum; already finished. The Austrian Research Centre GmbH-ARC, the Austrian Worker's Compensation Board (AUVA) and the Österreichische Staub- und Silikosebekämpfungsstelle, Leoben, worked on a project

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

## 6. Information on any public/ stakeholder consultation

A nanotechnology information platform is currently built up to discuss and focus on how to deal with information & communication needs of the public.

The Austrian Umweltbundesamt in co-operation with the quality radio station Radio Österreich 1 launched the "Initiative Risiko:dialog". The aim is to open dialogues on risk topics – with potential effects on human health, environment and society – with stakeholders and the public in an early stage. One of the started dialogue processes concerns nanotechnology and potential risks. Several open events talks and expert discussions were held to support an open dialogue about potential risks, regulation topics and risk communication with civil society, economy, science, media and stakeholders from politics and administration. These activities are supplemented by the Homepage:

<http://www.risikodialog.at/nanotechnologie/nanotechnologiedialog/>.

Partners of the dialogue process on nanotechnology are the Federal Ministry of Agriculture, Forestry, Environment and Water Management., the Federal Ministry for Health, Family and Youth, the Federal Ministry for Transport, Innovation and Technology, the Institute of Technology Assessment, the Austrian Agency for Health and Food Safety (AGES), the Austrian Research Centres GmbH, and Joanneum Research/NANONET Styria/BioNanoNet GmbH.

Currently NanoTrust is working on an encompassing, annotated bibliographic database (NanoLit) on potential environmental and health risks as well as on risk governance, which will be made publicly available via the internet. Partners in this project are BioNanoNet Forschungsgesellschaft mbH and the Austrian Umweltbundesamt.

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

## BELGIUM

### *Highlight of developments since the 5th meeting of the WPMN*

The highlight below corresponds to the period December 2007 to September 2009

- A geno/eco/tox study of polymer: DNA polyplexes has been completed. Results show more toxicity and ecotoxicity for nanomaterials in some tests, but at the same time in other tests, the bulk material (polymer) is more toxic. Scientific publication to be published in the near future. Contact: [jamas@var.fgov.be](mailto:jamas@var.fgov.be)
- A new project started for characterization of nanoparticles (NP) used as vaccines or present in food using advanced electron microscopic techniques. EM-unit and the operational unit trace elements of CODA-CERVA. Contact: [jamas@var.fgov.be](mailto:jamas@var.fgov.be)
- Activities in standards development for AFM microscopy, gold nanoparticles measurement, standard grid 2D measurement with 100nm à 10µm pitch. Contact: [Jasmine.Petry@economie.fgov.be](mailto:Jasmine.Petry@economie.fgov.be)
- Be planified 200.000 € to contribute to the study of silicon dioxide, TiO<sub>2</sub> and CNT OECD testing, in a co-financed study by BE, other UE MS and the EU Commission (nanogenotox). Study will start in 2010.
- Creation of a new regulatory decision organ devoted to nanomaterials (cooperation between federal and regional authorities for coordinating the international nanomaterials policy of BE)
- Improving communication and information through: the construction of a BE Federal nanomaterials website by the end of 2009 (by BE Health & Environment Ministry), information on nanomaterials and the protection of workers added to the website of the Belgian Federal Public Service Employment, Labour and Social Dialogue and to the website of the “Belgian Safe Work Information Centre” (BeSWIC). Links are provided to institutions that issue guidelines concerning the handling of nanomaterials at the workplace.
- First contributions of BE research to OECD nanomaterials safety database

- Planed in 2010:
  1. The possibility of organizing an EU-level event about the monitoring of nanomaterials on the market (by BE Health & Environment Ministry)
  2. A scientific event about food safety and nanomaterials (by AFSCA, the BE food safety agency)
  3. Information and consultation of stakeholders about nanosafety at work (by BE Labour Ministry)

## CANADA

### *Highlight of Developments since the 5<sup>th</sup> Meeting of the WPMN*

The following activities have taken place since the 5th meeting of the OECD Working Party on Manufactured Nanomaterials in March 2009:

- Following decisions made at the multi-stakeholder workshop held in September 2007, Environment Canada and Health Canada are pursuing a mandatory information gathering survey, under the authority of Section 71 of CEPA 1999. The objective of this survey is to gather use pattern information, including volumes and sectors of use, and any relevant toxicological data already available for nanomaterials in commerce during 2008. See Section 2.
- Health Canada is leading the development of the “Nanoportal” website which will act as a gateway to the latest information on nanotechnology. The target launch date for the Nanoportal is anticipated to be Spring, 2010.
- CSA Standards has formed a Technical Committee on Nanotechnologies - Occupational Health and Safety. Initial activities include working to adopt the published international ISO Technical Report, ISO/TR 12885:2008 on *Health & Safety Practices in Occupational Settings relevant to Nanotechnologies*, as well as to produce a national standard to provide guidance for workers using nanomaterials in the workplace. The Committee’s inaugural meeting was held on May 7<sup>th</sup>, 2009.
- The 4<sup>th</sup> Tri-National Workshop on Standards for Nanotechnology will take place in Ottawa, Canada on February 3rd and 4th, 2010. Lectures will include a variety of research and development topics focusing on measurement and characterization methods supporting toxicological research, health, safety and the environment consistent with the ISO/TC 229 Task Group “Measurands for Toxicology Research and Development”. See section 5.

***Work completed, underway or planned***

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

*Federal government actions*

A. The first multi-stakeholder workshop was hosted by Environment Canada and Health Canada (September 2007) brought together representatives from government, industry, public interest groups, and academia to obtain feedback on a proposed regulatory approach for nanomaterials under the *Canadian Environmental Protection Act, 1999*. In response to this workshop, the government is pursuing a mandatory information gathering survey under the authority of the *Canadian Environmental Protection Act, 1999*.

B. The proposed regulatory framework for nanomaterials under the *Canadian Environmental Protection Act, 1999* is continuing to be implemented by addressing regulatory and research considerations. At this time, planned regulatory activities include:

Phase 1 (started fall 2006):

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

Phase 2 (2008 – 2010):

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

C. Canada, through Environment Canada, is the lead for the ISO TC/229 WG1 Task Group on Nomenclature. This Task Group includes active representation from the United States, Japan, Germany, France, Australia, and includes regulators, industry, and academia, as well as observers from the Chemical Abstracts Service and IUPAC. The Group is tasked with developing a nomenclature system which meets the needs of regulators, industry, and academia. In July the Task Group completed the report: "Considerations for Developing a Nomenclature Model for Nano-Objects". Canada has now welcomed United States in co-chairing this activity, and is continuing development of a framework for nomenclature models for nano-objects. Canada has pursued and secured a liaison between ISO/TC 229 and the International Union of Pure and Applied Chemistry to further this nomenclature work.

D. Canada, through NRC-CISTI (National Research Council – Canada Institute for Scientific and Technical Information) is developing, under ISO TC/229 JWG1, a taxonomy system for nanomaterials which involves an intelligent organization of terms used in various communities pertaining to

nanomaterials (e.g., tubes, rods, nanoscale, etc). Also, Canada through NRC-SIMS (National Research Council – Steacie Institute for Molecular Sciences) is leading a project (JWG1-PG5) to develop definitions for core terms resulting from the taxonomy system. The NRC-INMS (National Research Council – Institute for National Measurement Standards) participates in the joint Task Group of ISO/TC229 and OECD on Measurands for Toxicological R&D by contributing text, references and reviewing the document.

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

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

Respondents will be required to submit information on:

- Identification of nanomaterials imported or manufactures in excess of 1 kg during the calendar year 2008;
- Includes research and development materials
- Basic use patterns including volumes, sectors of use, types of products
- Any physical-chemical property or toxicological data available.
- Available stewardship practices

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

### *Market Penetration and Industry Involvement in Nanotechnology in Canada*

Industry Canada is building its knowledge base on Canadian commercial activities involving nanotechnology and nanotechnology market penetration. Based on information drawn from its public website-based company database and independent web search, as of August 2009 Industry Canada had identified approximately 630 domestic or US-headquartered companies with business activities in Canada which have some sort of involvement in nanotechnology, including final goods production, R&D, intellectual property, services, intermediates and primary production of nanomaterials.

Of the 630 companies identified, 437 of the 630 companies are intermediate or final goods companies. Key nanotechnology application areas are healthcare, equipment & tools, structural materials (nano-enabled products), and electronics. Of these, pharmaceuticals and the treatment of disease or illness are very important applications for both intermediate and final goods companies, while electronic components are an important application area particularly for intermediate companies. Provinces with strong involvement in nanotechnology currently are Ontario, Quebec, Alberta and British Columbia.

In collaboration with Environment Canada, in February 2009 Industry Canada collected data on the number of consumer products on the Canadian market that incorporated nanotechnology-based components or technologies. These were estimated at over 1600 products, with 68% being imported into Canada from more than 11 different countries. Products ranged from “stronger, more durable, lighter”

sports equipment, to stain & wrinkle-free pants, antimicrobial clothing and appliances, to cosmetics, sunscreens and drugs.

### **3 Information on any Risk Assessment Decisions**

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

- Industrial or commercial chemicals
  - To date, a total of 6 nanomaterials have been notified and assessed under CEPA 1999, and the Significant New Activity Provisions of CEPA 1999 have been used for 11 substances to require the submission of additional information and assessment prior to use of the substance at the nanoscale or in other nanoscale applications.
- Pharmaceuticals
  - A number of nanotechnology based products in the areas of medical devices and drugs are currently under review by Health Canada, under the current regulations and policies.
- Pesticide applications
  - Some inquiries have been made, but no notifications have been submitted.
- Food related applications
  - Six notifications have been received by the Food Packaging Material and Incidental section of Health Canada. Two letters of no objection have been issued, the other four are still under review.
- Others
  - No notifications with respect to fertilizers, veterinary biologics, or animal feed have been received to date.

### **4 Information on any Developments Related to Good Practice Documents**

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

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

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

C. Industry Canada and a number of provincial partners, along with partners in 9 other countries, are helping to fund the International Council on Nanotechnology's (ICON) GoodWiki project. Managed by Rice University's Centre for Biological and Environmental Nanotechnology, this project is being developed as an Internet-based collaboration platform designed to enhance the ability of industry experts to exchange ideas on current good practices for the handling of nanomaterials in an occupational setting. The beta site is now complete, and ICON/Rice University is demonstrating the site's usefulness at various nanotechnology conferences in order to start the process of adding members (both public and private-sector experts) to the site.

D. CSA Standards is adapting the published international ISO Technical Report, ISO/TR 12885:2008 on *Health & Safety Practices in Occupational Settings relevant to Nanotechnologies* for use in Canada, through its accredited standards development process, to produce a guideline standard for workers using nanomaterials in the workplace. Labour and government interests at the Sep. 2009 CSA Nano-Occupational Health and Safety Technical Committee meeting stressed the importance of, and agreed to pursue, within this same committee, the development of plain-language means for education on these guidelines to workers. CSA Standards has experience in providing such services through education, training and e-learning solutions for standards and has indicated that they will work with the committee towards achieving these needs.

E. Government, industry, research, user, and consumer interests are participating as designated experts from Canada on international standards development through the Canadian Advisory Committee to ISO/TC229 Nanotechnologies, facilitated by CSA Standards. This includes active participation on terminology, nomenclature, measurement, characterization, material specification and health, safety, environmental aspects of nanotechnologies standards under development. Some highly-relevant work items include *Nanomaterial Risk Evaluation Framework*, *Occupational Risk Management- Control Banding Approach*, *Guidance on Safe Handling and Disposal of Nanomaterials*, *Guidance on Labelling of Nanoparticles and Products*, and *Material Safety Data Sheet (MSDS) for Nanomaterials*.

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

### *Scientific research*

Beginning in 2007, Environment Canada helped support two projects under the Strategic Grants Program of the Natural Sciences and Engineering Research Council (NSERC). Priority nanomaterials such as TiO<sub>2</sub> were examined in terms of their fate in both the aqueous and the subsurface compartments and include establishing methodologies for suspension and phys-chem characterization of the nanomaterials prior to any exposure testing.

A third larger Canadian initiative, funded jointly by the National Research Council, NSERC, the Business Development Bank of Canada (BDC) and supported by Environment Canada, has begun this year. This multidisciplinary, 3-year collaborative project brings together: 1) industry and academic/NRC researchers involved in the engineering and production of new and existing commercial NMs, 2) representatives involved in the current regulatory testing industry that require new, cost-effective, time-sensitive, and efficient testing methods, 3) academic/NRC researchers who can develop and apply new technologies to the area of safe NM production and effective ecotoxicology testing, and 4) Canadian regulatory community.

Funding and partnering opportunities are currently being considered by the Food Directorate of Health Canada to a) develop in-house analytical chemistry infrastructure for the measurement of nanoparticles in food; b) to assess the health effects of orally ingested nanomaterials for addressing

exposure through food contamination from packaging materials, or through nanostructures in food additives; c) to evaluate the effects of nanomaterials in food on nutrient bioavailability, functionality and efficacy for addressing the regulation of nanotech products designed, for example, to deliver or alter the bioavailability of essential nutrients or other bioactive substances in standard ingredients; and d) to develop diagnostic tools, such as biosensors used in the detection of food pathogens, to increase the safety of the food supply.

Health Canada and Environment Canada are also currently engaged in both in-house and collaborative research projects involving a range of different nanomaterials (e.g., nanoparticulates of zero-valent iron, gold, silver, TiO<sub>2</sub>, also carbon black, single walled carbon nanotubes, and C<sub>60</sub> fullerenes). Testing at Health Canada includes pulmonary and cardiovascular injury; reproductive, developmental and transgenerational effects; exposure and tissue penetration, interactive effects with microorganisms, immune defences, and genotoxicity. Alternative tests such as molecular (genomic/proteomic) and cellular in vitro techniques play an important part of the repertoire for such investigations.

Health Canada is working with Environment Canada to enhance research capacity to support regulation of manufactured nanomaterials including benchmarking specific current nano-analytical capacity, assessing adequacy of various analytical tools, hazard effects and characterization methods.

Environment Canada has also increased its research program to better understand the fate and potential effects of nanomaterials in the environment. This work includes developing bioassays and biomarkers for nanomaterials, harmonizing and standardizing chemical and toxicological assays, toxicogenomics and evaluating fate in aquatic environments. New projects include understanding the interaction of nanoparticles with microbial cells, soil effects research and characterization, and bioaccumulation and toxicity in benthic invertebrates.

Either directly or indirectly these research efforts contribute towards several of OECD's subgroups (e.g., SG1, SG2, SG3 and SG4, SG5 and SG-8) as well as priority testing and topics of the Molecular Screening Project (e.g., Thyroid signaling, Cancer epigenetics, Sensitization/Immunotoxicity, Developmental and Reproductive Effects, Developmental Neurotoxicity). Combined, they support international EHS and R&D efforts, the application of new tools for those priority nanomaterials identified by OECD countries and are consistent with directions that OECD and ISO work is taking.

