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

CURRENT DEVELOPMENTS/ACTIVITIES ON THE SAFETY OF MANUFACTURED NANOMATERIALS

**Tour de Table at the 8th Meeting of the Working Party on Manufactured Nanomaterials
16-17 March 2011, Paris, France**

**No. 29
Series on the Safety of Manufactured Nanomaterials**

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Series on the Safety of Manufactured Nanomaterials

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IOMC

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, 2011

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)*

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No. 22, *OECD Programme on the Safety of Manufactured Nanomaterials 2009-2012: Operational Plans of the Projects (2010)*

No. 23, *Report of the Questionnaire on Regulatory Regimes for Manufactured Nanomaterials (2010)*

No. 24, *Preliminary Guidance Notes on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials (2010)*

No. 25, *Guidance Manual for the Testing of Manufactured Nanomaterials: OECD Sponsorship Programme: First Revision (2010)*

No. 26, *Current Development/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 7th Meeting of the Working Party on Manufactured Nanomaterials (2010)*

No. 27, *List of Manufactured Nanomaterials and List of Endpoints for Phase One of the Sponsorship Programme for the Testing Manufactured Nanomaterials: Revised (2010)*

No. 28, *Compilation and Comparison of Guidelines Related to Exposure to Nanomaterials in Laboratories (2010)*

ABOUT THE OECD

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

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

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

This publication is available electronically, at no charge.

For this and many other Environment, Health and Safety publications, consult the OECD's World Wide Web site (www.oecd.org/ehs/)

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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 8th Meeting in March 2011. This document is published under the responsibility of the Chemicals Committee of the OECD. It is intended to provide information on the outcomes and developments of the WPMN related to the safety of manufactured nanomaterials.

TABLE OF CONTENTS

THE WORKING PARTY ON MANUFACTURED NANOMATERIALS (WPMN)

The Working Party on Manufactured Nanomaterials[1] was established in 2006 to help member countries efficiently and effectively address the safety challenges of nanomaterials. OECD has a wealth of experience in developing methods for the safety testing and assessment of chemical products.

The Working Party brings together more than 100 experts from governments and other stakeholders from: a) OECD Countries; b) non-member economies such as China, the Russian Federation, Singapore, South Africa, and Thailand; and c) observers and invited experts from UNITAR, FAO, WHO, ISO, BIAC[2], TUAC[3], and environmental NGOs.

Although OECD member countries appreciate the many potential benefits from the use of nanomaterials, they wished to engage, at an early stage, in addressing the possible safety implications at the same time as research on new applications are being undertaken.

The Working Party is implementing its work through specific projects to further develop appropriate methods and strategies to help ensure human health and environmental safety:

- OECD Database on Manufactured Nanomaterials to Inform and Analyse EHS Research Activities;
- Safety Testing of a Representative Set of Manufactured Nanomaterials;
- Manufactured Nanomaterials and Test Guidelines;
- Co-operation on Voluntary Schemes and Regulatory Programmes;
- Co-operation on Risk Assessment;
- The role of Alternative Methods in Nanotoxicology;
- Exposure Measurement and Exposure Mitigation; and
- Environmentally Sustainable Use of Manufactured Nanomaterials

Each project is being managed by a steering group, which comprises members of the WPMN, with support from the Secretariat. Each steering group implements its respective "operational plans", each with their specific objectives and timelines. The results of each project are then evaluated and endorsed by the entire WPMN.

More information about the work of the WPMN, as well as OECD's publications regarding safety issues of nanomaterials, is available at www.oecd.org/env/nanosafety.

[1] Updated information on the OECD's Programme on the Safety of Manufactured Nanomaterials is available at: www.oecd.org/env/nanosafety

[2] The Business and Industry Advisory Committee to the OECD

[3] Trade Union Advisory Committee to OECD

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 7th meeting held 7-9 July 2010 in Paris, France. This document compiles information provided by member countries and other delegations on current developments on the safety of manufactured nanomaterials (section I) in their countries or 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 II).

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 8th meeting of the WPMN (March 2011).

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

Background

The purpose of 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 facilitates the implementation of the projects of the WPMN by allowing delegations to share their experiences and preoccupations with respect to safety, and identifies opportunities for future co-operation and co-ordination.

At with 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 are 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* [ENV/JM/MONO(2010)42].

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 7th meeting of the WPMN (July 2010) 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 7th meeting of the WPMN (July 2010) as highlights to appear at the top of your document:

Highlight of developments since the 7th meeting of the WPMN

- Request for information on nanomaterials issued on…..…… (Day/Month/20XX)
-

2) Secondly, please 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).

Work completed, underway or planned

1. Any national regulatory developments on human health and environmental safety including recommendations or discussions related to adapting existing regulatory systems or the drafting of laws/ regulations/ guidance materials;
2. Developments related to voluntary or stewardship schemes;
3. Information on any risk assessment decisions;
4. Information on any developments related to good practice documents;
5. Information on any developments related to Integrated Testing Strategies and/or Alternative test methods;
6. Research programmes or strategies designed to address human health and/ or environmental safety aspects of nanomaterials;
7. Information on any public/ stakeholder consultation; and
8. Information on research programmes or strategies which focus on life cycle aspects of nanomaterials, as well as positive and negative impacts on environment and health of certain nano-enabled applications.

Additional Information

Delegations are invited to provide any additional information, for example on:

> Any consideration on the benefits of nanotechnologies;
> Consideration of ethical implications; and
> Information on past, current and future activities on nanotechnologies that are being done in your respective countries in co-operation on a bilateral basis with non-OECD countries.

RESPONSES FROM DELEGATIONS

AUSTRALIA

Highlight of developments since the 7th meeting of the WPMN

- The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) has introduced a working definition for industrial nanomaterials and new administrative arrangements for regulating nanoforms of new chemicals, effective from 1 January 2011.
- Safe Work Australia is implementing a Nanotechnology Work Health and Safety Program. Six research reports and a work health and safety assessment tool for handling engineered nanomaterials have been published.
- Safe Work Australia and the Department of Innovation, Industry, Science & Research (DIISR) hosted the Nanotechnology Work Health and Safety Symposium on 9-10 September 2010. The symposium brought together a wide range of stakeholders, and featured presentations on projects commissioned under the Nanotechnology Work Health and Safety Program and panel discussions to examine the implications of the research findings and options for addressing work health and safety issues in nanotechnology.
- FSANZ has completed a review 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 government regulator for industrial chemicals, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), has developed a strategy for the regulation of industrial nanomaterials. NICNAS has completed its first round of public consultation on a discussion paper for regulatory reform in 2010. The proposal presented in this discussion paper utilised the existing industrial chemicals regulatory framework and proposed some adjustments to address uncertainties in the potential risks posed by these substances. Individual submissions and a summary of issues with corresponding NICNAS responses are available on the NICNAS website.

NICNAS has developed and obtained stakeholder agreement on a working definition for industrial nanomaterials as follows:

… industrial materials intentionally produced, manufactured or engineered to have unique properties or specific composition at the nanoscale, that is a size range typically between 1 nm and 100 nm, and is either a nano-object (i.e. that is confined in one, two, or three dimensions at the nanoscale) or is nanostructured (i.e. having an internal or surface structure at the nanoscale)"

[Explanatory Notes to the working definition:

- intentionally produced, manufactured or engineered materials are distinct from accidentally produced materials
- 'unique properties' refers to chemical and/or physical properties that are different because of its nanoscale features as compared to the same material without nanoscale features, and result in unique phenomena (e.g. increased strength, chemical reactivity or conductivity) that enable novel applications.
- aggregates and agglomerates are considered to be nanostructured substances
- where a material includes 10% or more number of particles that meet the above definition (size, unique properties, intentionally produced) NICNAS will consider this to be a nanomaterial.]

Stakeholders generally supported a flexible approach to a definition at this stage recognising the need to accommodate future developments in light of the rapid advances in the science. Therefore, NICNAS will utilise the working definition while keeping abreast of national and international approaches. Some adjustments and explanatory notes were added to the working definition proposed in the public discussion paper in response to stakeholder feedback.

NICNAS has also implemented administrative adjustments to the notification and assessment of nanoforms of new chemicals (i.e. chemicals not on the Australian Inventory of Chemical Substances) from 1 January 2011. The impact of these changes on industry is that nano forms of new chemicals may not be introduced into Australia under exemptions where human and environmental exposure can reasonable be anticipated. In addition, industry self assessment categories may not be used for nano forms of new chemicals. These changes will ensure that pre-market evaluation of all new nanomaterials will be conducted by NICNAS. Stakeholders and the NICNAS Nanotechnology Advisory Group were overwhelmingly supportive of this proposal.

To support industry compliance with these new regulatory arrangements NICNAS has developed comprehensive guidance material (available from the NICNAS website) and has undertaken a series of stakeholder workshops and one-on-one discussions with specific companies. Compliance monitoring activities will commence around April/May 2011 and is expected to provide NICNAS with information on the extent of industry compliance.

Stakeholder views were also sought on the concept of notification and assessment of nanoforms of existing chemicals. While in-principle support was provided by the NICNAS Advisory Group and stakeholders, further information was requested. NICNAS is currently developing options for notification and assessment of existing chemicals including an option for integrated notification and assessment for new and existing nanomaterials, in consultation with its Nanotechnology Advisory Group. Public consultation on these options is scheduled for late 2011.

Information on NICNAS's regulatory activities is available from the NICNAS website at
http://www.nicnas.gov.au/Current_Issues/Nanotechnology.asp

Safe Work Australia drafted information relating to nanomaterials for inclusion in the draft Codes of Practice for; (a) Safety Data Sheets (SDS) for Hazardous Chemicals and (b) Labelling of Workplace Hazardous Chemicals. These documents are currently available for public comment. http://www.safeworkaustralia.gov.au/Legislation/PublicComment/Pages/PublicComment.aspx

For engineered or manufactured nanomaterials, or chemicals containing engineered or manufactured nanomaterials, it is recommended that an SDS and label should be provided unless there is evidence that the nanomaterials are not hazardous.

The following label statements are recommended for products containing nanomaterials when the hazards are not fully characterised:

- *Contains engineered/manufactured nanomaterials. Caution: Hazards unknown.*
- *Contains engineered/manufactured nanomaterials. Caution: Hazards not fully characterised.*

These phrases are for the use on an interim basis, as the manufacturer/importer has a duty to correctly classify the chemical and include information on known hazards on the label in accordance with the Work Health and Safety Regulations.

In the SDS section which lists physicochemical parameters for which information on chemicals should be provided (Section 9), 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). An Australian paper on SDS and nanomaterials was presented to the Sub-Committee of Experts on the Globally Harmonised System of Classification and Labelling of Chemicals (UNSCEGHS) meeting in December 2010. Safe Work Australia is also considering the addition of a section on engineered nanomaterials to the Australian Criteria for the Classification of Hazardous Chemicals.

2. Developments related to voluntary or stewardship schemes

No developments since the 7th meeting of the WPMN.

3. Information on any risk assessment decisions

No developments since the 7th meeting of the WPMN.

4. Information on any developments related to good practice documents

Australia's Committee on Nanotechnology (NT-001), established under the national standards authority, Standards Australia, continues to provide input to the International Organisation for Standardisation (ISO) Nanotechnology Committee (TC229) for the development of international nanotechnology standards and good practice documents. NT-001 is also represented on the ISO TC229 HSE Working Group, which coordinates the development of international HSE related nanotechnology standards, and on three project groups:

- Development of safe handling and disposal guide for manufactured nanomaterials
- Occupational risk management approach for manufactured nanomaterials based on control banding
- Preparation of SDS for nanomaterials

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

Food Standards Australia and New Zealand (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. FSANZ is continuing to monitor the potential applications of novel nanotechnologies to food and food packaging.

NICNAS continues to progress the technical component of its overall nanotechnology strategy that complements 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;
- Leveraging linkages with national and international agencies that are working in the same area to maximise efficiency of research;
- Continuing participation in the activities of the OECD Working Party on Manufactured Nanomaterials; and
- Continuing participation in ISO TC229, through the Standards Australia Nanotechnology Committee (NT-001) to facilitate reliable characterisation and testing of nanomaterials.