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

The National Research Council of Canada (NRC) has launched R&D initiatives which support collaborative projects between Institutes ([http://www.nrc-cnrc.gc.ca/institutes/index\\_e.html](http://www.nrc-cnrc.gc.ca/institutes/index_e.html)). These cross-NRC Programs in nanotechnology exploit the multi-disciplinary strengths of the NRC with focus on fundamental R&D topics which underpin EHS research. One of the supported projects focuses on: airborne nanoparticles (nano-aerosols) that contribute to poor air quality, another project focuses on development of metrology instrumentation and measurement of material properties. The NRC also launched collaboration with the Natural Sciences and Engineering Research Council of Canada (NSERC) and the Business Development Bank of Canada (BDC) offering opportunities for NRC scientists and Canadian academic researchers in nanoscience and nanotechnology to collaborate on large technology

development-driven research projects in the critical areas of: Energy; Environment; and Information and communications technologies (ICT).

NRC-INMS will host the 4th Tri-National Workshop on Standards for Nanotechnology on 3-4 February 2010 at Sussex Drive Auditorium, Ottawa to address Measurement and Characterization in Support of Toxicology R&D for Human Health and Environment, focusing on identification of measurands for toxicological research on nano-objects, and the measurement science supporting accurate measurement and characterization. These are the topics of the joint Task Group of ISO/TC229 & OECD (above). This Workshop supports the Canadian contribution to the North American Platform Program (NAPP) in Metrology in Support of Nanotechnology, strengthening partnerships between Canada, the United States and Mexico. Information is available on the Workshop website: <http://www.nrc-cnrc.gc.ca/eng/events/inms/2010/02/03/tri-national-workshop.html>.

The Canadian Institutes of Health Research (CIHR) has been strategically funding research into nanomedicine (nanotechnology applied to health) through its Regenerative Medicine and Nanomedicine Initiative (RMNI). As of December 2008, RMNI has committed a total of \$65M in grants and awards funding to these research domains. Through its most recent Request for Applications (RFA), launched in July 2009, CIHR has allocated an additional \$16.5M over 5 years (<http://www.cihr.ca/e/39585.html>). This RFA specifically includes support for multi-disciplinary teams engaged in all areas of nanomedicine, including the health impacts of nanotechnology (e.g. the interactions of nanomaterials with biological systems, rational design of nanostructures, assessment of nanotoxicity, etc) and novel drug delivery approaches using nanotechnology.

In January of 2008, CIHR co-sponsored the Canadian Workshop on Multidisciplinary Research on Nanotechnology: Gaps, Opportunities and Priorities, in collaboration with the other two federal research funding agencies (NSERC and SSHRC), Health Canada, the National Research Council, Environment Canada and Industry Canada. The summary report of this workshop (<http://www.cihr.ca/e/38469.html>) details key research gaps in nanotechnology, including basic science gaps; ethical, legal, economic and social gaps; health and environmental risks; governance, regulatory and policy gaps; public engagement and communication needs; and challenges for interdisciplinary collaborations. This report has informed additional funding opportunities offered by CIHR-RMNI (<http://www.cihr.ca/e/36884.html>).

### *Policy research*

Canada, under the leadership of Industry Canada, remains an active participant and bureau member of the OECD's Working Party on Nanotechnology (WPN). In 2007-2009, Industry Canada and Switzerland co-led WPN work on "business environments" which examined challenges for business investment in innovation and the responsible commercialization of nanotechnologies and the extent to which these might present unique policy challenges. The final project report has been completed and will be released by the OECD shortly. Statistics Canada has collaborated with the OECD Secretariat in leading WPN work on developing indicators and statistics for nanotechnology, one early result of which was the publication this year of an OECD overview of nanotechnology, drawing on available patent data and statistics. Industry Canada, Health Canada, and other departments also contributed to development of a WPN inventory of national science, technology, and innovation policies for nanotechnology, completion of a listing of national facilities for international R&D collaboration, and work on public outreach/engagement.

The Council of Canadian Academies is a non-profit organization which acts as a source of independent, expert assessment of the science underlying pressing issues and matters of public interest. The Council has completed their assessment of the current state of knowledge regarding the health and environmental risks potentially associated with nanotechnology.

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

None to report.

**CZECH REPUBLIC**

***Highlights of developments since the 5th meeting of the WPMN***

- The activities addressing health, safety, and environmental aspects of manufactured nanomaterials were mainly conferences, seminars, and short courses. No systematic activities and programmes at a governmental, NGO, academic level or in private sector (except one, see below) have been established or performed.
- A questionnaire study “Inventory of Workplaces with Nanomaterials in the Czech Republic: Public Health Aspects” continued in 2009.
- The awareness of public health authorities towards growing use of nanomaterials and the associated public health risks has been enhanced through education in seminars, local conferences, short courses and lectures.
- Large number of research projects on nanomaterials and nanotechnologies has been funded in the Czech Republic, however, none of them addresses predominantly health, safety, and environmental aspects of nanomaterials.
- Two international conferences on nanotechnologies were held in the Czech Republic: EuroNanoForum (Prague, June 2-5, 2009), and NANOCON 2009 (Rožnov pod Radhoštěm, October 20-22, 2009: [www.nanocon.cz](http://www.nanocon.cz)). The programmes of the conferences also included contributions dealing with health, safety, and environmental aspects of nanomaterials.

*Work completed, underway or planned*

**1. National Regulatory developments**

No developments

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

No developments

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

No developments

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

No developments

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

Inventory of Workplaces with Nanomaterials in the Czech Republic: Public Health Aspects (2009)

In June 2008, Chief Public Health Officer of the Czech Republic (Deputy Minister of Health) launched a questionnaire study aiming at identification of health risk of NM in the workplaces in the Czech

Republic. The study was conducted jointly by the National Institute of Public Health and Regional Public Health Offices. The primary database of the workplaces to be addressed (both production enterprises and research institutions) was a list of organizations participating in the research projects funded by or through major national agencies (source of information: Nanotechnologies in the Czech Republic 2005 and 2008). The questionnaire comprised of 7 sections: 1) Data about the enterprise/ institution; 2) Data about the manufactured/ studied/ used NM; 3) Data about the production or research activity; 4) Data about the potential exposure to NM; 5) Reported health effects; 6) Perception of the potential health risk on handling NM; 7) Occupational health services. The requested data was collected on site jointly by the public health officer and a person responsible for the workplace (Safety Officer, Head of Laboratory, etc.). The Final Report (9 pg) was approved by the Chief Public Health Officer in November 2008. Since then, data from another 47 workplaces were collected.

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

No information

## **FINLAND**

### ***Work completed, underway or planned***

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

The various ministries (environment, health, education, technology, economy) have established an *ad hoc* discussion forum on the nanotechnology in order to follow and participate to the national and international discussions.

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

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

Finland is participating and following the regulatory developments at REACH CA- nano subgroup and the RIPon Nano- expert groups. Similarly the work on novel foods and cosmetics is followed at the EU level.

#### ***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***

The Finnish Institute of Occupational Health, Finnish Funding Agency for Technology and Innovations (TEKES) and Technical Research Centre of Finland (VTT) organized 4<sup>th</sup> International Conference on Nanotechnology- Occupational and Environmental Health 26-29 August 2009 in Helsinki.

The Ministry of the Environment and the Finnish Funding Agency for Technology and Innovation have guaranteed research funding for the ongoing 3rd SKEP ERA-NET call "Impacts of converging technologies for environmental regulation".

The University of Joensuu participates in the OECD Sponsorship Programme with aquatic ecotoxicology testing of nano-silver and nano-iron as a part of the Nordic group.

University of Technology, VTT, and UPM Kymmene have established Nanocellucenter with 40 researchers concentrating on innovations but also on safety assessments.

The laboratory of Finnish Environment Institute (SYKE) has started studies on aquatic exposure concentrating especially on the nanomaterial detection and characterization. SYKE has also started planning a research project considering both the environmental benefits and risks of nanotechnology e.g. nanocellulosa.

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

### **GERMANY**

#### ***Highlight of developments since the 5<sup>th</sup> meeting of the WPMN***

- Feasibility study Nano Products' Register
- Launching of diverse research projects
- Continuation of German NanoKommission's work

#### ***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***

**A) Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit, BMU):** The Federal Ministry has launched a feasibility study on the introduction of a Nano Products Register in Germany with emphasis on legal and regulatory aspects. A preliminary report has been accomplished recently. The final report - in German with an English short version - will be available by early 2010.

**B) Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit, BMU):** German NanoKommission (2009-2011), German government's shareholder dialogue, has agreed on the work programme for the running period and has installed four expert working groups that will deal with specific subjects, i.e. implementation of the principles adopted in phase 1 (2006-2008), benefit and risk potentials of nano products taking two examples, regulation in the context of nanomaterials and further development of criteria on concerns and reliefs.

The English version of the final report of the commission's first working period (2006-2008) is meanwhile available under: [http://www.bmu.de/files/pdfs/allgemein/application/pdf/nanokomm\\_abschlussbericht\\_2008\\_en.pdf](http://www.bmu.de/files/pdfs/allgemein/application/pdf/nanokomm_abschlussbericht_2008_en.pdf)

**C) Federal Institute for Occupational Safety and Health (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, BAuA)** reports that the German Committee on Hazardous Substances (AGS) has

included nanomaterials as a topic to his working plan. The first step is a monitoring phase that will result in the identifications of necessary actions.

**2** *Developments related to voluntary of stewardship schemes*

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

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

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

**A) Federal Institute for Occupational Safety and Health (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, BAuA):** BAuA will fund a project “Toxic effects of different modifications of a nanoparticle after inhalation” which should be completed in 2011. The aim is to test specific nanoparticles in unchanged and in two surface-modified versions in order to look at the impact of surface modifications on the toxicological properties. The experimental set-up will be a 28-day inhalation study according to method b.8 of EC/440/2008 (i.e. OECD 412) in extended form. It is intended to include a 90-d post observation period be able to study the course of selected toxicity markers which describe the toxicological profile of the nanoparticles under consideration.

**B) Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR):** Joint Action Project in the field of Health Community Action “Safety evaluation of manufactured nanomaterials by characterisation of their potential genotoxic hazard” (coordinated by France): Germany as one of the co-sponsors is participating via promoting the establishment of a robust methodology for the *in vitro* assessment of the genotoxic potential of manufactured nanomaterials (WP leader Finland). To achieve this, fully characterized MNs (Denmark), namely TiO<sub>2</sub> and SiO<sub>2</sub> MNs, but also carbon nanotubes (CNT) are to be tested. Using these results, Germany will participate in round robin tests for the relevant assays.

This methodology may be used by regulatory control bodies and industry to check for possible genotoxic effects as alternative techniques to animal experimentation. Standard operating procedures (SOP) will be used and if lacking, will be established as a priority.

Major expected outcomes are: i) Increasing health information and knowledge about the genotoxic potential of MNs by generating relevant and reliable data and ii) Promoting a robust reliable methodology for testing potential genotoxicity of MNs by exchanging best practices through a round robin test. The JA shall provide quick, reliable and economical tests to assess potential genotoxicity of MNs with alert signals useful for society and industries.

**C) Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR):** A national project at the BfR is addressing the uptake and cellular localisation of metallic oxide NM *in vitro* by human enterocytes (Caco-2) cells.

**D) Federal Environmental Agency (Umweltbundesamt, UBA):** Development of test procedures for Nano-Silver and Titanium Dioxide (R&D Id 3709 65 416, 3709 65 417, 3709 65 418). Up to date the risk evaluation of nanomaterials does not take into account size and size-dependent characteristics. In consequence, in standard toxicity test procedures to evaluate the potential hazardous effects on human and environmental health the new functionalities of nano-sized substances are not regarded sufficiently. As a contribution to the sponsorship programme, Germany currently launched three research projects, dealing with the application and adaptation of OECD test guidelines on the safety testing of nanomaterials using different types of nano-TiO<sub>2</sub> and nano-silver. These projects will imply ecotoxicological short term tests, tests to evaluate the environmental behaviour and fate as well as tests to highlight the potential long term

effects of nanomaterials on biota. Environmental compartments which will be addressed include water, soil and sediment. TiO<sub>2</sub> and Silver materials of different characteristics will be considered.

All OECD tests will be performed under consideration that modification of the guideline to nanomaterial testing may be necessary. Adaptations will be documented and passed over to the SG 4 of the OECD WPMN.

**E) The Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung, BMBF)** funded research projects dealing with human health risks of manufactured nanomaterials between 2006 and 2009 (“NanoCare”, “INOS” and “Tracer”). The final report of the biggest project “NanoCare” is available under: [http://www.nanopartikel.info/fileadmin/user\\_upload/Publikationen/NanoCareFinalReport.pdf](http://www.nanopartikel.info/fileadmin/user_upload/Publikationen/NanoCareFinalReport.pdf).

These projects were mainly dealing with acute toxicity effects. Since big gaps of knowledge still remain – especially concerning long term effects and ecotoxicological risks of manufactured nanoparticles, the BMBF continued their “NanoCare”-initiative and complemented it by a new programme called “NanoNature”.

**F) German Research Foundation (Deutsche Forschungsgemeinschaft, DFG)** In 2008 the German Research Foundation (DFG) initiated the high priority programme “Biological responses to nanoscale particles” (SPP1313) focusing on characterization, transition into and the interaction with the cellular components and the impact on fundamental biological function of various nanoparticles. 12 different projects are involved in this programme (DFG SPP1313).

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

**Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR):** BfR is currently conducting a study on a media analysis of articles on nanotechnology published in internet fora and weblogs. This project called “Risk Perception of Nanotechnology“ investigates how nanotechnology is perceived by consumers, which argumentations and pictures are characterizing the debate on nanotechnology and how products are specifically discussed.

**Federal Institute for Occupational Safety and Health (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, BAuA):** Germany is going to update the 2006 Questionnaire on aspects of worker protection during the production and handling of engineered nanomaterials conducted by German BAuA and VCI. The interrogation period will start in the end of 2009 and is expected to be accomplished in spring 2010. It is planned to present the output in the end of 2010.

## **ITALY**

### ***Highlight of developments since the 5<sup>th</sup> meeting of the WPMN***

A certain (small) amount of the funding has been recently devoted to initiatives to investigate EHS issues associated with nanotechnologies.

Two governmental agencies: ISPESL (National Institute of Occupational Prevention and Safety) and INAIL (Italian Workers' Compensation Authority<sup>8</sup>) have activated two working groups for addressing the problem of risk assessment and mitigation in occupational environments where nanomaterials are used.

AIRI/Nanotec IT (Italian Centre for Nanotechnologies), which acts as a focal point of organisations dealing with nanotechnologies in Italy, with most of industry, academia and research institutions active in nanotechnologies being among its members, coordinates the FP7 project FramingNano and is a partner (dealing also with nano regulation) of the FP7 project ObservatoryNano<sup>9</sup>.

The Ministry of Health has decided to prepare a questionnaire to collect information from public and private organizations involved in nanotechnology in Italy.

Among the initiative activated in the last years there can be also cited CIGA (*Centre for Environmental Law Decisions and Corporate Ethical Certification*) at University of Padova<sup>10</sup> to study ethical implications of nanotechnologies.

### ***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 information 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.

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<sup>8</sup> Not just a compensation authority but a global protection system for all workers <http://www.inail.it/>

<sup>9</sup> <http://www.observatorynano.eu>

<sup>10</sup> [http://www.ciga.unipd.it/about\\_us\\_en.htm](http://www.ciga.unipd.it/about_us_en.htm)

#### **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 centres 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>11</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.

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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).

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

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

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

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

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

#### ***Additional Information/Comments***

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

- ECSIN (<http://www.ecsin.eu>) will be active in three main nanotech sectors, with a multilevel analysis approach:
  - Interaction human health / environment
- Public perception and social/ethical policies
- Education for a responsible use

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

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

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

## **JAPAN**

### ***Highlights of developments since the 5th meeting of the WPMN (March 2009)***

Three reports and one revised notification on safety of manufactured nanomaterials hereunder were published by the Japanese government in March 2009.

- Report: The Expert Meeting on Safety Measures for Nanomaterial Manufactures etc. (Ministry of Economy, Trade and Industry)
- Guidelines for preventing the environmental impact of manufactured nanomaterials: Expert committee on the environmental impact of manufactured nanomaterials (Ministry of the Environment)
- Report: The Committee on Safety Measure for Nanomaterials (Ministry of Health, Labour and Welfare)
- Revised notification for exposure prevention in the workplace (Ministry of Health, Labour and Welfare)

***Work completed, underway or planned***

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

No significant change after WPMN5

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

Ministry of Economy, Trade and Industry (METI) calls on the industries to voluntarily report their safety data of the manufactured nanomaterials to METI (see 4. in detail). METI is planning to publicise such data on its website.

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

No significant change after WPMN5

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

In November 2008, Ministry of Economy, Trade and Industry (METI) organised a study group (The Expert Meeting on Safety Measures for Nanomaterial Manufactures etc.) focusing its discussion on the safety measures introduced by nanomaterials manufactures in voluntarily basis. Experts from industries made presentations on their voluntary activities for safety production of nanomaterials in three meetings which were open to the public. A study report was published in March 2009<sup>12</sup>. Following the conclusion of the report, METI requested the manufacturers to further implement the voluntary safety measures, to enhance the communication with users and to provide voluntarily the information on test data and management methods to the public and METI.

The Ministry of Health, Labour and Welfare (MHLW) also established two committees on safety of manufactured nanomaterials. Those committees discussed safety of nanomaterials in occupational settings and in consumer products, respectively. The first committee issued the report in November 2008, and the second one in March 2009. According to the report of the first committee, called “Review Panel Meeting on Preventive Measures for Worker Exposure to Chemical Substances Posing Unknown Risks to Human

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[http://www.meti.go.jp/policy/chemical\\_management/files/The%20Expert%20Meeting%20on%20Safety%20Measures%20for%20Nanomaterial%20Manufactures%20etc..pdf](http://www.meti.go.jp/policy/chemical_management/files/The%20Expert%20Meeting%20on%20Safety%20Measures%20for%20Nanomaterial%20Manufactures%20etc..pdf)

Health (Nanomaterials)", MHLW revised the notification for exposure prevention in the workplace in March 2009.

In June of 2008, Ministry of the Environment (MOE) established an expert committee on potential risk of manufactured nanomaterials to human health and the environment by the exposure in the ambient environment. The "Guidelines for preventing the environmental impact of manufactured nanomaterials" was published to provide manufacturers with currently available information for the environmental sound management of manufactured nanomaterials including immediate countermeasures to be taken as a guideline in March 2009<sup>13</sup>.

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

METI launched a five-year programme on the "Evaluation of the Potential Risks of Manufactured Nanomaterials based on Toxicity Tests with Precise Characterization" in 2006, which focuses on toxicity test protocols and a risk assessment methodology of manufactured nanomaterials. The programme aimed at: 1) establishing preparation methods of test samples; 2) developing methods for measuring shapes and sizes of tested nanomaterials, for testing toxicity, and for analysing exposure; 3) publishing such results in the form of manuals; 4) carrying out risk assessment on typical of nanomaterials; and 5) proposing a risk management policy with formulating risk assessment documents. Fullerenes, carbon nanotubes (CNTs) and titanium dioxides are given priority as targeted nanomaterials. The programme is coordinated by the National Institute of Advanced Industrial Science and Technology (AIST), which also conducts much of this research in cooperation with the University of Occupational and Environmental Health and other universities. The New Energy and Industrial Technology Development Organisation (NEDO, an R&D management organisation) evaluates the progress of the programme and is to explore a possible next phase. On October 16, 2009, AIST released interim reports on the risk assessment of the aforementioned three nanomaterials, in addition to a concept paper "The Principles and Basic Approach to Risk Assessment of Manufactured Nanomaterials." The English version will be available for download from the AIST-RISS website by the end of 2009<sup>14</sup>. The final Risk assessment reports on three nanomaterials are envisaged at the end of the project in mid 2011.

The National Institute of Occupational Safety and Health Japan (JNIOSH) has been conducting a three-year project study on possible health issues due to exposure to manufactured nanomaterials in the workplace since April 2007. This project includes 1) a questionnaire survey on occupational health practices for handling and use of nanomaterials in the workplace, 2) studies on sampling and analytical methods, and 3) toxicological studies *in vitro* with human cultured cell lines and *in vivo* by intratracheal administration. MHLW has also promoted research on the human health aspect of several nanomaterials since 2003 through the Health and Labour Sciences Research Grants, etc. In 2009, six research projects, such as a basic research on development of methods for evaluating hazard and disposition of nanomaterials on human health, are progressing.

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

<sup>13</sup> [http://www.env.go.jp/chemi/nanomaterial/eibs-conf/guideline\\_0903\\_enab.pdf](http://www.env.go.jp/chemi/nanomaterial/eibs-conf/guideline_0903_enab.pdf)

<sup>14</sup> [http://www.aist-riss.jp/main/?ml\\_lang=en](http://www.aist-riss.jp/main/?ml_lang=en)

nanofibers has been installed and NIES has started an acute inhalation study on carbon nanotubes using small rodents.

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

No significant change after WPMN5

**7 Others (major budget plans on safety of manufactured nanomaterials in FY 2009)**

Project name	Governing ministry	FY2009 (million yen)
Research project on risk of chemicals Six projects, including a basic research on development of methods for evaluating hazard and disposition of nanomaterials on human health	MHLW	336
Research project on the potential hazards, etc. of nanomaterials	MHLW	402
Food Nanotechnology Project	MAFF	150
Evaluation of the Potential Risks of Manufactured Nanomaterials based on Toxicity Tests with Precise Characterization	METI	400
Study on the Environmental Impacts of Nano-particles in the Environment	MOE	3
Assessing the health risks associated with the disposition of environmental nanoparticles	NIES	50 (incl. other businesses)
Developing knowledge-based platform to support nanomaterial R&D for public acceptance	Cabinet office /MEXT	90

**KOREA**

***Highlight of developments since the 5th meeting of the WPMN***

- MKE established KSA 6202 (Guideline to safe handling of manufactured nanomaterials in workplace/laboratories) as a national standard in 2009.
- MOE has developed the mid-term plan for The Risk management for nanomaterials (2010~2014).
- MOE organized the Nanomaterial Risk Expert Committee in order to share the expertise and experiences and establish the collaborative system for potential risk of nanomaterials.

Work completed, underway or planned

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

The Korean government has not had any national regulatory development on human health and environmental safety on manufactured nanomaterials as yet. However, MOST (Ministry of Science and Technology) started the preliminary investigation of any needs in the new regulatory system and possibilities to apply the existing laws and rules to issues related to nanomaterials.

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

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

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

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

The KATS is developing a guideline for exposure monitoring of nanomaterials such as CNTs and silver nanoparticle, and method for exposure assessment.

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

The further Korean government initiated projects related to good practice as elaborated below in #5.

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

The Korean government has well recognized the importance of potential risks of nanomaterials, and several projects are on progress, regarding on the human health and environmental safety issues of nanomaterials.

### ***Ministry of Environment (MOE)***

MOE has conducted the Eco-technopia 21 project to promote the development of environmental technologies since 2001. Under this umbrella, MOE started a project on human health and environmental safety of nanomaterials, such as fullerene (C60), MWCNT, silver nanoparticles, TiO<sub>2</sub>, and SiO<sub>2</sub>, as target materials in the framework of Eco-technopia21 from April 2007, which will be continued until 2010. The ultimate goal of the research is to support the establishment of infrastructure in order to minimize potential risks possibly occurred from the manufacture, distribution and disposal of nanomaterials and nanomaterials-containing products. MOE implemented the projects such as ‘Research on the most relevant dosing metric for the ecotoxicity management system of manufactured nanomaterials (2009~2012)’ in order to find the correlation between the dosing metric and the risk assessment and ‘Genomic studies of nano-particles to bacteria, yeast and fish’ to develop alternative methods for nano-toxicity tests. Furthermore, ‘Guideline for the life cycle assessment (LCA) of nanomaterials’ and ‘Safety guideline for nano-safety management’ are under review.

MOE and NIER (National Institute of Environmental Research, a subsidiary body of MOE), have developed the Long-term Plan for the Risk Management for Nanomaterials including developing the inventory for nanomaterials, infra structures for the researches on the risk of nanomaterials, producing the data on the risk, toxicity, exposure, environmental fate, phy-chem properties of nanomaterials, etc. Furthermore, MOE and NIER take the key role on facilitating and conducting sponsorship programme under the close co-operation among ministries, academia, and industries.

NIER has been conducting 4 projects on the development of test methods and a database for risk assessment of manufactured nanomaterials (2007~2010). The prototype of the database and the environmental and mammalian toxicity tests for silver nanoparticles, MWCNT and titanium dioxide nanoparticles are on progress. NIER organized the Nanomaterial Risk Expert Committee and held the first meeting in September 2009. This committee handles the nanomaterial safety issues, which include the

areas on developing test methods, evaluating the validation of the data and national planning on the nanomaterial risk assessment.

### ***Ministry of Knowledge and Economy (MKE)***

The Ministry of Knowledge Economy (MKE) in collaboration with the Ministry of Education, Science and Technology (MEST) has initiated the programme "Strategy on Nano Fusion Industry Development" to strengthen research on the safety and social impact of nanomaterials. The MKE/KATS implemented "Platform Technology on Risk management for Green Nanoproduct Development (2009-2013)" which will provide an infrastructure for certification of nano products based on a risk management system including characterization, efficacy, quality and safety assessment along with standard development.

The Korean Agency for Technology and Standards (KATS), an organization under MKE, has been developing national standards to ensure safety and support marketing of consumer products containing silver nanomaterials and CNTs. This work is due to Korea's role as an exporting country and to prepare for TBT (technical barrier to trade). KATS has published "Nanoparticle diameter measurement using TEM" (KSD 2716, 2008), and published KSA 6202(Guideline to safe handling of manufactured nanomaterials in workplace/laboratories as a national standard in 2009. KATS further proposed an international standard on "Preparation of MSDS (material safety data sheet) for nanomaterials", and is simultaneously developing a Korean standard for the preparation of MSDS in 2009. Guidelines for exposure monitoring, characterization, and safety assessment of nanomaterials such as CNTs and silver nanoparticles are in development. Accordingly, a guideline for exposure monitoring of nanomaterials has already been launched.

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

KFDA has been operating the Nanotoxicology Project since 2007. The Nanotoxicology Project focuses mainly on preparing guidelines to evaluate safety and effectiveness in newly-developed foods, drugs, medical devices and cosmetics using nanoscale materials. Research areas in the Nanotoxicology Project encompass a wide range of safety issues related to manufactured nanomaterials including toxicological evaluation, risk assessment, reduction of potential health risk, toxico/pharmaco-kinetics (TK/PK) and physico-chemical characterization.

Silica, silver, gold, iron oxide, quantum-dot, zinc oxide, titanium dioxide, carbon nanotube and chitosan nanoparticles have been used as test materials for preparation of guidelines to evaluate safety and effectiveness. Effects of size, shape and surface character of nanomaterials on general toxicity, genotoxicity, immune response, developmental and reproductive toxicity, PK profile, uptake mechanism, interaction with biomaterials were mainly investigated. We plan to conduct in-depth studies on the nanomaterials mentioned above to understand the mechanism of toxicity and to identify physico-chemical characterizations.

### ***KRISS (Korea Research Institute of Standard Science)***

KRISS has been developing the National Measurement Standards of (nano) materials. In connection with this topic, the research projects on the physico-chemical properties in line with *in vivo* toxicity testing and the development of reference materials for silver, gold, titanium dioxide, polystyrene, silicon dioxide, CNTs and quantum dot are ongoing. Surface structures and its compositions are studied using XPS, MALDI-ToF, ToF-SIMS *etc...* The size measurement of nano particles is also executed out with SMPS, DLS, PBMS, TEM, BET and AFM as a part of OECD-WPMN and VAMAS (TWA34) projects. Nanoparticle trace technology using ToF-SIMS and Raman spectroscopy is under developing. Regarding ADME, studies on the transport and potential transformation of nanomaterials is under investigation.

## NETHERLANDS

*Highlights of developments since 5<sup>th</sup> meeting of the WPMN***- Motions of the Lower House concerning nanotechnology (2009)**

- The Lower House of Netherlands' Parliament has introduced three motions concerning nanotechnology. The first motion is a request to the Risks of Nanotechnology Knowledge and Information Centre (KIR nano) to coordinate the derivation of reference values. The second asks the government asked to oblige producers/importers of products containing nanomaterials to perform a risk analysis for their nanomaterials/products. The third asks government to introduce a duty to report the use of nanomaterials in products by producers/importers.