Australia's national medical research funding agency, the National Health and Medical Research Council (NHMRC), identified health and nanotechnology as a strategic plan issue under its 2009-10 project grant round, for funding commencing in 2011. From this funding round, 10 new projects totalling over $4.87 million over the life of the projects, will be funded. Research supported by NHMRC aims to increase knowledge of the effects, potential applications and hazards of nanomaterials, and may complement and/or inform regulatory regimes. More information about NHMRC research grants and policies is available at: http://www.nhmrc.gov.au/grants/index.htm. Nanotechnology and health was again identified as a strategic plan issue under the 2010-11 project grant round, for funding commencing in 2012. NHMRC is seeking to support projects that aim to investigate the health and safety aspects of nanotechnology, and to develop new diagnostics and/or novel treatments using nanotechnology. Applications opened on 13 December 2010 and close on 8 March 2011.

A Nanotechnology Work Health and Safety Program, managed by Safe Work Australia, is being implemented. The programme is Australia-focused, and also contributes to global efforts on nanotechnology work health and safety. The programme focus areas are:

- Ensure nanotechnology is covered appropriately within the Work Health and Safety Regulatory Framework;
- Improve understanding of the hazardous properties of engineered nanomaterials;
- Assess the effectiveness of workplace controls in preventing exposure to engineered nanomaterials;
- Develop procedures for detecting and measuring nanomaterials emissions and exposures in workplaces;
- Provide information and guidance for Australian nanotechnology organisations; and
- Ensure consistency with international approaches & contributing to international work.

Eleven projects have been commissioned by Safe Work Australia to progress work in these key areas. Six research reports have been published, with the following published since the previous Tour de Table report:

- *Engineered Nanomaterials: Investigating substitution and modification options to reduce potential hazards*
- *An evaluation of MSDS and labels associated with the use of engineered nanomaterials*
- *Engineered Nanomaterials: Feasibility of establishing exposure standards and using control banding in Australia*
- *Developing workplace detection and measurement techniques for carbon nanotubes*

Further research reports will shortly be published.

The work programme is supported by two reference groups:

- Nanotechnology Work Health and Safety Advisory Group. The role of the group is to provide support for a coordinated national approach to the management of nanotechnology work health and safety. Members are employee and employer representatives, work health and safety regulators, and representatives of other Australian Government agencies.
- Nanotechnology Work Health and Safety 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 work health and safety regulators.

Safe Work Australia has also published a *Work Health and Safety Assessment Tool for Handling Engineered Nanomaterials* which can be used by organisations and regulators when assessing the use of nanomaterials. The assessment tool allows the user to record the types of nanomaterials manufactured or supplied, the processes and controls used to prevent exposure to nanoparticles and problems faced with managing nanotechnology work health and safety.
http://www.safeworkaustralia.gov.au/AboutSafeWorkAustralia/WhatWeDo/Publications/Pages/AT201008WorkHealthAndSafetyAssessmentTool.aspx

6. Information on any public/ stakeholder consultation

In January 2011, NICNAS published on its website the results of its public consultation held in late 2009-early 2010 on the NICNAS *Proposal for Regulatory Reform of Industrial Nanomaterials*. Documents available on the website include a summary of results from stakeholder consultation with NICNAS responses, and all non-confidential written submissions received by NICNAS during the consultation period.

NICNAS continues to engage with stakeholders on industrial nanomaterials through periodic updates to its website, newsletter and fact sheets. From October 2010 through to January 2011 NICNAS published monthly notices foreshadowing industry administrative changes to new chemicals processes for nanomaterials, effective from January 1 2011. NICNAS responded to many queries from stakeholders as a result of these notices.

NICNAS has also recently published the outcomes of its 2nd voluntary call for information on nanomaterials that took place in 2008. The voluntary call aimed to gauge the extent of nanomaterial introduction into Australia and to ascertain what categories of physicochemical and toxicological data are held on each nanomaterial.

Information on the above is available from the NICNAS website at
http://www.nicnas.gov.au/Current_Issues/Nanotechnology.asp and
http://nicnas.gov.au/Publications/Information_Sheets/General_Information_Sheets/NIS_Results_Call_for_Information_2008_Nov_2010_PDF.pdf

FSANZ continues to receive and respond to enquiries relevant to nanotechnology in food. FSANZ has produced a fact sheet (Small particles, Nanotechnology and Food) as well as a web video and webinar which provide general information on nanotechnology, the application of nanotechnology in food and current regulations around the use of nanotechnology in food.

In 2010, the Australian Government, through the Health, Safety, and Environment Working Group, has engaged groups involved with the insurance industry to discuss implications of nanotechnology. The meetings were aimed at understanding the perspective of an industry that has the potential to be highly exposed to risks associated with nanomaterials. Discussions with this sector are planned to continue in 2011.

On 28 January 2011, the first National Enabling Technologies Stakeholder Advisory Council meeting was held. The council has been established to provide advice to the Government on issues related to enabling technologies and the National Enabling Technologies Strategy. It contains representation from industry, researchers, Non-Government Organisations, consumer groups, unions, ethicists, social scientists and an independent chair.

The National Enabling Technologies Strategy Public Awareness and Community Engagement (NETS-PACE) section of the Department of Innovation undertakes bi-annual research into public attitudes towards nanotechnology. This research seeks to obtain information on the Australian public's awareness and understanding of nanosafety issues, and any concerns regarding nanotechnology and its applications.

In late 2010 NETS-PACE organised two discussion sessions in Sydney between a panel of regulatory experts and members of the general public. The discussions provided information to the public through a question and answer session, and also provided feedback to the experts on the public perspectives towards nanotechnology. Input was also received on a nanotechnology regulation brochure NETS-PACE had developed with regulatory agencies. Two public groups were used in the workshops, one holding little to no opinion on nanotechnology, and a second that was interested with either a positive or negative view towards the technology.

NETS-PACE has also undertaken nanotechnology information and awareness activities in schools through its outreach programme with CSIRO Education, and the provision of education resources to teachers in its AccessNano (www.accessnano.org) programme. Other education and community awareness programmes are run through techNyou, NETS-PACE's technology information service provided in partnership with the University of Melbourne.

AUSTRIA

Highlight of developments since the 7th meeting of the WPMN

- **Implementation of Austrian Nanotechnology Action plan recommendations**:
  - A **national EHS programme focusing on nanosafety** is going to release a first call for nanosafety research in spring 2011. This EHS programme has been founded and mainly funded by the Federal Ministry of Federal Ministry for Transport, Innovation and Technology and the Federal Ministry of Agriculture, Forestry, Environment and Water Management with contributions of the Ministry of Labour, Social Affairs and Consumer Protection, the Federal Ministry of Health and the Chamber of Commerce. The Programme is funded with approximately 500.000 EUR and will probably issue a first call focusing on occupational health.
  - An Austrian **Nanotechnology Information Platform (NIP**) lead-managed by the Federal Ministry of Health and including stakeholders from several ministries, agencies, NGOs, research institutions and industry has been built up to discuss and focus on how to deal with information & communication needs of the public: Currently the setup of a national website for the public including chances and risks of nanomaterials is in progress.
- **NanoTOES** (Nanotechnology: Training Of Experts in Safety), a Network of Initial Training (ITN) in the framework of FP7 coordinated by Prof. Dr. Albert Duschl from the University of Salzburg has started on 1. 11. 2010. It comprises 12 partners in 9 European countries and will run for 4 years. NanoTOES aims at development and validation of methods for examination of possible nanorisks for health and environment coupled with research for a better understanding of the involved mechanisms. Furthermore it will focus on the education of young academics in the field of nanosafety and will be a

European best practice" example in this respect. University of Salzburg´s main specialist work will be research on the effects of **nanomaterials on the immune system**.

- **Vienna City Administration** commissioned a study dealing with a first evaluation of chances and risks for nanotechnology in respect to acquisition of the City Vienna (in German with English summary): http://www.wien.gv.at/umweltschutz/oekokauf/pdf/nanotech-studie.pdf

Work completed, underway or planned

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

No national Austrian laws/regulations are planned at the time being.

The Austrian Nanotechnology Action plan (adopted on 2nd March 2010 by the Austrian government, an English and German version can be downloaded on http://www.umweltnet.at/article/articleview/81646/1/7033/), includes about 50 measures which will be implemented by Austrian stakeholders on national, EU and international level till 2012. The action plan was lead-managed by the Federal Ministry of Agriculture, Forestry, Environment and Water Management (BMLFUW) and elaborated on basis of a broad stakeholder involvement (see also chapter 7). The work for preparing an implementation report will start mid 2011.

The central labour inspectorate (part of the Federal Ministry of Labour, Social Affairs and Consumer Protection) mandated a project investigating Austrian **nano-workplaces** to get a preliminary overview on different **uses and risk management applied:** A final report in German can be found under http://www.arbeitsinspektion.gv.at/AI/Arbeitsstoffe/nano/default.htm. A new project was started to **develop guidance for preliminary risk management**. It will follow the precautionary principle and ensure safe and healthy workplaces regarding nanomaterials. The guidance is targeting small and medium enterprises and shall support the central labour inspectorate in advising enterprises dealing with nanomaterials. The guidance is currently finalised and will be published in German language.

A **conference** on **"Approaches to risk assessment and risk management of nanotechnologies"** has taken place on September 23th 2010 in Vienna at the premises of the Austrian Academy of Sciences. (See also http://nanotrust.ac.at/nano10/)

An **informative event on occupational health** is organised by the Austrian Compensation Board AUVA in March 2011.

2. Developments related to voluntary or stewardship schemes

No information provided.

3. Information on any risk assessment decisions

No information provided.

4. Information on any developments related to good practice documents

No information provided.

5. Information on any developments related to Integrated Testing Strategies and/or Alternative test methods

At the Institute of Pharmaceutical Sciences of the Karl-Franzens University Graz, an **alternative physiological in-vitro model** is under development to **investigate the action of nanostructured materials on the buccal mucosa** (contact: Eva Roblegg, EURO-NanoTOX).

Toxicological Investigation of Nanoparticles – "**Effects On Human Cells**" by Seibersdorf Labour GmbH, Toxicology, member of EURO-NanoTOX were performed.

A multi-parameter cell chip for **high-sensitive nanotoxicology assays** is currently developed by AIT Austrian Institute of Technology, Health & Environment Department, Nano Systems.

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

EURO-NanoTOX is an open virtual national platform which is co-ordinated by the BioNanoNet Forschungsgesellschaft mbH. It elaborates strategies to conduct standardised toxicological in vitro as well as in-vivo methods on nanostructured 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 **SiO2** and **polystyrene** are performed (contact: Eleonore Fröhlich, EURO-NanoTOX).

In the FP7 project **MARINA** Austrian partners from University of Salzburg (contact: Prof. Dr. Christian Huber) and from Department for Environmental Geosciences, University Vienna (UNIVIE, contact: Frank von der Kammer) are involved in several work packages. UNIVIE is involved in material characterisation and developing analytical methods for the **quantification of ENPs in environmental samples**. University of Salzburg plans to investigate nanoparticle **effects on the proteome level**.

In the FP7 project **NanoLyse** the Department for Environmental Geosciences, University Vienna (UNIVIE, contact: Frank von der Kammer) is leading the work package for the **sample preparation and quantification of inorganic nanoparticles in food**. UNIVIE is responsible member of the project management board and also involved in the development of organic nanoparticle analysis.

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 (also in English language) on specific nano-related topics are released: http://nanotrust.ac.at/dossiers.html.

7. Information on any public/ stakeholder consultation

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 to exchange information and discuss specific nanomaterial related topics.

The **Austrian Nanotechnology Action Plan** was published 2010 after taking into account comments from public consultation (http://www.umweltnet.at/article/articleview/78793/1/7033). The consultation was managed via web and by taking into account guidelines for public consultation which were adopted by the Austrian Government in 2008 (contact: Renate.Paumann@lebensministerium.at, Austrian Federal Ministry of Agriculture, Forestry, Environment and Water Management).