**- Dutch Action Plan Nanotechnology (2008)**

- A result of the paper on the Dutch government's vision on nanotechnologies (Netherlands' government, 2006) is a Dutch Action Plan Nanotechnology, concentrating on ethics, risk research, innovation and development. The action plan includes proposals on managing risks, research and innovation, the communication of the technology with the wider society and legal aspects and is in line with the European action plan. In relation to risks the most significant actions are:
- Proposal of a new strategic research agenda in summer 2008 by the Netherlands' Nano Initiative (NNI). The proposed research budget is 100 million/year of which 15% should be used for risk research, starting in 2010.
- A Risks of Nanotechnology Knowledge and Information Centre (KIR nano) at the National Institute for Public Health and the Environment (RIVM),
- Participation in OECD sponsorship programmes (co-sponsor cerium oxide, dosimetry).
- To stimulate sharing of knowledge and information on risks of nanotechnology between companies and institutions, the government founded the 'Stakeholder group Nanotechnology Risks' in which business, social, and societal organizations participate,
- Furthermore, a broad societal committee is formed to facilitate and stimulate a public dialogue on nanotechnologies in the Netherlands and to advise the government on ethical aspects, societal dialogue and communication (Committee Public Dialogue Nanotechnology, see [www.nanopodium.nl](http://www.nanopodium.nl) (in Dutch)),
- Several initiatives are started to stimulate the sharing of knowledge and information between industry and government.

**- Risks of Nanotechnology Knowledge and Information centre (KIR nano).**

- KIR nano aims at observing and monitoring the potential risks of nanotechnology, gathering relevant scientific literature, generating overviews of relevant legislation, and advising and informing governmental bodies and professionals. These activities are always performed from a risk assessment viewpoint. Its signalling function is put into practice by participating in national and international networks (e.g. OECD WPMN, REACH CASG Nano, ISO, SCENIHR, ILSI, EFSA, SETAC, WHO/FAO, ETP NanoMedicine) and bringing experts together into national expert panels on different topics (environment, food, consumer products, medical applications, and workers). In addition, KIR nano is involved in the EU FP-7 projects: EU Observatory Nano NanoImpactNet and FramingNano. In this way, KIR nano acts as an information exchange platform without performing research itself. As a first achievement, a report giving an overview of risks for man and the environment and knowledge gaps in the entire field of nanotechnology was published (RIVM Report 601785003 and 601785004, [www.rivm.nl](http://www.rivm.nl).)

**- Participation in international organizations: REACH-CA subgroup**

- The subgroup of nanotechnology under REACH competent authorities works on a first step to include nanoparticles within the implementation of REACH. In this context, RIVM has studied the

suitability of REACH for ensuring the safety of nanomaterials for man and the environment. This was done by performing a hypothetical registration under REACH of silver, a substance that exists both in nano and non-nanoform (i.e. bulk form). The study revealed the problems that potential registrants may encounter when trying to register a substance such as nano silver under REACH. Also, a risk assessment framework for first generation nanomaterials under REACH was proposed, based on the information generated in the case study. The final report is expected to become available on the RIVM website ([www.rivm.nl](http://www.rivm.nl)) in October 2009.

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

The Netherlands participates in the REACH CA Subgroup on nanomaterials (see above).

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

As a result of ongoing dialogue with the Dutch authorities, VNO/NCW (Business organization of the Netherlands) has taken the initiative together with the VNCI (United Dutch Chemical Industry) to enter into a voluntary agreement with the Dutch government on communication and risk assessment issues of nanomaterials. They are currently working on a Letter of Intent. Initiatives for a structural dialogue with multiple stakeholders have started in 2008.

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

The Social and Economic Council of the Netherlands (SER, consisting of representatives from business, labour unions and academia) published an advisory report 'Nanoparticles in the Workplace: Health and Safety Precautions' as a response by the Working Conditions Committee of the Social and Economic Council of the Netherlands (SER, 2009) to the request for advice sent to the Council by the Minister of Social Affairs and Employment (SZW) on 5 September 2008. That request for advice concerns how to deal with the uncertainties related to the risks associated with nanotechnology, in particular with persistent synthetic nanoparticles, in an occupational environment.

The Committee's central concern is with the health and safety of employees who are required to work with nanoparticles in the workplace. It is the employer that bears primary responsibility for this in the light of its duty of care as set forth in the Working Conditions Act. The basic principle is that substances attended by uncertain or unknown risks – which include nanoparticles – should be treated as hazardous (or extremely hazardous) substances. This means that the policy and implementation measures in such cases should focus on preventing or minimising exposure of employees to those substances.

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

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

## NORWAY

### *Highlight of developments since the 5<sup>th</sup> meeting of the WPMN*

- The Norwegian Pollution Control Authority (SFT) has introduced a voluntary scheme to get a better overview of nanomaterials in chemical products. The Product register in SFT has included a question in their declaration form about the content of nanomaterials in their chemical products.
- The Norwegian Institute of Occupational Health has established a working group together with The Norwegian Labour Inspection Authority and The Norwegian Pollution Control Authority related to primarily occupational health aspects of nanotechnology.

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

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

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

See first bullet point under “Highlight of developments...”

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

Norway is a member of the REACH Competent Authorities subgroup on nanomaterials and follows their regulatory developments.

#### ***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 a strategic research programme on nanoscience, nanotechnology and new materials, called NANOMAT. The programme period is 2002-2011. NANOMAT also supports research on ethical, legal, social and environmental aspects, including human health and risks (ELSA). The Council published in 2005 a report where these aspects are discussed. From 2005 funding of relevant projects started. 3 % of NANOMAT’s funding so far is related to ELSA.

A national strategy for nanoscience and nanotechnology was adopted by the Council in autumn 2006 and forward to the Minister of Education and Research. NANOMAT hosted a major conference in Lillehammer June 15th-19th 2009, where presentations from several acclaimed researchers, also in the field of safety for human health and environment were hold. More info on this website:

<http://www.forskningsradet.no/servlet/Satellite?c=Page&cid=1226993562769&p=1226993562769&pagenname=nanomat%2FHovedsidemal>

With support from The Norwegian Research Council, Bioforsk Soil and Environment has established a national network for health, environment and ethic aspects of nanotechnology as a part of a project funded by NANOMAT. One of the targets of this network is to define research needs and exchange ideas on research projects both nationally and internationally and to communicate contact between scientists and trade and industry in relation to any need for health, environmental and ethical assessments.

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

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

The Norwegian Board of Technology published a report in 2008 regarding Nanomaterials, risk and regulation (only in Norwegian). Download the report via this link:

[http://nano.teknologiradet.no/Nanotox\\_rapport\\_for\\_web\\_nR1yA.pdf.file](http://nano.teknologiradet.no/Nanotox_rapport_for_web_nR1yA.pdf.file)

They also had a public meeting 12 March 2009 where the main topic was how the health and environment authorities deal with the uncertainties regarding nanomaterials in a regulatory context. They also launched a public website in September 2009: <http://nano.teknologiradet.no/>

### **Additional Information**

None.

## **RUSSIA**

### **Highlight of developments since the 5<sup>th</sup> Meeting of the WPMN**

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

### **Work completed, underway or planned**

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

All basic regulations were adopted by the Federal Consumer Rights and Human well being Department (Rospotrebnadzor) in 2007 (<http://www.rospotrebnadzor.ru>):

-Regulation № 54 concerning the inspection of new products containing nanomaterials (July 23, 2007);

-Regulation № 280 regarding the approval and implementation of methodological recommendations on the assessment of nanomaterials safety” (October 12, 2007);

-Regulation № 79 regarding the Conception of the toxicological studies, risk assessment methodology, methods of identification and quantitative description of nanomaterials (October 31, 2007);

-A special plan of priority actions aimed at implementing the Nanoindustry development Programme in Russia 2015 has been adopted by the Federal Consumer Rights and Human well being Department (Rospotrebnadzor) in 2009. This plan covers different environment, health and safety (EHS) aspects of manufactured nanomaterials.

(<http://www.rospotrebnadzor.ru/events/2749/>)

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

No information

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

No information

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

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

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

- Federal Target-oriented Programme “Development the Infrastructure of Nanoindustry in Russia for 2008-2010”. This programme includes “Development of a methodological component of Nanotechnology infrastructure” sub programme, dedicated to safety, metrology and standardisation in this area.

-Programme of Nanoindustry development in Russia 2015 includes a special section “Potential threats to human health in connection with Nanotechnology development” (<http://dis2.informika.ru/>).

-Programme of the Russian Academy of Medical Sciences “Nanotechnologies and nanomaterials in Medicine for 2008-2015” includes studies of physicochemical properties of nanomaterials (nanoparticles), toxicity studies.

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

-Analytical Programme of Russian Foundation for Basic Research.

A number of R&T projects on impacts of nanoparticles on health and environment are funded by Russian Foundation for Basic Research and by Federal Agency for Science and Innovation (ROSNAYKA) within the thematic priority “The industry of nanosystems and materials” of the Federal Target-oriented Programme “Research and Development in Priority Fields of S&T Complex of Russia for 2007-2012”.

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

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

1. The 2-d International Conference on NanoBioTechnologies “NanoBio’2008”. Saint-Petersburg, June 16-20, 2008 ([www.spbcas.ru/nanobio](http://www.spbcas.ru/nanobio)),

The special session in the frame of this Conference: “The International Dialog on Nanotechnology Risk Assessment and Management. Opportunities for Russia”

2. NATO Advanced Research Workshop on Biological and Environmental Risks of Nanotechnology, Nanobionics and Hybrid Organic-Silicon Devices (Silicon vs. Carbon), Saint-Petersburg, June 16-20, 2008
3. “EU-Russia Co-operation in Biotechnology, Agriculture, Forestry and Food”, V International Symposium, Pushchino, October 1-3 2008.

Special session “Nanotechnology in food industry”

4. The First Nanotechnology International Forum, Moscow, December 3-5, 2008.

The organizer of this event is Russian Corporation of Nanotechnologies.

Two panel discussions:

Nanotechnologies in medicine and biotechnologies

Safety and quality of Nanoindustry

5. The Second Nanotechnology International Forum, Moscow, October 6-8, 2009 “Standardization, metrology, certification, and technical regulation for safety and quality in Nanoindustry” (panel discussion)

<http://www.rusnanoforum.ru/Home.aspx>

6. Workshop “Production and Application of nanomaterials in Russia: Toxicological, Exposure and Regulatory Issues”, Moscow, September 14-16, 2009

Supported by: International Science and Technology Centre

Environment Protection Agency (USA)

Research Institute of Hygiene, Toxicology and Occupational Pathology, Russia part of the Federal Medical and Biological Agency of Russia

[http://www.istc.ru/istc/istc.nsf/va\\_WebPages/NanoWSEng](http://www.istc.ru/istc/istc.nsf/va_WebPages/NanoWSEng)

Activities regarding information dissemination

-The article “Risks to the list” (M. Melkonyan) will be published in “Poisk” newspaper of the Scientific Society of Russia (July, 2008)

-Special newsletters of Russian FP7 NMP National contact point, devoted to OECD WPMN and WPN projects, especially, OECD Database on Research into the Safety of Manufactured Nanomaterials, European initiatives in this area in the frame of FP7

-Some Russian thematic web-sites include the special section on risks of Nanotechnologies: <http://www.nanonewsnet.ru/>; <http://www.nanometer.ru/>; <http://www.nanoware.ru/>

### ***Additional Information***

In October 2008 a non-commercial, non-governmental organization «Nanotechnological Society of Russia» (NTSR) was created (<http://ntsr.info/>)

In the frame of this Society two special committees were established

- The committee for international cooperation
- Nanobiosafety committee

NTSR will establish collaboration with the similar European and International organizations on EHS issues of N&N.

## **SOUTH AFRICA**

### ***State of nanotechnology research and industry in South Africa***

South Africa is among the developing countries that have launched several nanotechnology national initiatives to strengthen her national capabilities in this field. Notable initiatives include the formation of the South African Nanotechnology Initiative (SANi) in 2002 with membership comprising of academics, researchers, engineers, private sector companies, and research councils. Secondly, in 2003, the South Africa's Advanced Manufacturing Technology Strategy (AMTS) was launched by the Department of Science and Technology (DST). And finally, the National Strategy on Nanotechnology (NSN) was published by the DST in 2005 – making South Africa among the first countries globally to have an official nanotechnology strategy. The strategy's focus is in four areas namely; the establishment of characterisation centres (national multi-user facilities), the creation of research and innovation networks (to enhance collaboration: inter-disciplinary, national and internationally); building of the human capacity (development of skilled personnel) and setting up of flagship projects (to demonstrate the benefits of nanotechnology towards enhancing the quality of life, and spurring economic growth).

As a result of these national initiatives, currently there are numerous technical projects in progress including the synthesis of nanoparticles, development of better and cheaper solar cells, nanophase catalysts and electro-catalysts, fuel cell development, synthesis of Quantum dots, composites development, atomic modelling, just to mention a few. The research projects are carried out in diverse institutions and organizations, namely: eleven universities, four research organisations, and eleven private sector companies – in fields of mining, paints to paper manufacturing.

South Africa launched the first nanotechnology innovation centres in 2007 at the CSIR and MINTEK. Each of these centres have developed collaborative research programmes with other national institutions in designing and modelling of novel nano-structured materials (at the CSIR) as well as the application of nanotechnologies in the fields of water, health, mining and minerals (at MINTEK) For example, AuTEK Biomed, a collaborative project between gold mining industry and MINTEK focuses on creating gold-

based chemo-therapeutics for treating diseases such as cancer, malaria and HIV and AIDS. Rand Refinery, the world's largest gold refinery intends to build a nanotechnology plant if ongoing experiments prove gold nanoparticles can be used as catalysts for detoxifying air in mines. South African paper manufacturer – Sappi is currently investigating the possibility of using nanotechnology to monitor temperature, termites, and fungus in forests.

South Africa has also established international collaborations with other developing countries which includes a focus on the field of nanotechnology. For example, the India–Brazil–South Africa (IBSA) - is a joint project for the departments of science and technology in Brazil, India and South Africa which was recently established. The initiative provides a suitable platform for collaborative research among scientists and organizations among these countries. A good example is the running of joint program for the three countries in equipping researchers with the latest nanotechnology skills by running nano-schools, and in 2009, one of the IBSA Nano Schools will be held in South Africa from 22<sup>nd</sup> November to 2<sup>nd</sup> December 2009.

Another collaborative initiative is between the South African and European scientists under the EU's Framework Programme Six (FP6). Under FP6, South African researchers can participate in projects in all activity areas, and respective National Contact Points (NCPs) have been set up in South Africa to optimise mutual benefits between the participating parties under this initiative. In addition, the European - South African Science and Technology Advancement Programme (ESASTAP) is a dedicated platform for the advancement of European and South African scientific and technological cooperation comprising of projects related to nanotechnologies towards treating tuberculosis with nano drug delivery system, preparation and characteristics of CNT-metal composites, and generating MnO<sub>2</sub> nanoparticles using simulated amorphization and recrystallization.

However, until recently one peculiar aspect of the funding model in South Africa for nanotechnologies was the lack of government or industrial research support in establishing the potential risks of nanotechnology-based materials and products to both humans and the environment. Interesting, this phenomenon is similar in other countries during their infancy phases of nanotechnology programmes. For instance, recent studies to track the growth of nanotechnology in South Africa measured in terms of publications since 2000 only reported research on the synthesis and characterization of nanomaterials. No single paper was cited with specific focus on the risk assessment of nanomaterials in the country. This implies that risk assessment research is yet to take root in the country despite the increasing exposures to humans working in research facilities to personnel handling nanoscale materials, and rising numbers of nanoproducts in the South African market.

Presently, the current status on risk assessment is likely to change dramatically because of a recently launched initiative driven by the DST dedicated towards an establishment of a research platform on health, safety and environmental aspects related to nanotechnology. In addition, a national steering committee tasked with examining the ethical and risks associated with nanotechnology have been establishment – and its work is in progress. Centres that are involved in this are the National Institute for Occupational Health (NIOH) and the Council for Scientific and Industrial research (CSIR).

Therefore, it is anticipated that once the funding and establishment of a research platform concerning risk assessment of nanotechnologies is fully operational – South Africa research and development in this field will be in par with best international practices. Secondly, the establishment of potential risks of nanotechnology at early phases of its development and application – has the merit of enhancing the development of technologies and practices that eliminates, or prevents potential unintended effects to workers, consumers, and the environment. Notably, because of the complexity and diversity of the skills required in risk assessment of nanomaterials, it is recommended that research in this field should comprise of multi- and intra-disciplinary specialists including; toxicologists, environmental scientists,

nanotechnologists, risk assessors, epidemiologists, among other. Such approach would aid in deriving useful results that enhances our understanding on the influence of both the physicochemical properties and abiotic factors on the observed toxicological, behavioural or morphological effects on the humans and other ecological systems as well as the fate and behaviour of NMs in the environment. It is mandatory that such studies are initiated in light of the recent announcement by Industrial Nanotech, In. of its intention to manufacture nanotechnology-based products in South Africa.

## 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;*

Sweden is a member of the EU and accordingly follows the EU regulation

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

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

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

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

- a) The Swedish Chemicals Agency (KemI) is commissioned by the Government to analyse the need for regulations and other measures in the EU and in Sweden in order to make a satisfactory assessment of the risks posed by nanomaterials to human health and the environment. The commission is to be reported on 31 January 2010.
- b) The Swedish Governmental Agency for Innovation Systems (Vinnova) is commissioned by the Government to, in consultation with the Research Council (Vetenskapsrådet) and after consultation with the Swedish Research Council for Environment, Agricultural Sciences and Spatial Planning (Formas) and the Swedish Chemicals Agency (KemI) in accordance with their respective competence to develop a strategy for addressing how the opportunities and risks, which may be associated with the use of nanotechnology, can be exploited and taken into account in light of the fast developments in the field of nanotechnology. The commission is to be reported on 31 December 2009.
- a) The Swedish Research Council for Environment, Agricultural Sciences and Spatial Planning (Formas), a governmental research-funding agency related to the Ministry of Environment will finance a number of large initiatives related to strong research environment. In the field "Nanotechnology – the hazards associated with new materials" a single project "NanoSphere: Centre for interaction and risk studies in Nano-Bio-Geo-Sociotechno-sphere interfaces" will be funded by Formas with approximately 25 million SEK (approximately 2.5 million euro) for a period of five years. The funding of Formas in the field of nanotechnology focus on both the development of nanomaterials in the areas of relevance for Formas and on the potential risks for humans and the environment related to the use of nanomaterials.

- b) In the ERA-Net program, a research project “Nanomaterials in REACH – evaluation of applicability of existing procedures for chemical safety assessment of nanomaterials” will be financed by the Skep program (Scientific Knowledge for Environmental protection) with partners from Sweden, Finland, UK and Ireland. A formal final decision is awaited Oct 28 2009. The Swedish EPA is one of 17 partners from European government ministries and agencies responsible for funding environmental research. The Skep program aims to improve the co-ordination of environmental research in Europe.
- c) The Swedish Governmental Agency for Innovation Systems (Vinnova) and the Research Council (Vetenskapsrådet) participate in the European ERA-Net Program for nanomedicine, EuroNano-Med. EuroNano-Med has opened the first call on investment focused on diagnostics, drug delivery and regenerative medicine.
- d) During the Swedish EU presidency, Sweden is together with the EU Commission and others the organiser of two workshops related to nanomaterials and nanotechnology namely
  - “Nanomaterials on the market: What regulators need to know”; Brussels, 9 October 2009 and
  - “Nanotechnology for Sustainable Growth”; Brussels, 12 November 2009

## THAILAND

Since the 5<sup>th</sup> meeting of WPMN, a number of nano-safety development and activities have taken place in Thailand.

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

### ***The National Nanotechnology Centre (NANOTEC), National Science and Technology Development Agency (NSTDA)***

The National Nanotechnology Centre (NANOTEC) has established:

1. Strengthening nanotoxicity and ecotoxicity research of nanosilver and TiO<sub>2</sub>.
2. A Nanosafety Strategic Plan as an integral part of the National Chemical Safety Strategic Plan
3. Collaborative research programs with the Swiss Federal Institute for Materials Testing and Research (EMPA)
4. Participation as part of the Thai Delegation in the ISO/TC229 Nanotechnologies standard development activities
5. Collaboration with the steering group of the Intergovernmental Forum on Chemical Safety (IFCS) forum VI with the lead of the Ministry of Health and the Ministry of Science and Technology.
6. Collaboration with SAICM/UNEP in chemical and nanosafety management issues

***Strategic goals of NANOTEC:***

1. Conduct research on measuring nanomaterials in the workplace, including developing new measurement methods and validating measurement methods. Also, the nanotoxicity in human health and environment is being investigated.
2. Strengthen the capability of nanosafety and risk assessment program.
3. Integrate nanosafety guideline into the National Chemical Safety Strategic Plan.
4. Evaluate the role of nanoparticle properties in exposure-dose-response relationships, develop and validate models for nanoparticle risk assessment, and determine risk estimates of occupational exposures.

Furthermore, NANOTEC has initiated a new Nanosafety Monitoring Centre (NMC) in collaboration with Chulalongkorn University. NMC will serve as the focal point in monitoring movements in issues related to nanomaterials and nanotechnology. It will also serve as a focal point in disseminating such knowledge to the Thai public. Over time, NMC is expected to become an independent agency in order to boost its credibility as an impartial organization.

***Thai Industrial Standard Institute (TISI)***

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

***Chulalongkorn University***

In addition to the scientific and technological components, the Centre for Innovative Nanotechnology (CIN) of Chulalongkorn University has two built-in programs or units that cover the topics of nanosafety and nanoethics, respectively. The nanosafety program, led by Dr. Lerson Tanasugarn, is preparing the budget for funding in 2010. The nanoethics program, led by Dr. Soraj Hongladarom, is already funded and has recently organized the “NanoEthics Asia 2009 Workshop” in Bangkok, Thailand.

***Nano-safety in Thailand Q&A:***

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

As of March 2007, nanosafety and nanoethics were being considered in the forums of local ISO TIS (Thai Industrial Standard). Currently, Nanomaterials Safety Projects have been funded with three objectives: to support R&D in the area of nanosafety; to drive nanosafety policy into the national level; and to establish a nanostandard for industrial use. Moreover, the Nanosafety Strategic Plan is being developed by the Nanosafety Committee, comprising of representatives from Ministry of Science and Technology, Ministry of Public Health, Industrial Federation, and NGO. In the international level, Thailand has participated in the working parties of international organizations such as OECD and ISO TC 229.

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.

NANOTEC consequently commissioned Chulalongkorn University to prepare a nano-safety status report in 2007. The main objective of this exercise was to gather international information on all aspects of nanosafety and nanoethics. Data sources include university centres 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, this exercise attempted to familiarize a dozen of experts in various fields with the foundation and features of nanotechnology. These experts from the fields of environmental law, consumer protection law, economics, and political science, would become invaluable resource persons and reviewers of the national nanosafety guideline.

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

Stewardship schemes are being studied in parallel with the nanosafety guideline development effort and the nano-label initiative for specific products.

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

NANOTEC has regularly exchanged nanosafety information with the Thai FDA and Office of the Consumer Protection Board. Several misleading advertisements of nano-products were removed from the public media i.e. nano-water, nanosilver coated refrigerator, TiO<sub>2</sub> coated air conditioner, etc.

## **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 stage.

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

During the past few 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 a model (pig) skin. Ecotoxicity of nanosilver in waste water was also tested. More comprehensive nanomaterial safety data resulting from program specifically designed to address the human health and environmental safety aspects should be available through NANOTEC after such research works are completed.

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

NANOTEC has organized nanosafety public seminars several times during the past few years, e.g. NanoThailand 2008 and the Nanosafety and Ethics Forum, and is planning to arrange a nanosafety and nanoethics workshop in December 2009.

### **Box 1. About NANOTEC**

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 to establish, 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.

## **UNITED KINGDOM**

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

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

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

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

## **2** *Recently concluded projects*

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

The objectives of this study, which was undertaken by the Institute of Occupational Medicine and funded by Defra, were to provide:

- A detailed review and analysis of research carried out worldwide on Environment, Health and Safety aspects of engineered nanomaterials including issues relating to hazard, exposure and risk assessment and regulation
- An evaluation of how far research objectives outlined in the 2005 UK Government Research Report have been met and to identify which gaps still remain to be filled
- An appraisal of research results with a view to highlighting any new information on hazards and risks to human health and/or the environment from nanomaterials that may trigger consideration for the need for regulation of nanomaterials
- An interim risk assessment appraisal identifying the need for control or management of risk, including an opinion of whether there is sufficient information to invoke the precautionary principle for one or more nanomaterials
- Specific recommendations for new research to fill gaps in the understanding of the potential risks posed by engineered nanomaterials taking into consideration, as far as practicable, work currently in progress.

A report from this study was published in April 2009 and is available via the following link: <http://randd.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&ProjectID=16006&FromSearch=Y&Publisher=1&SearchText=cb0409&SortString=ProjectCode&SortOrder=Asc&Paging=10#Description>

An examination of the nature and application among the nanotechnologies industries of corporate social responsibility in the context of safeguarding the environment and human health

A study undertaken by the ESRC Centre for Business, Relationships, Accountability, Sustainability & Society (BRASS), Cardiff University

This report aims to provide a clearer understanding of the role which corporate social responsibility (CSR) currently plays in influencing the activities of companies involved in the nanotechnologies industries in the UK, and how CSR may contribute to protecting society from any health and environmental risks which may emerge from nanotechnology applications in the future.

This report is now available and can be accessed via the following link: <http://randd.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&ProjectID=16262&FromSearch=Y&Publisher=1&SearchText=CB0417&SortString=ProjectCode&SortOrder=Asc&Paging=10#Description>

## *Recently commissioned projects*

The UK Government's Department of Health has commissioned work on:

- Carbon nanotubes and the asbestos/fibre structure activity relationship – January 2009 for three years. The work is being carried out at Edinburgh University, supervised by Professor Ken Donaldson.
- Quantitative and kinetic measurements of carbon nanotubes transport across pulmonary epithelium using an isolated perfused rat lung preparation – January 2009 for one year at Cardiff University, supervised by Professor Ian Matthews.
- Factors that may affect the nanotoxicology of hard materials for surgical applications – January 2009 for one year at the University of Bristol, supervised by Dr Charles Patrick Case.
- Nanoparticles and Atherothrombosis: Resolving the Paradox – January 2009 for 3years at Edinburgh University, supervised by Dr Nicholas Mills.

***Phase 2 of the Environmental Nanoscience Initiative announced by a UK-US funding partnership***

The Natural Environment Research Council, in cooperation with the Engineering & Physical Sciences Research Council, the Department for Environment, Food & Rural Affairs, the Environment Agency and the United States Environmental Protection Agency, is in the process of considering research proposals against a major joint research effort to develop and validate predictive tools and similar conceptual models that predict exposure, bioavailability and effects of manufactured nanomaterials in the environment. In addition, researchers will be asked to develop novel techniques for detection and characterisation of nanomaterials in complex environmental and biological systems. Total funding should be in the region of \$8M.

It is expected that successful grants will be announced in early 2010.

The Engineering and Physical Sciences Research Council has just announced a four year research grant to a research consortium at Swansea and Leeds University with the aim of developing techniques to accurately measure the nanoparticle dose delivered to biological cells, track the dose dilution as cells reproduce thereby providing vital information for researchers studying any potential toxic responses. The total grant value is £1.2M

**3 Information on any public/ stakeholder consultation**

The UK government has recently funded a pilot trial of a website which aims to provide balanced, easy to understand information for the general public on nanotechnology, and providing ways of understanding their views and engaging them in the development of the technology as it progresses. The aims of the Nano&Me trial are:

- To develop a pilot website to engage opinion formers and the general public to help with the development of a public focused website on nanotechnology.
- To build relationships with key stakeholders to assist in the development of the final site through an inclusive approach to the development of the content for the pilot.
- To build the confidence of opinion formers and the public in the information available on the site through this inclusive development process

This initiative has been developed using guidelines developed by the OECD Working Party on Nanotechnology's Engagement and Outreach Project.

## UNITED STATES

### *Highlight of developments since the 5<sup>th</sup> meeting of the WPMN*

- EPA issued several Consent Orders regulating new chemical submissions of carbon nanotubes under TSCA (Spring and Summer 2009)
- EPA will propose a Significant New Use Rule for two specific carbon nanotubes that were subject to new chemical notification under TSCA (October 2009)
- EPA announced that it is reviewing the basis and reasoning for the decision made in January 2008 on how a nanoscale substance is a new or existing chemical for purposes of TSCA.
- EPA also announced on September 16 that the FIFRA (Federal Insecticide, Fungicide and Rodenticide Act) Scientific Advisory Panel will meet November 3-6 in Arlington, Virginia to consider and review a set of scientific issues associated with nanosilver and other nanometal pesticide products and. EPA is seeking advice and guidance regarding hazards and exposures related to such products.
- NIOSH updated its guidance on nanomaterial handling in the workplace "Approaches to Safe Nanotechnology: Managing the Health and Safety Concerns Associated with Engineered Nanomaterials" which is available at <http://www.cdc.gov/niosh/docs/2009-125/>.
- The President's Budget Request for Fiscal Year 2010 proposes \$12 million in funding for NIOSH's strategic nanotechnology research program <http://www.hhs.gov/asrt/ob/docbudget/2010budgetinbrief.pdf>. More information on the FY10 budget request generally for federal nanotechnology research can be found at [http://www.nano.gov/NNI\\_2010\\_budget\\_supplement.pdf](http://www.nano.gov/NNI_2010_budget_supplement.pdf).
- NIOSH is sponsoring an upcoming conference on "Nanomaterials and Worker Health: Occupational Health Surveillance, Exposure Registries, and Epidemiological Research", which will be held in Colorado in July 2010. More information is available <http://www.cdc.gov/niosh/topics/nanotech/NanoConfJuly2010.html>.