The project **SEBEROC** (Simulation and Evaluation of Better Regulation of Converging Technologies, carried out on behalf of the SKEP Network) aims at **applying the "Better regulation"** approach to the regulation of nanotechnology and genetic engineering. Focus groups to be carried out in Austria, Finland,

Germany, the Netherlands and the United Kingdom lie at the heart of the project. The specific topics to be used for the focus group discussions will be determined in coordination with non-governmental organisations (NGOs). The Austrian partner in the Project is IFZ-Inter-University Research Centre for Technology, Work and Culture Graz (contact: Manfred Klade). The Austrian request for project financing was filed with the Austrian BMLFUW. (see also: http://www.seberoc.info/home0.0.html)

The **Sparkling Science project "Nanomaterials – Possibilities and Risks of a New Dimension",** sponsored by the Federal Ministry of Science and Research focuses at daily and practical experiences of students with nanomaterials: After researching the basics of nanotechnology and discussing with nanoscientists, the students explore – supported by scientists and experts – approaches of assessing the societal and individual dealing of nanomaterials including gender aspects. The project is lead-managed by the Austrian Environment Agency (contact: Simone Mühlegger), four Austrian schools as well as three research Institutions. (University of Vienna, Department of Social Studies of Science & the Department for Environmental Geosciences, and the Medical University of Graz) as well as the environmental education partner Forum Umweltbildung, Umweltdachverband GmbH are included (see also: http://www.sparklingscience.at/en/projekte/401-nanomaterialien-chancen-und-risiken-einer-neuen-dimension)

A **consumer brochure** on nanotechnology was compiled by the Austrian Environmental NGO "GLOBAL 2000" and funded by BMLFUW.

The project **"Making Futures Present, On the Co-production of Nano and Society in the Austrian Context"** is carried out by the Department of Social Studies of Science, University of Vienna (contact: Prof. Ulrike Felt) and sponsored by FWF. The goal of the project is to analyse the fundamental construction processes of possible futures in the present and the "technoscientific promises" connected to them (see: http://sciencestudies.univie.ac.at/en/research/making-futures-present-nano-and-society/).

The Environment Agency Austria in co-operation with the quality radio station Radio Österreich 1 launched the "Initiative **Risiko:dialog**". The aim was to open dialogues on risk topics – with potential effects on human health, environment and society – with stakeholders and the public in an early stage.

8. Information on research programmes or strategies which focus on life cycle aspects of nanomaterials, as well as positive and negative impacts on environment and health of certain nanoenabled applications.

BioNanoNet Forschungsgesellschaft mbH is partner in the project **NANOFORCE** "Nanotechnology for Chemical Enterprises – how to link scientific knowledge to the business in the Central Europe"; and responsible for the work package **"How to foster the responsible use of nanotech and manage associated risks"**. Aim of the project is to foster the innovative nanotechnology-sector networks across Central Europe regions by bringing together public and private organisations to carry out collaborative & interdisciplinary researches on nanomaterials (in the frame of REACH Regulation) and to turn the most promising laboratory results into innovative industrial applications, not only to produce new materials but also to improve the industrial sustainability (more security & lower environmental impact in the life cycle of products)

In the project **NanoRate** risks and benefits of nanoproducts were assessed: For download of final report (see: http://www.umweltnet.at/article/articleview/83094/1/7033)

A scientific study regarding "**Sustainability assessment of nano-products**" was conducted in cooperation of the Environment Agency Austria and the University of Applied Sciences, Technikum Wien (contact: Jana Slamaj).

BELGIUM

Highlight of developments since the 7th meeting of the WPMN

- The Belgian Presidency of the Council of the European Union took the initiative of organising a high level event on September 14th 2010, bringing together representatives of various associations (consumers, environmental protection, workers, and industrial federations), scientists, regulatory experts as well as national and European regulatory bodies, in order to take stock of the situation. The program and conference presentations of the high level event "Towards a regulatory framework for nanomaterials traceability" are available at: http://www.health.belgium.be/eportal/Aboutus/eutrio/environment/Nanomaterials/index.htm?fodnlang=en
- The Belgian Presidency of the Council took the initiative to invite representatives from IT, FR, BE with the presence of observers from DE and NL in order to initiate an harmonization project regarding the possibility and suitability of a database of products containing nanomaterials that are on the market.
- BE contributed to the study of silicon dioxide, TiO2 and CNT OECD testing, in a co-financed study by BE, other UE MS and the EU Commission (Nanogenotox). Contact: P. Troisfontaines (Paul.Troisfontaines@wiv-isp.be) and J. Mast (jamas@var.fgov.be).
- Different new projects started for :
  - Development of methods to assess adverse effects of ingested engineered nanoparticles on health (Nanorisk). Contact: L. Pussemier (lupus@var.fgov.be); and
  - Development of analytical methods for detection and characterisation of nanoparticles in food and beverages (Nanolyse). Contact: P. Delahaut (P.Delahaut@cergroupe.be)

CANADA

Highlights of Developments since the 7th Meeting of the Working Party on Manufactured Nanomaterials

The following activities have taken place since the 7th meeting of the Organisation for Economic Cooperation and Development (OECD) Working Party on Manufactured Nanomaterials (WPMN) in July 2010:

- Health Canada adopted the Interim Policy Statement on Health Canada's Working Definition for Nanomaterials and invited comments from stakeholders. The public consultation period closed on August 31, 2010 and currently, Health Canada is reviewing comments.
- Canada participates in an ad hoc working group under the International Co-operation on Cosmetic Regulation (ICCR). In July 2010, the document *Criteria and Methods of Detection* was accepted and outlines criteria to define nanomaterials in cosmetics. The criteria can be used by cosmetic regulators to support regulatory activities or definitions.

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. In March 2010, Health Canada announced the adoption of the Interim Policy Statement on Health Canada's Working Definition for Nanomaterials and its public posting (http://www.hc-sc.gc.ca/sr-sr/consult/_2010/nanomater/draft-ebauche-eng.php). The Interim Policy went into effect immediately and was open for public consultation.

Currently, the Acts and Regulations administered by Health Canada have no explicit reference to nanomaterial. Among four key objectives, this policy statement establishes a transparent working means of identifying nanomaterials. It will also provide Health Canada with a consistent set of approaches and a trigger to request information. Given the range of nanomaterial-related regulatory responsibilities in Health Canada, the working definition is intentionally broad and will be applied more specifically in each regulatory programme area.

The six month web-based public consultation for the *Interim Policy Statement on Health Canada's Working Definition for Nanomaterials* ended on August 31, 2010. A total of 29 submissions were received from a range of stakeholders. The majority of comments were received from industry; however, public interest groups, government bodies, and private individuals also submitted comments. The comments focussed on the process of the development of the working definition, the content or meaning of particular terms, and its application or use. Health Canada is currently reviewing and considering all comments received as well as key developments of other definitions of nanomaterials, including those of the International Organisation for Standardisation and the European Commission.

B. Under the International Cooperation on Cosmetic Regulation (ICCR), Canada is participating in the international ad hoc working group on nanomaterials in cosmetics (ICCR Nano Working Group) that was initiated in December 2009. This Working Group (WG) is composed of regulators and industry representatives in the European Union, Japan, US and Canada. The WG completed a report entitled "Criteria and Methods of Detection" which was accepted in July 2010. The criteria statement was as follows:

> *For purposes of the International Cooperation on Cosmetic Regulation, a substance used in a cosmetic is considered a nanomaterial if it is an insoluble ingredient, intentionally manufactured, with one or more dimensions in the realm of 1 to 100 nanometres in the final formulation and is sufficiently stable and persistent in biological media to allow for the potential of interaction with biological systems.*

The criteria can be used by cosmetic regulators to support regulatory activities or definitions and is expected to be used as a basis for a guideline for the notification of nanomaterials under the Canadian *Cosmetic Regulations*. A regrouped ICCR Nano WG will commence work on elaborating on characterisation methods, as well as determining endpoints for risk assessment relevant to cosmetics safety in March 2011.

2. Developments related to voluntary or stewardship schemes

No information provided.

3. Information on any Risk Assessment Decisions

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

- *Industrial or commercial chemicals:* Since June 2010, additional notifications have been received for assessment as nanomaterials under the *Canadian Environmental Protection Act, 1999* (CEPA 1999). The Significant New Activity Provisions of CEPA 1999 have been applied for these notifications. These provisions would require the submission of additional information and assessment prior to use of the substances at the nanoscale or in other new nanoscale applications.

- *Pharmaceuticals:* A number of nanotechnology based products in the areas of medical devices and drugs are currently under review by Canada, under the current regulations and policies.
- *Pesticide applications:* Some inquiries have been made, but no notifications have been submitted to date.
- *Food related application:* Six notifications have been received. Two letters of no objection have been issued; the other four are still under review.
- *Others:* No notifications with respect to fertilisers, veterinary biologics, or animal feed have been received to date.

4. Information on any Developments Related to Good Practice Documents

A. Canadian Standards Association (CSA) Standards 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. Work has continued in subsequent meetings through 2010 and early 2011.

B. Government, industry, research, user, and consumer interests are participating as designated experts from Canada on international standards development through the Canadian Advisory Committee to International Organisation for Standardisation/Technical Committee 229 (ISO/TC229) Nanotechnologies, facilitated by CSA Standards. This includes active participation on terminology, nomenclature, measurement, characterisation, material specification and health, safety, environmental aspects of nanotechnologies standards under development.

C. Canada is the lead for the ISO TC 229 Working Group 1 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 the International Union of Pure and Applied Chemistry (IUPAC). The Group is tasked with developing a nomenclature system which meets the needs of regulators, industry, and academia. A liaison between ISO TC 229 and IUPAC has been secured and a subcommittee has been formed to pursue work on developing nomenclature.

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

Scientific research

Health Canada is starting a research project to investigate the toxicity of surface-modified silica nanoparticles entitled "Evaluation of Toxic Potency of Silica-based Nanoparticles using High-throughput Integrated *In Vitro* Cytotoxicity Assay Platform". The aim of the project is to investigate the importance of size and surface modification on the toxicity of silica nanoparticles. The silica nanoparticles used in the project will be synthesised and modified according to specific parameters to better reflect those that are of greatest interest to the New Substances Program. This project is designed as a proof of concept and will be extended over the fiscal years 2010-2011 and 2011-2012.

Canada has supported multiple research projects under the Strategic Grants Program of the Natural Sciences and Engineering Research Council (NSERC). The nanomaterials used in these projects have included OECD priority nanomaterials such as TiO_2. The projects examined fate both in the aqueous and the subsurface compartments and include establishing methodologies for suspension and physical-chemical characterisation of the nanomaterials prior to any exposure testing.

A larger Canadian initiative is a multidisciplinary, 3-year collaborative project that brings together: 1) industry and academic/government researchers involved in the engineering and production of new and existing commercial nanomaterials, 2) representatives involved in the current regulatory testing industry that require new, cost-effective, time-sensitive, and efficient testing methods, 3) academic/government researchers who can develop and apply new technologies to the area of safe nanomaterials production and effective ecotoxicology testing, and 4) Canadian regulatory community. The goal of the project is to understand the fate and effects of nanomaterials (including OECD priority materials) in the aquatic environment, with specific themes targeting (1) synthesis; (2) characterisation in complex media; (3) methods for biological effects testing; and (4) establishing collaborative dialogue between key stakeholders.

Funding and partnering opportunities are currently being considered by 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.

Canada is 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, TiO2, single walled carbon nanotubes, and C_{60} fullerenes). Testing 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. Other on-going projects include developing bioassays and biomarkers for nanomaterials, harmonising and standardising chemical and toxicological assays, toxicogenomics, evaluating fate in aquatic environments understanding the interaction of nanoparticles with microbial cells, soil effects research, and bioaccumulation and toxicity in benthic invertebrates.

Canada (Environment and Health Canada), together with Government agencies in the United States, Non-Governmental Organisations and Industry are supporting a project lead out of the International Life Sciences Institute (ILSI) to look at releases of nanomaterials from industrial matrices (e.g., coatings). The purpose of the project is (a) to compile literature information on different test methodologies and nanomaterials used to study releases from matrices (e.g., coatings); and (b) develop standard methodologies (validated through round-robin testing) to quantify releases of nanomaterials from a matrix. At the current stage, the Steering Committee for the project is selecting primary materials in advance of an expert workshop being planned in Fall 2011. The expert workshop will inform on path forward on a testing regime for the materials and matrices selected. Additional information can be found at http://www.ilsi.org/ResearchFoundation/Pages/NanoRelease1.aspx

Policy research

Canada participates in the project on Regulatory Framework for Nanotechnology in Food and Medical Products, The project is composed of two independent surveys addressing the same set of questions related to: (1) the regulatory frameworks being used to provide oversight for the use of nanotechnology in food and medical products, (2) the legislative frameworks relevant to these regulatory frameworks, and (3) relevant government-supported research programmes and institutions. The surveys have been circulated to member countries to be filled by March 2011.

The information generated by the surveys will be used to populate inventories, and draft a report on areas of shared interest and highlight opportunities for enhancing communication related to regulation and applications of nanotechnology in food and medical products. The report is expected to be completed in 2011/2012.