### *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*

Since January 2005 EPA has received and reviewed more than seventy new chemical notices for potential nanoscale materials under TSCA including fullerenes and carbon nanotubes. EPA has permitted manufacture of these nanoscale materials under limited conditions.

On January 24, 2009 EPA issued direct final Significant New Use Rules (SNURs) for two new chemical substances identified as carbon nanotubes. EPA received a notice of intent to submit adverse comments. Under its regulations withdrew the direct final SNURs and will publish a proposed rule that will have a public comment period.

EPA issued several Consent Orders regulating new chemical submissions of carbon nanotubes. A sanitized version of such a consent order is available to date EPA has issued SNURs for less than 30 new chemical nanoscale materials. Because of confidential business information claims by submitters, EPA is unable to identify the chemical substance as a nanoscale material in every new chemical SNUR it issues for nanoscale materials. EPA will continue to issue SNURs for new chemical nanoscale materials in the coming year.

EPA is developing a section 8(a) rule under TSCA for nanoscale materials. The rule would propose that persons who manufacture these nanoscale materials notify EPA of certain information described in the rule which includes use, production volume, certain physical properties and chemical/structural characteristics, methods of manufacture and processing, exposure and release information, and available health and safety data.

EPA is also developing a section 4 rule which would propose test requirements for certain nanoscale materials. When deciding which nanoscale materials and tests to require EPA will consider ongoing testing programs including the OECD sponsorship program.

EPA announced that it is reviewing the basis and reasoning for the decision made in January 2008 on how a nanoscale substance is a new or existing chemical for purposes of TSCA.

The EPA in cooperation with the U.K. Natural Environment Research Council, the U.K. Engineering and Physical Sciences Research Council, the U.K. Department for Environment, Food and Rural Affairs, and the U.K. Environment Agency has initiated a major joint research effort to develop and validate predictive tools and similar conceptual models that predict exposure, bioavailability and effects of manufactured nanomaterials in the environment. This activity is being implemented through a joint call issued by all organizations involved and will incorporate a common review and evaluations process. The intent is to form consortia of both UK and US investigators using combined but independent national funding arrangements.

On April 8, 2009, NIOSH published a Federal Register Notice on “Request for Information on Carbon Nanotubes (CNTs) Including Single-Walled Carbon Nanotubes (SWCNTs) and Multi-Walled Carbon Nanotubes (MWCNTs).” The notice informed the public that NIOSH intends to evaluate the scientific data on CNTs and develop appropriate communication documents which will convey the potential health risks and recommend measures for the safe handling of these materials. In the notice NIOSH also requested pertinent safety and health information on CNTs.

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

In March, 2009, NIOSH updated its guidance on nanomaterial handling in the workplace “Approaches to Safe Nanotechnology: Managing the Health and Safety Concerns Associated with Engineered Nanomaterials which is available at <http://www.cdc.gov/niosh/docs/2009-125/>. This document reviews what is currently known about nanoparticle toxicity, process emissions and exposure assessment, engineering controls, and personal protective equipment. This updated version of the document incorporates some of the latest results of NIOSH research, but it is only a starting point. The document serves a dual purpose: it is a summary of NIOSH's current thinking and interim recommendations; and it is a request from NIOSH to occupational safety and health practitioners, researchers, product innovators and manufacturers, employers, workers, interest group members, and the general public to exchange information that will ensure that no worker suffers material impairment of safety or health as nanotechnology develops.

NIST representatives, in their roles as chair of two of the mirror committees of the US Technical Advisory Group to ISO TC229 (Nanotechnologies) have facilitated cooperation and coordination between OECD-WPMN and ISO TC229. The WPMN has a formal liaison with the ISO TC229 and the two organizations share work results prior to public release. ISO TC229 is assisting the WPMN Sponsorship Programme for the Testing of Manufactured Nanomaterials by compiling information that will be used by the Programme participants to prepare Dossier Development Plans for testing of the 14 priority nanomaterials in the Programme. Specifically, the TC229 is developing a list of physical-chemical parameters such as particle size that should be determined prior to toxicity testing, and the relevant measurands and measurement methods for each parameter. In addition, the TC229 is compiling a list of existing toxicity testing protocols relevant to nanomaterials, including sample preparation and dosimetry information.

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

EPA has assessed more than seventy new chemical notices for potential nanoscale materials under TSCA since January 2005.

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

In March, 2009, NIOSH updated its guidance on nanomaterial handling in the workplace "Approaches to Safe Nanotechnology: Managing the Health and Safety Concerns Associated with Engineered Nanomaterials which is available at <http://www.cdc.gov/niosh/docs/2009-125/>". This document reviews what is currently known about nanoparticle toxicity, process emissions and exposure assessment, engineering controls, and personal protective equipment. This updated version of the document incorporates some of the latest results of NIOSH research, but it is only a starting point. The document serves a dual purpose: it is a summary of NIOSH's current thinking and interim recommendations; and it is a request from NIOSH to occupational safety and health practitioners, researchers, product innovators and manufacturers, employers, workers, interest group members, and the general public to exchange information that will ensure that no worker suffers material impairment of safety or health as nanotechnology develops.

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

To review the status of the implementation of its nano EHS research strategy, the National Nanotechnology Initiative is holding two workshops this fall: October 6-7 on ecological effects and environmental fate, and November 9-10 on human health effects. More information may be found at <http://www.nano.gov/html/about/symposia.html>.

EPA has issued its Nanomaterials Research Strategy, which may be found at [www.epa.gov/nanoscience](http://www.epa.gov/nanoscience).

The President's Budget Request for Fiscal Year 2010 proposes \$12 million in funding for NIOSH's strategic nanotechnology research program <http://www.hhs.gov/asrt/ob/docbudget/2010budgetinbrief.pdf>. More information on the FY10 budget request generally for federal nanotechnology research can be found at [http://www.nano.gov/NNI\\_2010\\_budget\\_supplement.pdf](http://www.nano.gov/NNI_2010_budget_supplement.pdf).

NIOSH joins the International Journal of Occupational and Environmental Health in inviting submissions of scientific papers for a special issue of the journal, provisionally titled, "Human and Environmental Exposure Assessment for Nanomaterials." More information is available from the journal at <http://www.ijoeh.com/index.php/ijoeh/information/callforpapers>.

In 2009, NIOSH researchers have published several leading scientific papers pertaining to occupational health and safety of workers producing or using nanomaterials. These papers include:

- “Understanding biophysicochemical interactions at the nano-bio interface,” Nel, A.E., Mädler, L., Velegol, D., Xia, T., Hoek, E.M.V., Somasundaran, P., Klaessig, F., Castranova, V., Thompson, M., *Nature Materials*, 2009, 8, 543-557.
- “Essential Features of Proactive Risk Management,” Murashov, V.V., Howard, J. *Nature Nanotechnology*, 2009, 4(8), 467-470.
- “National Nanotechnology Partnership to Protect Workers,” Murashov, V.V., Howard, J. *Journal of Nanoparticle Research*, 2009, doi: 10.1007/s11051-009-9682-2.
- "Occupational Safety and Health in Nanotechnology and Organisation for Economic Co-operation and Development," Murashov, V.V., Engel, S., Savolainen, K., Fullam, B., Lee, M., Kearns, P. *Journal of Nanoparticle Research*, 2009, doi: 10.1007/s11051-009-9637-7.

### ***New Research Centres***

- The US National Science Foundation and US Environmental Protection Agency are jointly funding two Centres for Environmental Implications of Nanotechnology (CEIN) one led by Duke University and the other led by the University of California-Los Angeles. The centres are dedicated to elucidating the relationship between a vast array of nanomaterials—from natural, to manufactured, to those produced incidentally by human activities—and their potential environmental exposure, biological effects, and ecological consequences.
- The Duke-CEIN is collaboration between Duke, Carnegie Mellon University, Howard University, and Virginia Tech, and investigators from the University of Kentucky and Stanford University. Other US academic collaborations include ongoing activities coordinated with faculty at Clemson, North Carolina State, Rice, and Purdue universities. The Duke-CEIN performs fundamental research on the behaviour of nano-scale materials in ecosystems that will provide guidance in assessing existing and future concerns surrounding the environmental implications of nanomaterials.
- The UC-CEIN proposes to conduct predictive toxicological science for engineered nanomaterials in partnership with UC Santa Barbara, UC Davis, UC Riverside, Columbia University (New York), University of Texas (El Paso, TX), Nanyang Technological University (NTU, Singapore), the Molecular Foundry at Lawrence Berkeley National Laboratory, Lawrence Livermore National Laboratory, Sandia National Laboratory, the University of Bremen (Germany), University College Dublin (Ireland), and the Universitat Rovira I Virgili (Spain). The goal of the Centre is to develop a broad based model of predictive toxicology premised on quantitative structure activity relationships and nanomaterial injury paradigms at the biological level.

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

NIOSH is sponsoring an upcoming conference on “Nanomaterials and Worker Health: Occupational Health Surveillance, Exposure Registries, and Epidemiological Research”, which will be held in Colorado in July 2010. More information is available at <http://www.cdc.gov/niosh/topics/nanotgech/NanoConfJuly2010.html>.

NIST, NIOSH, NIEHS, and NCI co-sponsored an international Workshop on “Enabling Standards for Nanomaterial Characterization” held in Maryland in October 2008. More information is available at [http://csn.ncifcrf.gov/nist/Site/\\_html](http://csn.ncifcrf.gov/nist/Site/_html)

NIST and the Army Corps of Engineers co-sponsored a Workshop on Nano-silver Standardization held in Mississippi in April 2009. The goal of the workshop was to establish criteria for the selection of materials for the OECD nano-silver testing program. More information is available at <http://nanobiology.ncifcrf.gov/groups/silver/>

## EUROPEAN COMMISSION

### *Highlight of developments since the 5th meeting of the WPMN*

- May 2009 the Commission, JRC and ECHA established an Administrative Arrangement enabling the development of a technical basis for guidance to ECHA with respect to nanomaterials. Based on the methodology used to develop other guidance, a **REACH Implementation Project on Nanomaterials (RIPoN)** would be established and the timeframe is until end 2010. The three key tasks to be tackled are:
  - Substance Identification (based on 3 – 4 case studies)
  - Information requirements
  - Chemicals safety assessment

JRC and ECHA will lead the work and an expert group.

- **15-16 June:** The 2nd Meeting of the **Competent Authorities for REACH and Classification and Labelling (CARACAL)** took place in Brussels. The CARACAL is the main EU policy body regarding implementation of REACH and Classification and Labelling, including nanomaterials. The JRC-IHCP contributed to the discussions regarding the future scope and format of the Test Method Regulation, a central piece for the implementation of REACH and other regulations, the process for regulatory acceptance of methods in the EU and the new mandate and procedures for the EU National Coordinators Group.
- July As a follow-up to the European Food Safety Authority (EFSA) on "**The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety**"<sup>15</sup> this opinion, health and Consumer Directorate General (**DG SANCO**) gave EFSA mandate to elaborate a **guidance document for the safety assessment of applications of nanoscience and nanotechnologies to food**<sup>16</sup>, **feed and feed additives, and pesticides**. The mandate aims at offering legal predictability for sponsors of products and ensuring that EFSA has the means to assess products and deliver conclusive scientific opinions.

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<sup>15</sup> scientific opinion adopted on 10 February 2009 and published on 5 March 2009 [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1178680051172.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178680051172.htm)

<sup>16</sup> food additives, enzymes, flavourings, food contact materials, novel foods

- 7-8 July Since previous report **the REACH Competent Authorities subgroup on Nanomaterials** held a 3rd The CASG-NANO updates on activities in the OECD, ISO and CEN. The next meeting is tentatively scheduled to take place in December 2009.
- 8-9 July the JRC-IHCP in collaboration with the DG Enterprise (**DG ENTR**) organised and hosted the International Workshop on Regulatory Issues regarding the use of Nanotechnologies in Cosmetics. Participants came from the four International Cooperation on Cosmetic Regulation (**ICCR**) jurisdictions (Canada, EU, Japan and the USA) and represented regulatory bodies, industry associations and scientific committees/academia. The workshop dealt with regulatory issues regarding products in the field of cosmetics. In particular, the interface between scientific and regulatory questions was addressed in order to identify principles and constraints of the different regulatory frameworks and approaches to regulation.
- 10 September DG SANCO held a scientific hearing on the risk assessment of nanotechnologies<sup>17</sup>
- 9 October Stakeholder conference "**Nanomaterials on the market: What Regulators need to know**", organised by DG Environment (**DG ENV**) in cooperation with the Swedish Chemicals Agency (KemI) and the Swedish EU Presidency, in the context of a commissioned study<sup>18</sup>.

### ***INCOMING EVENTS***

- 3-4 November: Annual **Nano Safety for Success Dialogue** organised by DG SANCO. To discuss issues related to the use of nanotechnologies and to identify appropriate means for strengthening the guidance in support of the safe, integrated, and responsible development of these technologies. The 3<sup>rd</sup> Nano Safety for Success Dialogue will focus on case studies of specific applications that are already on the market.

### ***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's Communication on "Regulatory Aspects of Nanomaterials"<sup>19</sup> was discussed in the European Parliament (**EP**) and, on 24 April the EP adopted a resolution in response. The resolution considers that it is particularly important that relevant legislations (such as REACH) will address explicitly nanomaterials within their scope. Moreover, the EP had introduced legal provisions in the two legislative proposals on Cosmetics and Food.

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

The European Commission has not developed any voluntary programmes or stewardship schemes. However, the Directorate General for Environment has requested a contractor to make a survey on what nanomaterials exist on the EU market and in what quantities. This was followed by a study presented in a

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<sup>17</sup> See paragraph 6 for details

<sup>18</sup> <http://nanomaterialsconf.eu/> See paragraph 2 for details

<sup>19</sup> See previous TdT highlights; according to the Commission Communication, existing EU legislation covers in principle the potential health, safety and environmental risks in relation to nanomaterials

Conference in autumn 2009<sup>20</sup>. The study being carried out by Milieu and Risk & Policy Analysts is aimed at assessing whether the reporting requirements under the REACH Regulation are adequate for gathering the necessary information to address potential risks associated with nanomaterials on the EU market today in order to ensure safe use. The study considers whether additional information from industry is needed and, if so, how this information could be gathered.

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

7th EU Research Framework Programme (FP7). A High-Level Experts Group of Member States and FP7 Associated States has held their second meeting in June 2009. Research in the area of risk management, in particular the study of the impact of nanoparticles to health and environment, has been agreed as a priority.

The European Commission is working towards clustering the safety related projects in view of joint elaboration of common deliverables and strategic planning. Several meetings have been held and about 30 EC and national projects are members. The cluster welcomes international cooperation.

The second call for proposals in the 7th EU Research Framework Programme (FP7) was completed and the five proposals selected are being launched:

- Impact of engineered nanoparticles on health and the environment

**ENNSATOX:** Engineered Nanoparticle Impact on Aquatic Environments: Structure, Activity and Toxicology

**ENPRA:** Risk Assessment Of Engineered Nanoparticles

**HINAMOX:** Health Impact of Engineered Metal and Metal Oxide Nanoparticles: Response, Bioimaging and Distribution at Cellular and Body Level

**INLIVETOX:** Intestinal, Liver and Endothelial Nanoparticle Toxicity Development and evaluation of a novel tool for high-throughput data generation

**NEPHH:** Nanomaterials Related Environmental Pollution And Health Hazards Throughout Their Life Cycle

The third call addressed:

- Proposals on use, recycling and final treatment of nanotechnology based products as well as coordination on exposure scenario to nanoparticles.
  - Five proposals currently being negotiated.
  - Another proposed project is under negotiation dealing with nanoparticles detection in food
- Activities towards the development of appropriate solutions for the use, recycling and/or final treatment of nanotechnology-based products (Joint call with Theme 6: 'Environment - Climate Change')

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<sup>20</sup> "Nanomaterials on the market: What Regulators need to know" paragraph 1, proceedings not available yet

- Four proposals selected for negotiation
- Exposure scenario to nanoparticles
  - One proposal selected for negotiation
- Analytical tools for characterisation of nano-particles in the food Matrix
  - One proposal selected for negotiation

The fourth FP7 – NMP calls now open include i.a. :

- methods for managing the risk of Engineered Nanoparticles (**ENs**)
- modelling toxicity behaviour of ENs (joint call with USA)
- Coordination of national programmes on nanotechnologies including nanotoxicology
- Support to dialogue for responsible social acceptance of nanotechnology

The call now open on Capacities includes infrastructure integration on the impact of ENs on health and environment.

### ***Research on materials science***

Five projects already selected in the first FP7 call are now up and running<sup>21</sup>. They relate to polymer nanocomposites, nanotubes and nano-structured polymer matrix composites.

- Processing and up scaling of nanostructured materials

Two of these projects are already running (namely **NANOCLEAN** and **SIMBA**), other three (namely **ADVANCE-FP**, **THEMA-CNT** and **POLYFIRE**) are expected to start very soon.

Several proposals coming from last year's call are currently under negotiation

- Nano-structured materials based on grapheme
- Oxide materials for electronics applications
- New biomass-based composite materials and their processing

6 proposals selected by panel of experts are undergoing negotiations

These projects are expected to start in the very near future.

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

The Commission considers that dialogue is indispensable for emerging technologies such as nanotechnologies. DG SANCO launched a **public consultation** that was finalised on the Scientific

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<sup>21</sup> ref previous TdT highlights

Hearing on Risk Assessment of Nanotechnologies<sup>22</sup>. The Hearing enabled to discuss the scientific comments and questions of stakeholders and, through this dialogue, to support the future work of the independent Scientific Committees of the European Commission in the area of risk assessment of nanotechnologies. Specifically, the main objectives were (i) to identify scientific topics that had not yet been addressed, (ii) to determine the main potential risks that could emerge from the use of nanomaterials in the future, and (iii) to acquire relevant background information on those issues. A wide range of stakeholders - including members of the EC scientific committees, NGOs, industry representatives and concerned citizens- attended the hearing.

## **BUSINESS AND INDUSTRY ADVISORY COMMITTEE (BIAC)**

### ***PART I: ACC***

The American Chemistry Council Nanotechnology Panel (Panel) presented at numerous national and international presentations and workshops on nanotechnology and manufactured nanomaterials. Presentations ranged from technical workshops focusing on the health and environmental aspects of specific nanomaterials to policy meetings on US and global approaches for conducting risk assessments and developing regulatory policies. The Panel and the California Nano Industry Network in conjunction with the California Department of Toxic Substances Control are planning a workshop in Sacramento, California on November 16, 2009 to discuss California's data call-in for carbon nanotubes and exchange related information.

The Panel continued to support and participate in the voluntary EPA Nanoscale Materials Stewardship Program (NMSP). The Panel continues to discuss with EPA the further implementation of the Toxic Substances Control Act (TSCA) authorities to collect data and implement test rules for specific types of manufactured nanomaterials and the data to be generated by the contributions of BIAC to the OECD testing program. EPA and the Panel continue to discuss risk and exposure related research follow up activities.

The Panel continued to provide input to the reauthorization process of the US National Nanotechnology Initiative. While the NNI reauthorization legislation has been approved by the US House of Representatives, the Panel is encouraging its passage in the Senate before the end of 2009. The Panel supports the NNI reauthorization and seeks to build upon the National Research Council review and recommendations for the NNI environment, health, and safety (EHS) program. Focusing on supporting increased funding and prioritization of EHS research at the federal level, the Panel continues to support the development of a comprehensive roadmap for EHS federally funded research with progress markers clearly identified that are measurable over specified time intervals.

ACC and its Nanotechnology Panel support the modernization of TSCA. ACC prepared a list of basic principles for TSCA modernization for use in Congressional and other discussions on chemicals management policies. See: [www.americanchemistry.com](http://www.americanchemistry.com) and <http://www.americanchemistry.com/nanotechnology> for additional information.

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<sup>22</sup> on 10 September 2009 also ref. paragraph 1 [http://ec.europa.eu/health/nanohearing\\_en.htm](http://ec.europa.eu/health/nanohearing_en.htm)

## ***PART II: CEFIC***

### ***Highlights***

- Active contribution of industry to national and international regulatory initiatives to effectively manage nanomaterials and nanotechnologies
- Through its Long-range Research Initiative (LRI), Cefic sponsors safety research on nanomaterials
- External stakeholder events and projects on nanomaterials and nanotechnologies

### ***Background***

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

### ***Work underway or planned***

To achieve their vision for sustainable nanomaterials and nanotechnology, Cefic is undertaking a range of activities. A few of these activities are highlighted below:

#### ***National and regional regulatory developments on human health and environmental safety including recommendations or discussions related to implementing, and if needed adapting, existing regulatory systems and the drafting of guidance materials***

Cefic and its members actively contribute to the REACH Competent Authority subgroup on nanomaterials, initiated by the REACH Competent Authority Meeting. The aim of the subgroup is to consider how the provisions of REACH and its guidance documents could be applied to nanomaterials. Cefic will contribute to the 3 RIPS on nanomaterials, one will start in 2009 on Substance Identity.

Cefic continues to contribute to the public debate regarding nanomaterials by providing scientific input to discussions on risk assessment methodologies and risk assessment measures to adequately control potential risks with nanomaterials.

Through close collaboration with its national member federations Cefic contributes to nanomaterials and nanotechnology management discussions at the national level. At the international level, Cefic works through the ICCA (International Council of Chemical Associations) to contribute to such initiatives at the global level.

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

Through its Long-range Research Initiative (LRI), Cefic sponsors health and environment safety research on nanomaterials. For example, one project led by Dr Otto Creuzenberg at the Fraunhofer Institute

will test the suitability of OECD testing guidelines for nano zinc oxide and nano amorphous silicium dioxide particles and define a tiered testing strategy for these nanoparticles.

In order to address regulatory and public concerns, industry is evaluating in another Cefic-LRI research project the ecological risks that maybe associated with nanoparticles. Currently accepted testing strategies will be evaluated, supplemented and improved, where needed, to address potential nano-specific effects focusing on ecologically relevant exposures. Through the LRI, the European chemical industry is sponsoring a project on the “assessment of nanoparticle specific effects in environmental toxicity testing”. The research is being led by the group of Dr Alistair Boxall, at the University of York. The outcomes of the project will help determine the environmental impact of nanomaterials in aquatic systems.

Both projects are contributions of Cefic (via BIAC) to the Sponsorship Program of the OECD Working Party of Manufactured Nanomaterials and started in December 2008 and will be finalized in December 2010. For more information visit <http://www.cefic-lri.org>

Still another Cefic-LRI project about to be launched is on testing and assessment of reproductive toxicity of Nanomaterials. The overall objective of this proposal is to analyze the suitability of current OECD guidelines to assess the reproductive toxicity of nanomaterials. Using two reference materials, present on the OECD list of ‘representative manufactured nanomaterials for testing’ (1), nano silicium dioxide and nano zinc oxide, the ability of current reproductive toxicity OECD guidelines to identify hazard associated with nanomaterials will be tested in this project. The results of this project should address the following questions: do the existing OECD reproductive toxicity test guidelines adequately assess a potential hazard posed by nanoparticles, can the existing guidelines benefit from some revisions to better understand health risks posed by nanoparticles, and are there endpoints used to assess the potential hazard of industrial chemicals which may be inappropriate for testing nanoparticles?

### ***Stakeholder Engagement***

In June 2008, Cefic organized an external stakeholder event. The aim was to facilitate an open and frank exchange of information so that industry, policy makers and other stakeholders can gain a better understanding about each other’s point of view. Four chemical companies shared detailed information on four real-life nano-enabled products, discussing how and why nanomaterials work inside the product to improve its functionality and how they are tested for safety across their life cycle. This event will be followed up in the first half of 2009 with smaller, more focussed “stakeholder participative projects” where a maximum of 10-15 stakeholders will work together on pre-consulted projects. Possible projects currently under discussion include a review of the global chemical industry’s Responsible Care<sup>®</sup> Program to assess how it addresses novel technologies, with a focus on nanotechnologies – and to make suggestions for adaptation where appropriate. Cefic has set up a “Cross Industry Platform” for organisations which have an interest in nanomaterials either as producers or downstream users. This platform will give possibilities to exchange views and information about all aspects of the nanomaterial issues at European and international level.

### ***PART III: JCIA***

The Japan Chemical Industry Association (through its Working Group to Address New Issues) has been working toward the sound development of nanotechnology while keeping a close eye on safety evaluation related programs both here in Japan and overseas based on the action plan for the “Written Opinions regarding Nanomaterials,” which was formulated in July, 2008.

The specific activities we have been engaged in are as follows:

1. JCIA participated in study groups on nanomaterials safety that were initiated by the Ministry of Economy, Trade and Industry (METI), Ministry of Health Labour, and Welfare (MHLW), and Ministry of the Environment (MOE) in 2008, and was actively involved in formulating the reports that were drafted by making suggestions and proposals on behalf of the chemical industry.

Reports formulated by the three ministries:

METI: Study Group on the Proper Form of Safety Measures at Nanomaterials Manufacturers;

MHLW: Notification on preventive measures for the prevention of exposure for nanomaterials;  
and

MOE: Guideline for Preventing Environmental Impact from Industrial Nanomaterials.

All of these reports were published in March 2009, with notifications being sent to all relevant organizations and industries.

1. As part of the above activities, METI issued an advisory to the relevant manufacturers associations asking that companies voluntarily report safety information regarding the following six nanomaterials: titanium oxide, zinc oxide, silica, carbon black, CNT, and fullerene. The associations have responded to the request by actively preparing information for a report to be submitted by the end of September regarding the safety, voluntary control conditions, production quantities, and uses of these nanomaterials.
2. In 2009, some researchers also reported the results of safety evaluations in Japan, but these are not necessarily scientifically valid. JCIA collected opinions regarding such reports to help the manufacturers concerned, while also acting as a media liaison.
3. JCIA sent an expert to attend ISO Technical Committee (TC) 229, held in Seattle in June 2009, to contribute suggestions regarding analytical problems arising in the discussion of standardization for TiO<sub>2</sub>.
4. Representatives of JCIA have attended meetings concerning projects being undertaken by the “Study Session on Research on the Utilization and Communication of Information for the Promotion of Public Acceptance” and “Japanese National Committee for ISO/TC229,” which are groups within the Advanced Industrial Science and Technology (AIST) that were established to follow up on OECD-related issues. JCIA has been offering their opinions to these groups as an active member since June and September 2008, respectively.

#### ***PART IV: VCI***

The German Chemical Industry has committed itself to a responsible production and use of nanomaterials. To support member companies, and customer companies in the value chain, to manage the health, safety and environmental aspects of nanomaterials throughout the life cycle, the German Chemical Industry Association VCI has issued the following series of documents in February 2008. They provide guidance on all aspects of a good product stewardship on nanomaterials.

#### ***Principle documents:***

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

***Regulatory documents:***

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

***Documents on safety research:***

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

These documents have been discussed with the public as well as national and European authorities and have been received by the OECD Working Party on Manufactured Nanomaterials (WPMN). The documents will be regularly updated and adapted to new developments.

Together with its sector groups VCI will present the results of research on potential release of nano particles from end products probably by 2010.

To track the implementation of its guidance and recommendations VCI is currently conducting a survey within its membership of how the VCI guidance documents are implemented in chemical companies dealing with nanomaterials. The results of the survey will be shared with the national and international community.

In 2006 VCI and the German Federal Institute of Occupational safety and health (BAuA) have already conducted survey on how industry is dealing with nanomaterials on a workplace safety. This survey is now carefully reviewed and reissued with an extended scope. First results will be deliverable by 2010.

VCI and the chemical industry are deeply engaged in the second phase of the dialogue activities called “Nano-Dialog” of the German government. Led the high levelled “NanoCommission” the “NanoDialog” sets its mission giving advice on monitoring the implementation of guidance for responsible handling and use of nanomaterials, evaluating measures to assess life cycle performance of nanomaterials, discussing risk assessment, and regulatory issues. The results of these activities will be fed into the international discussion.

Having discussed the issue within its membership, VCI plans to continue its engagement in stakeholder dialogue activities in the field of nanomaterials and environment. In 2010 a workshop with stakeholders and authorities will be held.

Furthermore VCI and its membership are supporting and sponsoring the international workshop on “Workplace aerosols” held in Karlsruhe, Germany in April 2010.

[www.vci.de](http://www.vci.de)

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

#### **THE INTERNATIONAL ORGANISATION FOR STANDARDIZATION TECHNICAL COMMITTEE- NANOTECHNOLOGIES (ISO/TC 229)**

The International Organisation for Standardization Technical Committee (ISO/TC) 229 - Nanotechnologies - was established in June 2005 with a UK secretariat and chair. It has held eight meetings to date - November 05 in London, June 06 in Tokyo, December 06 in Seoul, June 07 in Berlin, December 07 in Singapore, May 08 in Bordeaux, France, November 08 in Shanghai and June 09 in Seattle. The next meeting will be in October 2009 in Tel Aviv, Israel. The committee currently has 41 members - 32 "P" and 9 "O". The first two documents developed by the committee were published in 2008: ISO/TS 27687 – Nanotechnologies – Terminology and definitions for nano-objects – nanoparticle, nanofibre and nanoplate; and ISO/TR 12885 – Nanotechnologies - Health and safety practices in occupational settings relevant to nanotechnologies

The TC structure consists of 4 working groups (WG), the first two of which are Joint Working Groups (JWG) with IEC/TC 113 (Nanotechnology standardization for electrical and electronic products and systems): Terminology and Nomenclature (JWG1, convened by Canada); Measurement and Characterization (JWG2, convened by Japan); Health, Safety and Environment Aspects of Nanotechnologies (WG3, convened by USA), and Material Specifications (WG4, convened by China). The work programme at 16th September 2009 contained 37 work items – 7 in JWG1, 15 in JWG2, 9 in WG3, 5 in WG4 and 1 unallocated (Annex 1). Of the existing work items, the most relevant to the WPMN are those in WG3, though both the terminology work, in JWG1, which now includes an approved work item on nomenclature models for nano-objects, and the measurement and characterization work, in JWG2, have broad relevance.