6. Information on any public/ stakeholder consultation

Health Canada announced the adoption of the Interim Policy Statement on Health Canada's Working Definition for Nanomaterials and its publication. Currently, Health Canada is reviewing comments from stakeholders.

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

Finland is a member of the EU and accordingly follows the EU regulations. Finland is actively participating in REACH competent authority (CARACAL) subgroup on nanomaterials (CASG-nano) and in the development of technical guidance how to apply the regulation on nanomaterials in RIP oNs 1, 2 and 3. All the competent authorities for REACH, biocides, plant protection products and most other chemical safety issues are now nationally integrated to the new Finnish Safety and Chemicals Agency

Similarly the work on novel foods and cosmetics is followed at EU level.

The various ministries have established an *ad hoc* discussion forum on nanotechnology in order to follow and participate in the national and international discussions. There are plans to establish this group formally during the early part of 2011.

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. Information on any developments related to Integrated Testing Strategies and/or Alternative test methods

The alternative *in vitro* test methods are used in the several research projects among the *in vivo* tests.

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

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

The University of Technology, VTT Finland and UPM Kymmene have established The Finnish Centre for Nanocellulosic Technologies with 40 researchers concentrating on innovations but also on safety assessment of nanocellulose applications.

Forestcluster LTD (a public-partnership for science, technology and innovations) runs a EffNet (Efficient Networking towards Novel Products and Processes, 2010 – 2013) programme that focuses, on one hand, on developing radically new energy and resource efficient web production technologies and, on the other

hand, reengineering the product concept of fibre based products with nanocellulose[4]. The E15 million programme develops and demonstrates new types of products, but carries out also safety assessment of nanocellulose applications and studies their life-cycle.

Finnish Institute of Occupational Health has established Nanosafety Research Centre as of January 1, 2011. The centre has a staff of 25, and focuses on research on assessment of exposure to, and immuno- and genotoxic effects of engineered nanomaterials and urban air ultrafine particles. The centre also carries out research on nanoparticles characterisation and risk assessment of engineered nanomaterials, and prepares guidance on safe use of engineered nanomaterials in workplaces.

University of Helsinki (with Kungliga Tekniska Högskolan KTH, Sweden; University of Birmingham, UK; University College Dublin, Ireland) is participating in:

- European Commission 6thFramework Programme SKEP ERA-NET project (Scientific Knowledge for Environmental Protection) on "*Nanomaterials in REACH –evaluation of applicability of existing procedures for chemical safety assessment to nanomaterials (nanoREACH)*", in the Work package on Precautionary procedures for nanomaterial safety assessment.
- European Commission 7thFramework Large Scale Integrating Collaborative Project on "*Nanopatterning, Production and Applications Based on Nanoimprinting Lithography (NaPANIL)*", in the work package on dissemination and exploitation: social-ecological analysis of nanopatterning and related applications with a consortium of 20 European partners coordinated by VTT Finland.

The laboratory of the Finnish Environment Institute (SYKE) has started studies on aquatic exposure concentrating especially on nanomaterial detection and characterisation. SYKE has also started planning a research project on the integration of nanosafety concerns into processes of industrial product and process design.

SYKE takes also part in the "Simulation and Evaluation of Better Regulation of Converging Technologies" (SEBEROC) project carried out on behalf of the SKEP Network (www.seberoc.info).

The Ministry of Social Affairs and Health is a collaborator as the Finnish Institute of Occupational Health is an associated partner in the NanoGenotox project which is a Joint Action, and partly funded under the Commission's Second Health Programme focusing on Safety evaluation of manufactured nanomaterials by characterisation of their potential genotoxic hazard.

The Finnish Food Safety Authority (Evira) is coordinating the work of a newly established Nordic Network on nanomaterials in Foodstuffs. The work is financed by The Council of Nordic Ministers. The network is to start its operation in 2010.

The Finnish Food Safety Authority (Evira) and VTT Finland are participating in a European COST FA0904 project on "Eco-sustainable food packing base on polymer nanomaterials".

Finnish Institute of Occupational Health (FIOH) is leading or involved several ongoing research projects on nanomaterials:

- European Commission 6thFramework Programme project together with several institutes on "*Infalmmatory and genotoxic effects of engineered nanomaterials (NANOSH)" The project end date was March 31, 2010, but reporting of the results of the project is going on.*
- European Commission 7thFramework project "*Novel concepts, methods and technologies for the production of portable easy-to-use devises for the measurement and analysis of airborne engineered nanoparticles in workplace air (NANODEVISE)"*. Here FIOH has the lead.

[4] http://www.forestcluster.fi/d/content/efficient-networking-towards-novel-products-and-processes-2010-2013

- European Commission 7thFramework project "Scale-up nanoparticles in modern papermaking"
- Academy of Finland project "*Engineered nanoparticles: synthesis, characterisation, exposure and health hazards"*
- European Commission DG SANCO project "*Safety evaluation of manufactured nanomaterials by characterisation of their potential genotoxic hazard (NANOGENOTOX)*"
- European Network on the Health and Environmental Impact of Nanomaterials

7. Information on any public/ stakeholder consultation

8. Information on research programmes or strategies which focus on life cycle aspects of nanomaterials, as well as positive and negative impacts on environment and health of certain nano-enabled applications

Additional Information

Research Professor Kai Savolainen and Harri Alenius from the Finnish Institute of Occupational Health will attend the European Union-Unites States Workshop on Safe Use of Engineered Nanomaterials in Washington, D.C. on March 10-11, 2011.

FRANCE

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

Article 185 of the France's Environmental Commitment Bill, dated 12 July 2010, provides for the prevention of risks to human health and environmental safety arising from exposure to nanoscale substances.

Persons who manufacture, import or distribute nanoscale substances, either in pure form or contained in loose mixtures, or materials that will discharge such substances under normal or reasonably foreseeable conditions of use, shall periodically declare to the administrative authority, for the purposes of traceability and public information, the identity, quantities and uses of those substances, as well as the identity of the professional users to whom they were sold or given free of charge.

Substances which enter into the composition of health products (medicines for human and veterinarian use), pesticides and biocides, cosmetic products and food additives are subject to this declaration requirement. Information relating to the identity and uses of substances so declared shall be made available to the public.

An enabling interministerial decree (Environment, Health and Labour, Agriculture, Defence, Justice) relating to nanoscale substances traded on the market is currently being drawn up. A draft has been addressed to the various entities concerned (associations, professional federations and unions of importers, distributors, users and managers of wastes arising from nanoscale substances; environmental protection associations, workers' unions, representatives of local authorities, public institutes working in the area of health and environmental risk assessment, public research institutes, etc.) in order to seek their opinion. This proposal can be consulted on the Internet at: http://www.developpement-durable.gouv.fr/spip.php?page=article&id_article=20218

This decree defines the following terms: nanoscale substance, nanoscale substance contained in a loose mixture, manufacturer, importer, distributor, professional user.

The threshold above which a declaration must be made is: 10g/year.

The declaration should be made to the European Commission before the summer.

2. Developments related to voluntary or stewardship schemes;

See above with regard to France.

A project to develop and set up a harmonised European database was decided during the Belgian presidency of the Council of the European Union. This database, which is currently under development, is designed to provide a common framework for issuing declarations of nanoscale substances launched on the market and products containing such substances, regardless of whether these initiatives voluntary or mandatory, in the following Member countries: Belgium, France, Italy, Germany.

3. Information on any risk assessment decisions;

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

"Development of a control banding tool relating specifically to nanomaterials" by the *ANSES* (French Agency for Food, Environmental and Occupational Health and Safety).

There are many uncertainties about the quantitative assessment of the dangers and risks of exposure to nanomaterials that will only be dispelled as more is learnt about the properties of such materials.

The control banding method developed in the pharmaceutical industry to protect the safety of workers involved in processes using substances and products for which limited information regarding toxicity was available, is presented as an alternative form of prevention to the few solutions that currently exist besides the total confinement of nanomaterials. New substances and products are classified in defined "bands" (or hazard levels) after comparison in terms of the hazard level of known and/or similar products and after taking account of the assessment of the level of exposure in the workstation. In this process, a qualitative risk assessment is associated with a level of risk control which proposes minimum collective means of prevention to be put in place in accordance with the estimated level of risk. This is therefore a tool that allows risk to be managed on a graduated basis known as control banding.

The control banding method proposed by the *ANSES* experts could potentially be used in all professional environments in which nanomaterials are manufactured or used (industrial workshops, research laboratories, pilot units, etc.). In particular, the proposed tool is especially well suited to SMEs and SMIs which do not necessarily have measuring equipment available or the in-depth toxicological studies they would need to proceed with risk assessments in the proper sense of the term.

It is a simple, accessible method with a strong operational bias which must be integrated into a global health and safety management system. However, its use is subject to certain limitations:

- This tool is designed to be used solely for normal handling and use at the workstation, as part of the normal performance of the establishment's activity;
- It is suitable for any type of nanomaterial, provided that the amounts handled are neither too diluted nor too voluminous;
- Control banding can only be used to determine health risks. This approach does not address safety risks (risks of fire or explosion) or environmental risks; and
- It is essential that the user of the control banding be sufficiently skilled in the areas of chemical risk prevention (chemicals, toxicology, etc.), nanoscience and nanotechnology. The use of control

banding without the requisite level of expertise, without a critical approach or without support can lead to erroneous assumptions and consequently unsuitable choices of prevention actions, potentially putting at risk persons exposed to nanomaterials.

Report available in English on the *ANSES* site: http://www.afssa.fr/Documents/AP2008sa0407.pdf

5. Information on any developments related to Integrated Testing Strategies and/or Alternative test methods

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

The NP-Lung project, financed by the UTC foundation (*Université Technologique de Compiègne*) for innovation, was set up in 2010. It consists in studying the interaction between various nanoparticles with macromolecules of biological interest (lipids and proteins). The results obtained will be applied to the alveolar-capillary barrier and will provide information for use interpreting the toxic effects observed.

NanoGenoTox: "Safety evaluation of manufactured nanomaterials by characterization of their potential genotoxic hazard".

This three-year programme is primarily aimed at providing the European Commission with a robust and reliable method for detecting the genotoxic potential of manufactured nanomaterials, in view of the uncertainties over this potential compared with substances of the same chemical entity but on a larger scale. Few data are currently available and the findings of the studies that have been carried out remain contradictory (see the scientific Opinion published by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) in January 2009).

A genotoxic substance is likely to give rise to a risk of cancer or to be toxic for human reproduction. The development of this method also offers the possibility of developing alternative test methods aimed at reducing animal experimentation. This programme will use 3 families of nanomaterials: titanium dioxide, silicon dioxide and carbon nanotubes. These families have been selected on the basis of the following strategic criteria: possible use in different types of product (cosmetics, food, and common consumer products), potential exposure pathways (oral, cutaneous, inhalation), their production and/or use on European soil. 15 manufactured nanomaterials will be tested.

NanoGenoTox meets the objectives with regard to the safety of manufactured nanomaterials set out in the 2009 work plan of the programme of Community action in the field of health n terms of the safety of manufactured nanomaterials (ref.: Decision No. 1350/2007/EC). These objectives are as follows:

1) consolidate, extend and share the requisite knowledge regarding nanomaterials for the assessment of risks, of exposure and of overall risk;
2) step up the exploitation of existing data and the exchange of best practices with regard to risk assessment and management; and
3) promote the adoption of rigorous methodologies throughout the Union.

To see this project to a successful conclusion, NanoGenoTox will proceed in several stages:

1) comprehensive physical and chemical characterisation of the 15 nanomaterials that will be tested;
2) determination of the distribution of nanomaterials in the living body: toxicokinetics of nanomaterials; and
3) performance of suitable *in vivo* genotoxicity tests that will be compared with *in vitro* genotoxicity tests themselves carried out on specific cellular supports.

The work will be carried out in the following order:

1) development of a dispersion protocol for NMs with on-going characterisation of both dispersed and non-dispersed NMs;
2) development of protocols for *in vitro* genotoxicity tests, since the *in vivo* genotoxicity tests will begin much later the discussions on protocols are currently under way; and
3) introduction of *in vivo* detection methods for the three different families of NMs, development of the protocol for *in vivo* studies of toxicokinetics and distribution of nanomaterials in tissues.

Internet site: http://www.nanogenotx.eu

7. Information on any public/stakeholder consultation; and/ or environmental safety aspects of nanomaterials

Further to the national public debate on nanotechnologies, the government is preparing a document regarding its commitments to the follow-up to be given to the debate. This action falls under three main headings:

1) Gain a better understanding of the challenges and risk prevention relating to nanomaterials and nanotechnologies with regard to the research, developmental, social and ethical challenges;
2) Respond to the public's need for continuously updated information about nanotechnologies, their applications and public action in this area; and
3) Bring together the various actors concerned to ensure responsible development of nanotechnologies.

8. Information on research programmes or strategies which focus on life cycle aspects of nanomaterials, as well as positive and negative impacts on environment and health of certain nano-enabled applications. (You may wish to contact your colleagues participating in SG9.)

Additional Information

Delegations are invited to provide any additional information, for example on:

1) Any consideration on the benefits of nanotechnologies;
2) Consideration of ethical implications; and
3) Information on past, current or future activities on nanotechnologies that are being done in your respective countries in co-operation on a bilateral basis with non-OECD countries.

GERMANY

Highlight of developments since the 7th meeting of the WPMN

- German NanoKommission and its thematic groups present results at the Conference on 2nd of February 2011 in Berlin
- German Federal Government agreed on Nano Action Plan 2011-2015
- Launching and finalising diverse research projects

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):
Please refer to 6)

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):

The results of numerous research projects were presented to the public on occasion of the dialogue forum "Nanomaterials at the workplace" on January 17th, 2011. The documentation of the event (only in German) can be found at http://www.baua.de/cln_104/de/Themen-von-A-Z/Gefahrstoffe/Tagungen/Nano-2011/Nano-2011.html.

B) Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR):

1) BfR participates in a Coordination and Support Action for integrating activities within the 7th European Framework Programme. This action, called QNano and coordinated by Ireland, aims to promote the establishment of a pan-European infrastructure for quality in nanomaterials safety testing. Envisaged start is February 2011, duration of this project is five years.
2) Within the research programmes of the Federal Ministry of Education and Research a project called "NanoGEM (Nanostructured Materials - health, exposure and material properties)" started in August 2010 for the duration of three years. NanoGEM is a project combining several academic and private research institutions, industrial firms, and public authorities (BAuA and BfR) with the intention of answering today's open questions of sustainable development and risk assessment by use of specially adapted strategies. Apart from evaluating for the first time hazards of industrially relevant nanomaterials and nanoparticles being contained in processed products, NanoGEM gives special attention to changes of the nanoparticles during life cycle, to biokinetics i.e., to the uptake and distribution of nanoparticles in the human body as a function of size, structure, and surface properties and to the molecular mechanisms of action. Issues of safety at work and product safety during manufacturing, processing, application, and disposal will be approached, among other things, by means of newly developed portable measuring instruments. NanoGEM provides the data necessary for assessing the risks of an internal and external contact of nanoparticles with organisms. For further information please refer to http://www.nanogem.de.

C) Federal Environment Agency (Umweltbundesamt, UBA):

1) The UBA (together with Anses in France) is coordinating the activities within the SG3 Sponsorship Programme for nanosized Titanium dioxide. On 17th and 18th of January a TiO2 expert workshop was organized by UBA and Anses bringing together expert scientists involved in the testing activities under the Sponsorship Programme TiO2. The objectives of the meeting were to share the findings gained from testing TiO2, to discuss the challenges faced to date and to develop solutions. Ad hoc working groups discussed issues like sample preparation, applicability of OECD test guidelines and appropriate test designs. The outcomes of the meeting, as well as recommendations made by the experts will be reported to the SG3.

2) Toxicokinetics of short MWCNTs in rat: The research project addresses the tissue distribution of short Co60-labelled MWCNT (diameter 50 nm, length 5-20 µm) in rats after 6 hours nose only inhalation. Tissues and organs (lung, lung associated lymph nodes, liver, kidney, brain, heart, spleen, blood, urine and pleura, carcass and excrement) will be tested after 1 h, 24 h, 1 week and 1 month. Additionally, animals treated with non-labelled MWCNTs will be used for TEM analysis of organs with high MWCNT burden.

3) Development of a concept to assess the carcinogenic potential of nanoparticles: The project aims at correlating physicochemical and particle specific descriptors such as particle size, agglomeration, surface charge, crystalline structure, surface area etc. with the carcinogenic potential of certain nanoparticles using the RepDose Database of Fraunhofer ITEM. The main focus is on biopersistent, granular (nano) particles.

4) REPORT: The carcinogenic potential of nanomaterials: After a critical review of the available data, the report concludes that the potential carcinogenic risk of nanomaterials can currently be assessed only on a case-by-case basis. There is certain evidence that different forms of CNTs (carbon nanotubes) and nanoscale TiO2 particles may induce tumours in sensitive animal models. It is assumed that the mode of action of the inhalation toxicity of asbestos-like fibres and of inhalable fractions of biopersistent fine dusts of low toxicity (nano-TiO2) is linked to chronic inflammatory processes. Existing epidemiological studies on carcinogenicity for these manufactured nanomaterials are not sufficiently conclusive.

5) The Study of nanoparticle emission of selected products during their Life Cycle revealed that there is a serious lack of knowledge on the subject. Appropriate measuring methods by which nanoparticles in the environment can be detected and identified, for example, are still lacking. The final report is written in German, but includes an English summary [http://www.uba.de/uba-info-medien-e/4028.html].

D) Federal Ministry of Education and Research

Germany's Federal Government agreed on its new Nano Action Plan 2015 that has been worked out under the auspices of the Federal Ministry of Education and Research. Please refer to http://www.bmbf.de/en/nanotechnologie.php for the English document.

6. Information on any public/stakeholder consultation

The NanoKommission, established by the Federal Environment Ministry in 2006, concluded its work with a one-day conference on February 17 in Berlin and presented its final report. The NanoKommission had the task of discussing the opportunities and risks of nanotechnologies and formulating recommendations to the Federal Government regarding the responsible use of these technologies. In the NanoDialogue, 100 representatives from the scientific world, the business community, environmental, consumer and women's associations, trade unions, churches, ministries and authorities jointly undertook to:

- provide input to the public debate on the opportunities and risks of using nanotechnologies;
- identify areas in which nanotechnologies can make a contribution to sustainable innovation; and
- develop instruments for a responsible use of nanomaterials.

The final report and the reports of the thematic groups are available in German under http://www.bmu.de/allgemein/aktuell/160.php; the English versions are in preparation and will be published at the same site.

The "Review of Nanomaterial and Nanoproduct Regulation" – outcome of Thematic Group 3 of the NanoKommission - is available in English under

www.bmu.de/files/english/pdf/applicaton/pdf/nano_abschlussbericht3_en_bf.pdf

ITALY

Highlight of developments since the 7th meeting of the WPMN

The Ministry of Health, in close cooperation with National Institute of Health (ISS), Italian Workers' Compensation Authority (INAIL) and National Institute for Environmental Protection and Research (ISPRA), is now participating to an informal taskforce which has been set up between a number of Member States to coordinate the development of a harmonised national database for nanomaterials on the market. The legal instrument is a Ministerial Decree based on a voluntary contribution of industry and scientific institutions. It is foreseen to give a mandate to the European Commission's Joint Research Centre (JRC) in order to receive the technical support needed to generate a sustainable data collection tool.

Inside a Collaboration Agreement (CA) between Joint Research Center (JRC) and the National Institute of Health (ISS) a three years project in Nanobiosciences applications was established. The aim of this CA is to share technologies and competences available both at the JRC and ISS in the field of nanomaterials and nanotoxicology. It is involved at characterisation of nanoparticles and their toxicity testing *in vitro*.

At the end of last year the Italian Society of Nanotoxicology (Società Italiana di Nanotossicologia- SIN) was founded with the aim to be a reference point for the evaluation of the environmental and health impact of nanotechnology, with regard to scientific research, industrial innovation and regulatory issues.

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 working group promoted by the ISPESL - National Institute of Occupational Prevention and Safety (a governmental agency now incorporated to INAIL - Italian Workers' Compensation Authority) has concluded the phase one of its objectives by fulfilment of a report ("White book") on the health effects and safety in occupational environments where nanomaterials are used. The aim of this National Network (NanOSH Italia) is to promote the cooperation between the Italian scientific communities in order to develop a multidisciplinary approach to the risk assessment of nanomaterials in occupational environments.

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

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

A Collaboration Agreement (CA) between the Ministry of Health and the National Institute of Health (ISS) was ongoing. Research activities of this CA are focused on the implementation and transferability of alternative *in vitro* methods in the study of nanomaterials toxicity on the basis of specific requirements by REACH regulation.

JAPAN

Highlight of developments since the 7th meeting of the WPMN (July 2010)

- In September 2010, ISO published IS 29701 "Nanotechnologies - Endotoxin test on nanomaterial samples for in vitro systems -- Limulus amebocyte lysate (LAL) test", which is the first full international standard and the first EH&S document developed by ISO/TC229 (Nanotechnologies), and whose work had been proposed and led by the Japanese Industrial Standards Committee (JISC) established within the Ministry of Economy, Trade and Industry (METI).

- Ministry of the Environment (MOE) has started experimental study on effectiveness of the incineration of nanomaterials as a countermeasure to prevent releases of nanomaterials to the environment.

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 the 7th WPMN.

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 and management activities on the manufactured nanomaterials to METI. METI publicised each report on its website (see 4. in detail).

3. Information on any risk assessment decisions;

No significant change after the 7th WPMN.

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

In November 2008, METI organised a study group focusing its discussion on safety measures introduced by nanomaterial manufactures on a voluntary 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[5]. Following the conclusion of the report, METI requested the manufacturers to further implement the voluntary safety measures, to enhance their communication with users and to provide voluntarily information on test data and management methods to the public and METI. METI publicised information gathered through this survey on METI's website in March 2010 (only in Japanese). The information gathered from the manufacturers is to be revised and publicised within 2011.

Ministry of Health, Labour and Welfare (MHLW) established two committees on safety of manufactured nanomaterials in 2008. 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, which was translated into English. According to the report of the first committee, titled "Review Panel Meeting on Preventive Measures for Worker Exposure to Chemical Substances Posing

5 http://www.meti.go.jp/policy/chemical_management/files/The%20Expert%20Meeting%20on%20Safety%20Measures%20for%20Nanomaterial%20Manufactures%20etc.pdf

Unknown Risks to Human Health (Nanomaterials) [6] ", MHLW revised a notification for exposure prevention in the workplace in March 2009. Moreover, MHLW conducts commissioned surveys on the utilisation of typical nanomaterials and literature research on the toxicity of those nanomaterials, etc. every year since 2007, and published the report of FY 2009. The report includes results gained from interviews with manufacturers, and illustrates what kinds and what amounts of nanomaterials are manufactured and used, and what kinds of products contain nanomaterials in Japan.

Japanese Industrial Standards Committee (JISC), established within METI, is the national member body participating as a P-member in ISO/TC229 (Nanotechnologies). JISC nominated the Convenor and Secretary of TC229/JWG2 (Measurement and characterisation). Until the end of 2010, ISO had published eleven documents developed by TC229. Following two documents in 2008, the third document ISO TS 80004-3 "Nanotechnologies - Vocabulary - Part 3: Carbon nano-objects", was published in May 2010, whose work had been proposed and led by JISC. In September 2010, ISO published IS 29701 "Nanotechnologies - Endotoxin test on nanomaterial samples for in vitro systems - Limulus amebocyte lysate (LAL) test", which is the first full international standard and the first EH&S document developed by TC229, and whose work had been proposed and led by JISC as well. JISC's latest New Work Item Proposal for TC229 is a draft Technical Specification "Nanotechnologies - Nanoparticles in powder form: Characteristics and measurements", for which the three-month ballot started on 8 February 2011.

In June of 2008, 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 committee issued the "Guidelines for preventing the environmental impact of manufactured nanomaterials" to provide manufacturers with currently available information for the environmentally sound management of manufactured nanomaterials, in March 2009[7]. Based on "Future Challenges" which were identified in the Guideline, MOE has conducted and reported an experimental study on 1) effectiveness of countermeasures to reduce releases of nanomaterials to the environment, such as filters and coagulation sedimentation, and 2) applicability of existing measuring methods for nanomaterials in the ambient air and water in FY 2009. MOE has also started an experimental study on effectiveness of the incineration of nanomaterials as a countermeasure to prevent releases of nanomaterials to the environment in FY 2010.