The committee has Task Groups that are developing recommendations as to how it should address the areas of Nanotechnologies and Sustainability, and Consumer and Societal Dimensions of Nanotechnologies. Task Groups are disbanded once they have completed their work.

The TC works closely with the IEC (International Electrotechnical Commission) TC 113, chaired by the US, with Germany providing the secretariat. The two Technical Committees hold joint plenary meetings at least every two years, starting in December 2007. TC 229 also works closely with the CEN (European Committee for Standardization) TC in the area (TC 352 – Nanotechnologies, also chaired by UK), using the Vienna agreement where appropriate. Liaisons have been established with 25 other ISO TC's, with the OECD (Working Party on Manufactured Nanomaterials and Working Party on Nanotechnology), with the International Bureau of Weights and Measures (BIPM), with the EC Joint Research Centres (IRMM and Institute for Health and Consumer Protection, Ispra), with the Asia Nano Forum and with VAMAS.

Given the number of ISO and other committees and working parties with an interest in nanotechnologies standardization, and in particular in the development of test methods for measurement and characterization, the committee has established a Nanotechnology Liaison Coordination Group to ensure coordination of activities and harmonization of deliverables amongst liaison organisations. This group meets during the twice yearly plenary meetings of the committee.

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

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

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

Acceptance requires

- a) minimum of 5 P-members approving the work item and giving a commitment to participate actively in the development of the project; and
- b) approval of the work item by a simple majority of the P-members of the technical committee or subcommittee voting.

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

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

the WPMN are strongly encouraged to contact their national representatives on ISO/TC 229 in order to coordinate activities in this area. A list of national contact points for ISO/TC 229 is available on the password protected website of the WPMN.

## **ANNEX: ISO/TC 229 WORK PROGRAMME AT 16TH SEPTEMBER 2009**

### JWG1

- ISO/TR: Terminology and nomenclature for nanotechnologies — Framework and core terms - **approved for publication**
- ISO/TS: Terminology and definitions for carbon nanomaterials – **approved for publication**
- ISO/TS: Core Terms - Terminology and Definitions
- ISO/TS: Terminology and definitions for nanostructured materials
- ISO/TS: Terminology for the bio-nano interface
- ISO/TS: Terminology for nanoscale measurement and instrumentation
- ISO/TS: Terminology for medical, health and personal care applications of nanotechnologies
- ISO/TS: Terminology for nanofabrication/ nanomanufacturing
- ISO/TR: Nomenclature Models for nano-objects

### JWG2

- ISO/TS: The Use of Transmission Electron Microscopy (TEM) in the Characterization of Single-walled Carbon Nanotubes
- ISO/TS: The Use of Scanning Electron Microscopy (SEM) and Energy Dispersive X-ray Analysis (EDXA) in the Characterization of Single-walled Carbon Nanotubes
- ISO/TS: Technical Specification for the Use of UV-Vis-NIR absorption spectroscopy in the Characterization of Single-walled Carbon Nanotubes
- ISO/TS: Technical Specification for the use of NIR-Photoluminescence (NIR-PL) Spectroscopy in the Characterization of Single-Walled Carbon Nanotubes
- ISO/TR: Use of Thermo Gravimetric Analysis (TGA) in the purity evaluation of Single Walled Carbon Nanotubes

- ISO/TR: Use of Evolved Gas Analysis-Gas Chromatograph Mass Spectrometry (EGA-GCMS) in the Characterization of Single-Walled Carbon Nanotubes
- ISO/TS: Use of Raman Spectroscopy in the Characterization of Single Walled Carbon Nanotubes.
- ISO/TS: Measurement Methods for the Characterization of Multi-Walled Carbon Nanotubes
- ISO/TR: Guide to nanoparticle measurement methods (Joint development with CEN TC 352 – CEN led)
- ISO/TR: Guide to methods for nano-tribology measurements (Joint development with CEN TC 352 – CEN led)
- ISO/TS: Determination of meso-scopic shape factors of multiwall carbon nanotubes (MWCNTs)
- ISO/IS: General framework for determining nanoparticle content in nanomaterials by generation of aerosols
- ISO/TS: Electrical resistance of carbon nanotubes using 4 probe measurement
- ISO/TS: Artificial gratings used in nanotechnology - description and measurement of dimensional quality parameters
- ISO/TS: Carbon nanotubes - Determination of metal impurities in carbon nanotubes (CNTs) using inductively coupled plasma-mass spectroscopy (ICP-MS)

### WG3

- ISO/IS: Endotoxin test on nanomaterial samples for in vitro systems -- Limulus amoebocyte lysate (LAL) test
- ISO/IS: Standard for Generation of Metal Nanoparticles with the Evaporation/Condensation Method for inhalation toxicity testing
- ISO/IS: Standard for characterization of nanoparticles in inhalation exposure chambers for inhalation toxicity testing
- ISO/TR: Guidance on physico-chemical characterization of engineered nanoscale materials for toxicologic assessment (Harmonized with WPMN list – working closely to ensure that we complement each other's work and avoid duplication)
- ISO/TS: Guidance on safe handling and disposal of manufactured nanomaterials
- ISO/TR: Nanomaterial risk evaluation framework
- ISO/TS: Guidelines for occupational risk management of nanomaterials based on a "control banding" approach

- ISO/TR: Preparation of Material Safety Data Sheet (MSDS) for nanomaterials
- ISO/TS: Surface characterization of gold nanoparticles for nanomaterial specific toxicity screening - FT-IR method

#### *WG4*

- ISO/TS: Material specification - Nano-calcium carbonate, Part 1 – General requirements
- ISO/IS: Material specification - Nano-titanium dioxide, Part 1 – General requirements
- ISO/TS: Nanomaterial calcium carbonate (powdered form) — Part 2: Specifications for specific applications
- ISO/TS: Nanomaterial titanium dioxide (powdered form) — Part 2: Specifications for specific applications
- ISO/TS: Guidance on specifying nanomaterials.

#### *Unallocated*

- ISO/TS: Guidance on labelling of manufactured nanoparticles and products containing manufactured nanoparticles (Joint development with CEN TC 352 – CEN led).

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

Dr Peter Hatto, Chairman, 16<sup>th</sup> September 2009

## **THE FOOD AND AGRICULTURE ORGANISATION OF THE UNITED NATIONS (FAO) AND THE WORLD HEALTH ORGANISATION (WHO)**

### **Highlight of developments since the 5<sup>th</sup> meeting of the WPMN**

1. Joint FAO/WHO Expert Meeting on the Application of Nanotechnologies in the Food and Agriculture Sectors: Potential Food Safety Implications, Rome, 1-5 June 2009
2. Publication of the above mentioned meeting report (available online in November 2009, print available in December 2009)
3. A potential follow-up activity planned for establishment of an e-Discussion Group to develop the “Tiered Approach Diagram for Risk Assessment of Nanomaterials (NMs)”
4. FAO/Brazil conference on nanotechnologies in the food and agriculture sectors (San Carlos Brazil, 20 - 24 June 2010).

### **Activities on health and environmental safety aspects of manufactured nanomaterials**

1. Joint FAO/WHO Expert Meeting on the Application of Nanotechnologies in the Food and

Agriculture Sectors: Potential Food Safety Implications, Rome, 1-5 June 2009

The overall purpose of the Expert Meeting was to provide Member countries with comprehensive information on what is currently known about potential food safety risks, to identify priority areas of work required to better assess these risks and to advise on ways to promote transparent and constructive dialogue among stakeholders. The Expert meeting:

- reviewed actual and anticipated applications of nanotechnologies in the food and agriculture sectors;
- identified potential food safety implications associated with actual and anticipated applications of nanotechnologies in the food and agriculture sectors;
- determined the need for additional tools or metrics and to identify any data requirements and research gaps;
- considered the application of current risk assessment methodologies to evaluate the safety of nanomaterials used in the food chain;
- identified priority areas for which scientific advice should be requested from FAO/WHO in accordance with their Joint framework for the provision of scientific advice; and
- advised on ways and means of fostering transparent and trustful dialogue among all stakeholders.

2. Publication of the above mentioned meeting report

The report will be available online in November 2009 and the printed version will be available in December 2009. Following are key points of the results from the executive summary of the report:

Use of nanotechnology

- Nanotechnology based food and health food products, and food packaging materials are available to the consumers in some countries already today, and additional products and applications currently in research and development, may reach the market soon. In view of such progress, it is expected that nanotechnology-derived food products will be increasingly available to the consumers worldwide in the coming years.
- Materials that are intentionally produced with structural features at a nanoscale range (between 1 and 100 nm) may have different properties when compared with their conventional counterparts. They will be employed in a variety of applications e.g. in food packaging materials where they shall prevent microbial spoilage of food, as food additives modifying e.g. a food's texture and taste, in nutrients (vitamins) leading to increased bioavailability, in agrochemicals where they would provide novel routes to deliver pesticides to plants. The impact on human health will depend whether and how the consumer eventually is exposed to such material and whether this material will behave differently.
- The Expert Meeting recognized the need to agree on clear and internationally-harmonized definitions related to the application of nanotechnologies to the food chain and to develop a procedure for classifying nanostructures that would assist risk managers. At international level possible gaps in the food standard setting procedures as applied by the Codex Alimentarius Commission need to be identified and addressed.

Assessment of human health risks

- The Expert Meeting acknowledged that the current risk assessment approaches used by FAO/WHO and Codex are suitable for engineered nanomaterials used in food and agriculture and emphasized that additional safety concerns may arise due to the

characteristic properties of nanomaterials which need to be addressed.

- Due to their specific chemico-physical properties, it is to be expected that nanoparticles could interact with other substances present in foods such as proteins, lipids, carbohydrates, nucleic acids. Therefore, it is important that the effects and interactions of engineered nanomaterials are characterized in the relevant food matrix.
- The experts agreed that FAO/WHO should continue to review its risk assessment approaches, in particular through the use of tiered approaches, in order to address the specific emerging issues associated with the application of nanotechnologies in the food chain. A tiered approach might enable the prioritization of types or classes of materials where additional data are likely to be necessary to reduce uncertainties in the risk assessment.

#### Stakeholder confidence and dialogue

- The Expert Meeting analysed the general aspects required for an engagement of stakeholders which is acknowledged as imperative for any emerging or controversial issue in the area of food safety.
- The experts recognized that consumer attitudes toward nanotechnology applications in food and agriculture are complex: they want to understand the potential risks and benefits of nanotechnology and they want clear tangible benefits. Without obvious benefits, consumers are unlikely to have positive impressions towards nanotechnology-enhanced food products.
- The meeting proposed that FAO/WHO should provide a forum for continued international dialogue to develop strategies to address stakeholder issues surrounding the development of nanotechnologies in food and agriculture.
- The meeting also agreed that FAO/WHO should encourage Member countries to engage the public on applications of nanoscience and the nanotechnologies in food and agriculture.
- In recognition of the importance for trust building, the experts proposed to FAO/WHO to identify mechanisms to support the need for transparency and traceability of nano-enabled products or engineered nanomaterials in food and agriculture and their associated risks. The importance of communication and co-operation with other inter-governmental organizations was stressed.

3. A potential follow-up activity planned for establishment of an e-Discussion Group to develop the “Tiered Approach Diagram for Risk Assessment of Nanomaterials (NMs)”

Based on the recommendation made by the experts during the above mentioned expert meeting (the 3<sup>rd</sup> bullet point under “Assessment of human health risks”), FAO and WHO are currently considering the establishment of an e-Discussion Group for the possible development of “Tiered Approach Diagram for Risk Assessment of Nanomaterials (NMs)”. The overall objective of this activity is to seek further scientific advice from the experts on the use of a tiered risk assessment approach for application of nanotechnologies to food and feed.

4. FAO/Brazil conference on nanotechnologies in the food and agriculture sectors (San Carlos, Brazil, 20 – 24 June 2010).

Based on the recommendation made by the experts during the above mentioned expert meeting (the 3<sup>rd</sup> bullet point under “Stakeholder confidence and dialogue”), FAO is currently planning to organize in collaboration with the Ministry of Agriculture of Brazil (EMBRAPA) an International Conference on Food and Agricultural Applications of Nanotechnologies, which is tentatively planned for June 20 to 24, 2010 in São Carlos, SP, Brazil.

New and emerging applications of nanotechnologies in food and agriculture and issues related to their use will be the focus of this Conference. In addition to exploring relevant scientific and technological advances, the Conference will also seek to highlight areas of research with the greatest potential to benefit society. The overall objectives of the Conference are to:

- Provide a vehicle for debate among all stakeholders on priority areas for development of nanotechnologies relevant to food and agriculture
- Identify priority areas of research and development that are considered to have the greatest potential to contribute to the achievement of Development Goals
- Consider the social/ethical implications of Nanotechnologies applied in food, agriculture and sectors
- Consider the legal and business issues which influence the transition from research to commercialization of nanotechnologies
- Promote collaborative research among countries on issues of common interest
- Promote a harmonized approach toward the assessment and management of potential human health and environmental risks that may be associated with the use of nanotechnologies in the areas of food, agriculture, health and other sectors.

### **Additional Information**

The FAO international technical conference on: Agricultural biotechnologies in developing countries: Options and opportunities in crops, forestry, livestock, fisheries and agro-industry to face the challenges of food insecurity and climate change (ABDC-10)

FAO international technical conference on Agricultural Biotechnologies in Developing Countries (ABDC-10) will be held from 1 to 4 March 2010 in Guadalajara, Mexico. The conference touches the topics in the area of agriculture, which includes the production of crops, livestock, fish and forestry products, with a direct impact on the rural economy and therefore investment in agriculture. While the measures needed extend well beyond the issue of producing more food and agricultural products, boosting productivity of smallholders' farms through appropriate application of good practices and improved technologies must be a key ingredient of developing countries' development policies. Thus it is very likely that the application of nanotechnologies in the food and agriculture sectors will be discussed during this event. For more detail about this conference, see <http://www.fao.org/biotech/abdc/>.