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

METI launched a five-year programme for "Evaluation of the Potential Risks of Manufactured Nanomaterials based on Toxicity Tests with Precise Characterisation" 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) evaluated the progress of the programme. On 16 October, 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 is available for download from the AIST-RISS website[8]. The final Risk assessment reports

[6] http://www.jniosh.go.jp/joho/nano/files/mhlw/s1126-6a_en.pdf

[7] http://www.env.go.jp/chemi/nanomaterial/eibs-conf/guideline_0903_enab.pdf

[8] http://www.aist-riss.jp/main/?ml_lang=en

on three nanomaterials are envisaged at the end of the project in mid-2011. After that, NEDO/AIST is holding a two-day international symposium in Tokyo on 29-30 September 2011 to explain the achievements of the programme.

METI is launching a five-year programme for the "Development of Innovative methodology for Safety Assessment of Industrial Nanomaterials" in mid-2011, which aims to develop fundamental hazard assessment methodology leading to a tiered risk assessment approach for industrial nanomaterials. The programme has two R&D themes: 1) establishment of equivalence criteria of nanomaterials and 2) establishment of low-cost and convenient methods for hazard assessment to acquire basic hazard information.

METI launched a five-year programme on the "Innovative carbon nanotubes composite materials project toward achieving a low-carbon society" in 2010, which has three R&D Themes: 1) physicality and shape control of SWCNTs; 2) dispersion of SWCNTs; and 3) development of techniques for voluntary safety management of nanomaterials. The third theme focuses on development of toxicity testing and exposure assessment protocols for ensuring safety of manufactured nanomaterials and their applications. Study results from this programme will be contributed to OECD and ISO.

MHLW has promoted research on the human health aspect of several nanomaterials since 2003 through the Health and Labour Sciences Research Grants, etc. In 2010, six research projects, including a basic research on development of methods for evaluating hazard and disposition of nanomaterials on human health, are progressing.

The Japan Bioassay Research Center launched a "Research project on the potential hazards, etc. of nanomaterials", commissioned by MHLW, which focuses on carcinogenicity of nanomaterials used/manufactured in the workplace (six-year programme, FY 2009-2014). Two-week inhalation study is on-going now (FY 2010) as the preliminary studies for two-year inhalation study of MWCNT, and subsequent 13-week inhalation study will be carried out in FY 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. This three-year project was finalised in March 2010 and JNIOSH published a research report in December 2010 (in Japanese).

MHLW has started a one-year research project on "Behaviour of Nanomaterials in the Workplace" and JNIOSH was chosen to conduct this project in FY2010. This project includes the research on behaviour of several nanomaterials both in workplace and in an experimental chamber.

In 2006, the National Institute for Environmental Studies (NIES) launched a nanotoxicology programme to investigate both in vitro and in vivo toxicities of nano structured particulate materials. In the 1st nanotoxicology programme (FY 2006-2010), NIES has completed several studies concerning 1) interaction of nano fibres 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. From FY 2011 NIES will start the 2nd nanotoxicology programme in which the stability of nanomaterials in the environment, and health effects and ecotoxicological aspects of nanomaterials will be investigated in details.

On 10 and 11 June 2010, the National Food Research Institute (NFRI) and the Japan Food Machinery Manufacturers' Association (JFMA) held the "International Conference on Food Applications of Nanoscale Science Japan, 2010". In this conference, following topics about nanoscale materials of food origin were discussed: production and characterisation of particles, technologies for measurement of physical and chemical characteristics of materials and risk assessment of nano-food.

6. Information on any public/ stakeholder consultation

Three Ministries (METI, MOE and MHLW) together presented their latest activities at the UNITAR executive workshop in Tokyo on 8 March 2010, which was open to the public[9].

7. Others (major draft budget plans on safety of manufactured nanomaterials in FY 2011)

Project name	**Governing ministry or organisations**	**FY2011 (million yen)**
Innovative carbon nanotubes composite materials project toward achieving a low-carbon society / Theme No.3: Development of techniques for voluntary safety management of nanomaterials	METI	600
Research project on risk of chemicals	MHLW	To be determined
Research project on the potential hazards, etc. of nanomaterials	MHLW	111
Food nanotechnology project	MAFF*	128
Development of innovative methodology for safety assessment of industrial nanomaterials	METI	299
Study on the methodology to prevent environmental impacts posed by Nanomaterials	MOE	23
Health and ecotoxicological effects of nanomaterials	NIES	32
Developing knowledge-based platform to support nanomaterial R&D for public acceptance	Cabinet Office /MEXT**	80

Note) *MAFF: Ministry of Agriculture, Forestry and Fisheries

**MEXT: Ministry of Education, Culture, Sports, Science and Technology

KOREA

Highlight of developments since the 7th meeting of the WPMN

- Ministry of Environment (MOE) initiated to develop "National Nano-safety Strategic Plan (2011~2015)" on nanomaterials, nanotechnology, nanoproducts and occupational safety collaborating with Ministry of Education, Science and Technology; Ministry of Knowledge and Economy; Ministry of Employment and Labour; and Korea Food and Drug Administration.
- Ministry of Knowledge and Economy (MKE) has prepared a "Guidance on safe management of nanotechnology based product". The goals of this standard are to specify appropriate compliances for nanoproducts manufacturers 1) to enhance acceptance of nanoproducts to public; 2) to ensure sustainable development of nanotechnology; and 3) to promote safety for consumer and nanotechnology user. This guideline will give a responsibility and good practice on safety in developing nanotechnology or nanotechnology in commerce. This guideline will be published as a Korean Standard and effective from 1 May 2011.

9 http://www.unitar.org/event/unitar-executive-workshop-ii-nanotechnology-and-manufactured-nanomaterials-addressing-risks-and-bene

- Ministry of Education, Science and Technology (MEST) developed the 3rd Korea nanotechnology Initiative (KNI) in order to promote nanotechnology development.

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

Ministry of Environment (MOE) developed the guidance on the occupational safety management for nanomaterials.

The Korean Ministry of Knowledge and Economy (MKE) completed a "Guidance on safe management of nanotechnology based product". This guideline will give a responsibility and good practice on safety in developing nanotechnology or nanotechnology in commerce.

2. Developments related to voluntary or stewardship schemes

MOE initiated the project which is voluntary survey on the production, use, import and export volumes and use patterns of manufactured nanomaterials.

3. Information on any risk assessment decisions

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

The Korean Agency for Technology and Standards (KATS) has developed a draft guideline for exposure monitoring of nanomaterials such as Carbon nano tubes (CNTs) and silver nanoparticles, and method for exposure assessment. The guideline will be published as Korean standard after the standard committee review. KATS is developing the reference doses of silver nanoparticles for workers and consumers. The draft reference doses will be published the end of June 2011.

4. Information on any developments related to good practice documents

The further Korean government has implemented the projects related to good practice as elaborated below in the section 5.

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

The Korean government has well recognised 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), MWCNTs, silver nanoparticles TiO_2 and SiO_2, as target materials in the framework of Eco-technomia21 from April 2007~ 2010. The ultimate goal of the research is to support the establishment of infrastructure in order to minimise 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 dose metric and the risk assessment and "Genomic studies of nanoparticles to bacteria, yeast and fish" to develop alternative methods for nanotoxicity tests. Furthermore, "Guideline for the life cycle assessment (LCA) of nanomaterials" and "Safety guideline for nanosafety management" were developed.

MOE and NIER (National Institute of Environmental Research, an affiliated body of MOE) have conducted the nanomaterials hazard assessment projects to review and adopt the OECD TGs to nanomaterials and cumulate the data related to physico-chemical properties, eco-toxicity, environmental fate and human-health in order to contribute to the decision making since 2007. MOE and NIER launched the project to survey on the production, use, import and export volumes, use pattern and the information on the related enterprises of 13 OECD sponsorship programme nanomaterials in order to establish inventory for nanomaterials. NIER organised the Nanomaterial Risk Expert Committee and held the third meeting in December 2010. This committee handles the nanomaterial safety issues, which include the areas on reviewing and adopting test methods, evaluating the validation of the data and national planning on the nanomaterial risk assessment.

Furthermore, MOE and NIER take the key role on facilitating and conducting OECD sponsorship programme under the close co-operation among ministries, academia, and industries.

MEST (Ministry of Education, Science and Technology)

MEST developed the 3rd Korea nanotechnology Initiative (KNI) in order to promote nanotechnology development.

Korea Research Institute of Standard Science (KRISS, a subsidiary body of MEST) has been developing the National Measurement Standards of materials (including nanomaterials). In connection with this topic, the research project on "Development of Characterisation Techniques for Nanomaterials Safety (2009 – 2015)" was launched. This project is composed of four parts; 1) physic-chemical property characterisation of nanoparticles such as silver, gold, titanium dioxide, polystyrene, silicon dioxide, CNTs and quantum dot has been conducted in order to develop their CRMs; 2) Surface structures and its compositions are studied using XPS, MALDI-ToF, ToF-SIMS etc.; 3) The size measurement of nanoparticles is also executed with SMPS, DLS, PBMS, TEM, BET and AFM as a part of OECD WPMN and VAMAS (TWA34) projects. Nanoparticles trace technology using ToF-SIMS and Raman spectroscopy is under developing; and 4) The studies on the transport and potential transformation of nanomaterials (ADME) is under investigation.

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 Convergence Industry Development" to strengthen research on the safety and social impact of nanomaterials. The MKE/KATS implemented "Risk Management Platform Technology for NanoProducts (2009-2013)" which will provide an infrastructure for the certification of nanoproducts based on a risk management system including characterisation, efficacy quality and safety assessment along with standard development. MKE recently submitted a "Plan for safety management of nanotechnology based products" to National Science and Technology Council and the plan was approved by the council. The Korean Agency for Technology and Standards (KATS), an affiliated body of MKE, has been developing national standards to ensure safety and support marketing of consumer products containing silver nanomaterials and CNTs. Guidelines for exposure monitoring, characterisation, and exposure assessment of nanomaterials such as CNTs and silver nanoparticles were completed. Accordingly, a guideline for exposure monitoring of nanomaterials will be published in 2011 after standard committee review. KATS will develop a new standard for safe handling and disposal of nanomaterials in 2011. KATS is developing the reference doses of silver nanoparticles for workers and consumers. The draft reference doses will be published the end of June 2011.

Korea Food & Drug Administration (KFDA)

KFDA has been operating the Nanotoxicology Project since 2007. The Nanotoxicology Project focuses mainly on providing toxicity data for preparing guidelines to evaluate safety and nano risk management associated with foods, drugs, medical devices and cosmetics using nano-scale materials. Research areas in the Nanotoxicology Project encompass a wide range of safety issues related to nano-scale nanomaterials including toxicological evaluation, risk communication, kinetics, and physico-chemical characterisation behaviour.

Test materials such as SiO_2, silver, gold and ZnO etc. have been used for preparation of guidelines to evaluate safety. Effects of size, shape and surface properties of nanomaterials on general toxicity, genotoxicity, immune response, developmental and reproductive toxicity, brain uptake mechanism, interaction with biomaterials were mainly investigated. From 2010 to 2012, KFDA plans to conduct mainly studies on the selected nanomaterials, such as SiO_2 and ZnO to get the information on physico-chemical properties, kinetics, and toxicity.

6. Information on any public/ stakeholder consultation

The guidance for prevention of environmental impact by manufactured nanomaterials is under developing by MOE.

MKE held a public consultation meeting at 23 November 2010 to hear stakeholder's opinion of "Guidance on safe management of nanotechnology based product".

NEW ZEALAND

Highlight of developments since the 7th meeting of the WPMN

- Completed a review of the adequacy of New Zealand's regulatory systems for manufactured nanomaterials;
- Received submissions on the regulation of nanomaterials in cosmetics.

Work completed, underway or planned

1. 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 review of the adequacy of New Zealand's regulatory systems to manage the possible impacts of manufactured nanomaterials was finalised in January 2011. The review report will be publicly released in the next few months. The review found that:

- Existing regulatory instruments are likely to be suitable for managing most manufactured nanomaterials, but there is room for improvement in clarifying when nano-scale forms of existing substances should be considered new and consequently trigger further regulatory assessment.
- There is potential for some novel manufactured nanomaterials to miss regulatory scrutiny if there is a failure to recognise that the manufactured nanomaterials have properties that are distinct from those of existing larger-scale compositions of the same substance.
- The notification requirement on importers and manufacturers to submit information on the types of manufactured nanomaterials being used in cosmetics has provided only limited information.

- Further attention may be required on products that do not contain manufactured nanomaterials but may generate nanoparticles during use.

Despite the limitations above, if a nanomaterial has a known hazard or risk, there are existing regulatory systems in place in New Zealand that can regulate, eliminate or manage this hazard or risk. Depending on the circumstance in which the nanomaterial is used or poses a threat, a nanomaterial would be regulated under:

- the Hazardous Substances and New Organisms (HSNO) Act 1996 by the Environmental Risk Management Authority (ERMA);
- the Health and Safety in Employment (HSE) Act 1992 by the Department of Labour;
- the Food Act 1981, via the NZ (Maximum Residue Limits of Agricultural Compounds) Food Standards 2008[10], and the Australia New Zealand Food Standards Code[11], by the NZ Food Safety Authority; and
- the Fair Trading Act 1986 and the Consumer Guarantees Act 1993 by the Ministry of Consumer Affairs

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

2. Developments related to voluntary or stewardship schemes

None

3. Information on any risk assessment decisions

Cosmetics containing nanoparticles (other than zinc oxide or titanium dioxide[12]) must be notified to ERMA as a condition of the Cosmetic Products Group Standard[13]. The purpose of this provision is to provide information to inform technical review of such substances in the future, so that if necessary, the group standard can be amended to put in place controls relating to such substances. Only 5 notifications have been received from importers and manufacturers of cosmetics in the past 12 months.

"Nanoparticle" is defined in the group standard as "an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100nm". This is an interim definition that can be readily revised when international consensus on definitions emerges (see 7. below)

4. Information on any developments related to good practice documents

None

5. Information on any developments related to Integrated Testing Strategies and/or Alternative test methods

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

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

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

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

None

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

New Zealand's MacDiarmid Institute for Advanced Materials and Nanotechnology is concerned with high quality research and research education in materials science and nanotechnology. The Institute is a collaborative venture encompassing the knowledge and expertise of leading researchers and research facilities. Two research areas of relevance:

- Professor Richard Tilley (Victoria University), who has longstanding programmes with a Japanese group looking at designing safer nanoparticle markers (quantum dots) for biological imaging and medical diagnostics.
- Professor Jim Johnston (Victoria University) who, in the course of his work on nanoparticle-based wool dyes, has addressed issues of nanoparticle wash-out or release, and end-of-life recovery of the material to prevent environmental loading.

7. Information on any public/ stakeholder consultation

Public consultations were carried out on proposals to amend the definition of "nanoparticle" in the Cosmetic Products Group Standard to align it with the EU definition. Feedback obtained included:

- An industry organisation urged New Zealand to consider adopting a 'harmonised' definition which was expected to come out of a meeting of the International Cooperation on Cosmetics Regulation in July 2010.
- A non-governmental organisation queried the scientific/ risk management basis for excluding particles between 101 to 500 nm and soluble ones.
- A non-governmental organisation urged New Zealand to adopt EU requirements on the labelling of cosmetics containing nanomaterials.
- One submitter called for a moratorium on use of nanomaterials in cosmetics until adequate safety data is provided.

8. Information on research programmes or strategies which focus on life cycle aspects of nanomaterials, as well as positive and negative impacts on environment and health of certain nano-enabled applications. (You may wish to contact your colleagues participating in SG9.)

None

Additional Information

The Ministry of Science and Innovation (MSI) is continuing to run a scanning network that identifies emerging science trends and developments[14]. Nanotechnology is an area of active interest.

[14] http://www.morst.govt.nz/current-work/futurewatch/ MSI is the amalgamation of the Ministry of Research Science and Technology and the Foundation for Research, Science and Technology.

POLAND

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;

There are no national regulatory developments on human health or environment but Polish experts are involved in work on project RIPoN. This project will provide further advice to the Commission and to the European Chemical Agency (ECHA) on how the current guidance should address nanomaterials issues related to substance identification, information requirements and chemical safety assessment.

2. Developments related to voluntary or stewardship schemes

No developments

3. Information on any risk assessment decisions

No information

4. Information on any developments related to good practice documents

No information

5. Information on any developments related to Integrated Testing Strategies and/or Alternative test methods

No information

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

FOCUS 2010 edition - nano- and micro technologies in medicine

The purpose of this programme is to support young scientists in obtaining independence, building research groups in the selected disciplines. Disciplines are announced by the Foundation every year. In 2010 Focus call covers **research on nano- and microtechnologies in medicine.**

Winning projects:

- Zn II biosensors-coated quantum dots for medicinal diagnostic and *in vivo* applications; and
- Computational tools for risk assessment of nanomaterials used in medicine

7. Information on any public/ stakeholder consultation:

No information

8. Information on research programmes or strategies which focus on life cycle aspects of nanomaterials, as well as positive and negative impacts on environment and health of certain nano-enabled applications.

The Central Institute for Labour Protection has been realising the project no OPIE 01.01.02-10-018/09-01 "Innovative polymer and carbon materials for respiratory protection against nanoparticles, vapours and gases."

Period: 01.05.2009 r. - 30.06.2013

The project is implemented under the Operational Programme Innovative Economy OPIE, 2007-2013 Priority 1: "Research and development of new technologies" Measure 1.1: "Support for scientific research for the economy knowledge-based" Action 1.1.2: "The strategic research programs and work development"

Project leader: Central Institute for Labour Protection - National Research Institute CIOP-PIB

Project Partner: Technical University of Lodz. Faculty of Process and Environmental

The main goal is to improve the safety and comfort of workers exposed to aggressive work environment using personal protective equipment.

The indirect purpose - the development of innovative nonwoven materials based on polymers that are part of the design of filtering respiratory protective equipment in order to implement effective protection against nanoparticles of air pollutants and modified carbon materials with the properties to clean the air of specific vapours and gases.

***Additional information**:*

- Despite small expenditures on science and laboratory tests there is carried out research in nanotechnology in general. There are three main centres of research on nanotechnology (in total 25 centres): Institutions operating at the Academy of Sciences, Warsaw University of Technology and Wrocław University of Technology. The centres which are less concerned with these issues are: Poznan University of Technology and Silesian University of Technology. In these centres studies on the following issues are conducted: supporting information technology, bioengineering (biotechnology), new systems (nanosystems), new energy sources (e.g., using carbon nanotubes), and new materials (such as. "smart materials").
- In Poland 3 large nanotechnology centres have been started: in Lodz, Szczecin and Gdansk. In the framework of investment in Lodz, called "BioNanoPark", there is planned to be built a new Laboratory of Molecular and Nanostructural Biophysics that will have started its activity by the end of 2013. Laboratory of Molecular and Nanostructural Biophysics will deal with influence of products of nanotechnology on human's health and environment. It will also elaborate new generic medicines and therapeutic remedies.
- Two big national conferences on nanotechnology were held in Poland in 2010: 4th National Conference on Nanotechnology NANO 2010 and NANOTECHNOLOGIA-PL, 14.09.2010, Warsaw.

The Nofer Institute of Occupational Medicine NIOM is the leading institute in the field of occupational and environmental health in Poland having the status of WHO Collaborating Centre. Scientists from NIOM participated in several EU funded projects on nanosafety issues for ex ample NANOGENOTOX and recently - MARINA (Reference methods for managing the risks of engineered nanoparticles) project.

SLOVAKIA

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

There is exists the system of national legislation in Slovakia which protects the human health and environment from negative impacts of products. These legally binding instruments can be applied for protection of environment and human health in relation to the nanomaterials and nanotechnology. Slovakia as an EU member state is actively involved in the process of implementation of REACH activities at the field of nanomaterials and preparation of legally binding instruments for nanomaterials.

Inventory and evaluation of existing nanomaterials in market is under the development. From our point of view it is urgent need and demand for internationally acceptable methodology for establishing and evaluation of nanomaterials risks as a first step for preparation of new nano legislation.

The international exchange of information at the field of physical and chemical properties and environmental and health risks of nanomaterials is needed for better protection of our environment and human health from possible negative impacts of nanomaterials and nanotechnologies.

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

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

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

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

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

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

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

There is no existing joint governmental strategy for nanomaterials in Slovak republic or specific overall research programmes in this area. However several governmental strategies dealing partly with nanomaterials such as Economic development strategy, Health care strategy, Research strategy and Sustainable development strategy.

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

At the field of research Ministry for the environment and Slovak academy of Sciences sign up an agreement and create the working group for nanomaterials as an advisory body for research development at this area. Research institutions and universities have now issued a series of projects addressing aspects of further research on nanomaterials, including their health and environmental risks. One of the most important part of research at the field of nanomaterials are construction ceramics, such as silicon nitride, titanium nitride, boron nitride, silicon carbide and titanium nitride and colour pigments. Ultra fine nano scale powders for construction ceramics are prepared by chemical vapour deposition or sol – gel methods.

Further research is done at the field of adsorbents, catalytic processes and nano scale polymer additives and composites.

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

6. Information on any public/ stakeholder consultation.

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

SOUTH AFRICA

The establishment of the Nanotechnology Health, Safety and Environment (HSE) Committee in South Africa:

With the realization of the importance of nanotechnology, the Department of Science and Technology (DST) in South Africa published the National Nanotechnology Strategy (DST 2005) preceded by the South African Nanotechnology Initiative (SANi) –formed earlier in 2002 (SANI 2002). The strategy focuses on addressing social (energy, water and health) and industrial (materials, processing, mining and mineral) issues using nanotechnology. Subsequently, Nanotechnology Innovation Centres (based at Mintek and CSIR) and other national programmes were established to undertake fundamental and applied research in an area of nanoscience and nanotechnology.

The National Nanotechnology Strategy also prescribes that the physical infrastructure, including state of the art equipment must be put in place to ensure that Nanotechnology is applied according to international best practice. The National Nanotechnology Equipment Programme was put in place to address this objective. To this end, a Nano HSE Committee has recently been constituted with main responsibilities of:

- Investigating global approaches to risk and health issues in the research and application of Nanoscience and Nanotechnology;
- Prescribing frameworks for handling of such issues locally; and
- Developing policy framework governing research, manufacture and application of nanomaterials and monitoring implementation.

The scope of the responsibilities of the committee includes:

- Steer the development of the guiding framework for the establishment of the Nanotechnology HSE Research Platform;
- Develop risk assessment plan and guide (nationally)/establishing guidelines on handling risk for products coming into the country;
- Guide the platforms research agenda through scoping of international literature, identification(and analysis) of gaps relevant for SA;
- Identify and Address Gaps in teaching and training; and
- Interface between the Ethics and Standards.

DST (2005) National Nanotechnology Strategy, Department of Science and Technology, Pretoria, South Africa (Accessed at http://www.dst.gov.za/publications-policies/strategies-reports/reports/Nanotech.pdf)
SANI (2002) South African Nanotechnology Initiative (Accessed at http://www.sani.org.za/)
DST/Mintek Nanotechnology Innovation Centre (Accessed at http://www.nic.ac.org)
DST/CSIR Nanotechnology Innovation Centre (Accessed at http://www.csir.co.za/nic.ac.org)

THAILAND

Highlight of developments since the 7th meeting of the WPMN

Since the 7th meeting of WPMN, a number of nano-safety development and activities have taken place in Thailand.

- **Nano-safety Activities of Government Agency/ Organisation/ Research Institute:**

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

The National Nanotechnology Center (NANOTEC) has established:

1. Establishment of Nanosafety Information and Knowledge Management Center (NIKM);
2. Developing of "Nano Q" as a standard nanomark for selected Thai nano-products to identify the presence of nanoparticles and nano-properties e.g. anti-bacterial and water repellence;
3. Developing of National Nano-safety Guideline compliance with laboratory and industrial protocol;
4. Initiating nanosafety training programme with UNITAR;
5. Organising workshop and seminar in Nanosafety in Thailand: Status report of Thai Nano-products to disseminate knowledge in nanotechnology and its potential risk to the public;
6. Strengthening nanotoxicity and ecotoxicity research of nanosilver, TiO_2, fly ash particles;
7. Developing of the National Nanosafety Strategic Plan focusing on human health, environment, and national security;
8. Collaborative research programmes with the Swiss Federal Institute for Materials Testing and Research (EMPA);
9. Participation as part of the Thai Delegation in the ISO/TC229 Nanotechnologies standard development activities; and
10. Initiating the collaboration with the Ministry of Public Health and the Ministry of Labour for nanoparticle screening in plants and manufactures.

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 programme.
3. Standardise and validate nano-scale measurement and testing methods.
4. Integrate nanosafety guideline into the National Chemical Safety Strategic Plan.

5. 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 Information and Knowledge Management Center (NIKM) in collaboration with Chulalongkorn University. NIKM 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, NIKM is expected to become an independent agency in order to boost its credibility as an impartial organisation.

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 Center for Innovative Nanotechnology (CIN) of Chulalongkorn University has two built-in programmes or units that cover the topics of nanosafety and nanoethics, respectively. The nanosafety programme, led by Dr. Lerson Tanasugarn, is preparing the budget for funding in 2011.

- **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.

- At the beginning of 2011, three nano-safety activities have been conducted by NANOTEC. They were National Nano-safety Strategic Plan Assembly Forum, and the establishment of Nanosafety Information and Knowledge Management Center (NIKM), in collaboration with Chulalongkorn University. The nano-label, so called Nano-Q, have been initiated and planned to implement within six months by Nanotechnology Association of Thailand.
- Since 2007, nanosafety and nanoethics have been 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 organisations 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 organisations such as OECD, ISO, and APO (Asian Productivity Organisation). In addition, this exercise attempted to familiarise 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-mark 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, TiO2 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 programmes 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_2) 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 programme 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 regularly organised nanosafety public seminars, assembly forum, and international conferences including NanoThailand 2010, the largest international conference and exhibition of nanotechnology in Thailand, nanosafety session was included.

The National Nanotechnology Centre, Thailand, (NANOTEC) was founded on August 13th, 2003 as an autonomous agency under the umbrella of the National Science and Technology Development Agency (NSTDA), Ministry of Science and Technology (MOST). Our vision is to create micro- and nanotechnologies that would enrich Thai industries, protect the environment and give rise to niche innovative products, processes, and competitiveness in the global market. Our missions are 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-calibre 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

Highlight of developments since the 7th meeting of the WPMN

Publication of 'A comparative methodology for estimating the economic value of innovation in nanotechnologies' on 17 December 2010.

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

"Nanomaterials in REACH" Co-funded partnership desk study project under the Science Knowledge for Environmental Protection network (see http://www.skep-era.net/site/2.asp) that has been running for almost a year and will complete by March. The project is looking at how the current regulation covers nanomaterials, how the regulation should be changed to provide adequate protection of the environment and human health with respect to nanomaterials, and how any gaps may be dealt with through other regulatory mechanisms. It is complementary to the work of the Competent Authorities Sub-Group on Nano and will provide a useful comparison to that European Commission-funded work when submitted to the Commission for consideration.

2. Information on any developments related to good practice documents

Work by the British Standards Institute's (BSI) Nanotechnologies Committee is currently under way to develop a "Guide to Assessing Airborne Exposure in Occupational Settings Relevant to Nanomaterials", which will complement the guide to safe handling and disposal of manufactured nanomaterials. Also under development is a "Guide for SMEs on Legislation and Standards for Nanomaterials and Nanotechnology-based Products" (ref PAS137), which has been designed to support both new and existing SMEs to introduce nanotechnology based products and processes in a safe and responsible manner. Finally, a revision of the first UK nanotechnology terminology document (ref PAS71) – vocabulary – nanoparticles, published in June 2005, is underway following the publication of relevant documents by ISO. All three documents will be published in autumn 2010 following international review and comment. (See

http://www.bsigroup.com/en/About-BSI/News-Room/BSI-News-Content/Disciplines/Nanotechnology/Nano-nine-pre-launch/).

In October 2010 the BSI published PD 6699-3 'Guide to assessing airborne exposure in occupational settings relevant to nanomaterials', which complements the guide to safe handling and disposal of manufactured nanomaterials (PD 6699-2) published in 2007 – see ***http://www.bsigroup.com/en/About-BSI/News-Room/BSI-News-Content/Disciplines/Nanotechnology/Nano-nine-pre-launch/***

Plans are underway for the development of another two BSI standards documents: *A guide to disposal of wastes containing manufactured nanoscale materials*; and *A guide to the detection and identification of manufactured nanomaterials in complex matrices*.

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

A. Phase 2 of the Environmental Nanoscience Initiative

The Natural Environment Research Council, in cooperation with the Engineering & Physical Sciences Research Council; the Department for Environment, Food & Rural Affairs (Defra); 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 is expected to be in the region of $8M. It is expected that successful grants will be announced in 2010.

B. A Risk/Benefit Approach to the Application of Iron Nanoparticles for the remediation of contaminated sites in the environment

A voluntary moratorium currently prevents the use of iron nanomaterials for the remediation of contaminated sites in the UK. This study aims to re-evaluate this position by reviewing the knowledge base in the light of recent research and the deployment of nano-iron for trial and full-scale remediation processes around the world. A consortium led by *Contaminated Land: Applications in Real Environments (CL:AIRE)* are undertaking this desk-based study in order to ascertain whether it can now be determined whether the benefits offered by the use of nano-iron outweigh the potential risks.

It is acknowledged that permitting the use of nano-iron for remediation will have to be considered on a case-by-case basis, and this project's deliverables will therefore include a list of key risk considerations that could be used to inform such decisions. This project will report its findings in early 2011.

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.

The Engineering and Physical sciences Research Council has recently commissioned a £360k project at the University of York to improve the basic understanding of how nano-materials interact with cells and in particular to investigate the toxic effects triggered by nanoparticles through oxidative stress.

4. Research programmes or strategies which focus on life cycle aspects of nanomaterials

A. Modelling environmental concentrations of nanosilver in the UK

In view of the use of nanosilver as an antimicrobial agent in a growing array of consumer products, and mindful of widespread interest and concerns in some quarters regarding possible environmental impacts,

the UK Department for Environment, Food and Rural Affairs (Defra) has commissioned a monitoring and modelling study to ascertain likely environmental exposure to nanosilver in the UK aquatic environment. This study will undertake monitoring to measure concentrations at 6 'typical' UK sewage treatment plants (STP). The results will then be used to map current and foreseen UK environmental exposure, using a Geographical Information System (GIS)-based model of UK waterways, effluent sources and water treatment facilities.

This work will provide a geographical record of silver concentrations. It will also provide an analysis of that partition of silver which ends up in sludge at water treatment works, enabling an estimate to be made of amounts of silver in sludge which end up in soils and other environmental compartments.

B. A comparative methodology for estimating the economic value of innovation in nanotechnologies

While a great deal has been invested around the world on nano innovation, no robust methodology has existed until now to estimate the value of the potential benefits. The UK Department for Environment, Food & Rural Affairs (Defra) has recently published a methodology for estimating, in monetary terms, the benefits of nanotechnology. This ground-breaking toolkit will enable calculations to be made to estimate the monetary value of nanotechnology products and applications.

The toolkit has been funded by Defra and developed by the UK research consultancy Oakdene Hollins Ltd. It provides a methodology that enables users to value nanotechnology applications, by comparing them to alternative, incumbent technologies. It enables the economic benefits accruing to producers and consumers to be considered, as well as wider benefits to the economy, environment and society. The added value of a nano-application can be calculated over a specified timeframe and can be related to a particular geographical region. If human health or environment risk data is available, this can also be factored in to the calculation.

The project deliverables have been designed for use by (1) policy makers and governments, to perform costs benefit analysis; (2) industry, to estimate the social benefits of a product i.e. to compare against any potential risks; and (3) funders, to impartially appraise the relative benefits of proposals when reaching funding decisions.

The toolkit can be accessed via the link http://www.oakdenehollins.co.uk/sustainable-innovation.php

UNITED STATES

Highlight of developments since the 7th meeting of the WPMN

The National Institute for Occupational Safety and Health (NIOSH) released and requested comments on a draft Current Intelligence Bulletin **Occupational Exposure to Carbon Nanotubes and Nanofibre (**http://www.cdc.gov/niosh/docket/review/docket161A/**)**.

NIOSH sponsored a conference on "Nanomaterials and Worker Health: Occupational Health Surveillance, Exposure Registries, and Epidemiological Research", which was held in Colorado on July 21-23 2010. More information is available at http://www.cdc.gov/niosh/topics/nanotech/keystone2010/

EPA announced and asked for public comment on its proposed decision to conditionally register a pesticide product containing nanosilver as a new active ingredient for a period of 4 years. The antimicrobial pesticide product, HeiQ AGS-20, is a silver-based product that is proposed for use as a preservative for textiles. As a condition of registration, EPA is proposing to require additional product chemistry, toxicology, exposure, and environmental data. The Agency will evaluate these data as they are submitted during the period of the conditional registration to confirm the product will not cause unreasonable adverse effects to human health and the environment.

EPA issued several Consent Orders regulating new chemical submissions of carbon nanotubes and fullerenes under the Toxic Substances Control Act (TSCA) and plans to issue proposed Significant New Use Rules (SNURs) for them shortly.

EPA is developing a regulation under TSCA to require notification of any new or existing nanoscale materials based on existing chemical substances.

EPA released in October 2010 a document titled *Nanomaterial Case Studies: Nanoscale Titanium Dioxide in Water Treatment and in Topical Sunscreen*. The case studies incorporate a comprehensive environmental assessment (CEA) framework, which combines a product life-cycle perspective with the risk assessment paradigm. This document will be used as part of a process to identify and prioritise research needs in developing data to inform nanomaterials risk assessment. EPA's draft case study, Nanoscale Silver in Spray Applications, is available for external review at

http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=226723.

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**

On December 3, 2010, NIOSH released and requested comments on a draft Current Intelligence Bulletin **Occupational Exposure to Carbon Nanotubes and Nanofibres**. The document is available at http://www.cdc.gov/niosh/docket/review/docket161A/. NIOSH held a public meeting to discuss and obtain comments on the draft document on February 3, 2011 in Cincinnati, USA.

Since January 2005 EPA has received and reviewed more than 100 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 EPA withdrew the direct final SNURs and published a proposed rule on November 6, 2009. EPA issued a final SNUR on September 17, 2010.

On February 3, 2010, EPA issued a proposed SNUR for another carbon nanotube that is a different chemical substance than the carbon nanotube described in the previous paragraph. EPA has received several public comments and will also issue a final SNUR which will take into account those comments. EPA reopened the comment period in response to comments before issuing the final rule.

EPA issued a number of additional consent orders regulating new chemical submissions of carbon nanotubes and fullerenes. A sanitised version of such a consent order is available. To date EPA has issued SNURs for less than 40 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 and consent orders for new chemical nanoscale materials in the coming year.

EPA is developing a SNUR under section 5(a)(2) of TSCA to ensure that nanoscale materials receive appropriate regulatory review. The SNUR would require persons who intend to manufacture, import, or process new nanoscale materials based on chemical substances listed on the TSCA Inventory to submit a significant new use notice to EPA at least 90 days before commencing that activity.

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 programmes including the OECD sponsorship programme.

EPA announced and asked for public comment on its proposed decision to conditionally register a pesticide product containing nanosilver as a new active ingredient for a period of 4 years. The antimicrobial pesticide product, HeiQ AGS-20, is a silver-based product that is proposed for use as a preservative for textiles. As a condition of registration, EPA is proposing to require additional product chemistry, toxicology, exposure, and environmental data. The Agency will evaluate these data as they are submitted during the period of the conditional registration to confirm the product will not cause unreasonable adverse effects to human health and the environment.

EPA has received applications to register new antimicrobial pesticides containing nanoscale silver as an active ingredient. The application proposes that the products would be used as "materials preservatives," i.e., the antimicrobial pesticides would be added to other types of products -- textiles, plastic, adhesives, etc. - to control microorganisms that might grow on or in the treated products. EPA has published a notice in its Federal Register announcing it has these applications and is treating the nanoscale silver as a new active ingredient for purposes of the pesticide laws.

EPA has announced its plans to issue a new policy under which pesticide companies would be required to report the presence in their products of nanoscale materials and to provide to EPA any additional information relevant to assessing the safety of the nanoscale material. The new policy would also announce that EPA would presumptively treat nanoscale materials as new active or inert ingredients for purposes of the pesticide laws.

OSHA is developing several guidance documents including best-practices for R&D laboratories (academic and commercial), and hazard communication for nanomaterials to be compatible with the Globally Harmonised System of Classification and Labelling of Chemicals.

2. Developments related to voluntary or stewardship schemes

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 organisations 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 developing two new documents, one that will include a listing of existing toxicity testing protocols relevant to nanomaterials, and a sister document that describes relevant sample preparation and dosimetry information. NIST representatives, as Chairs of the mirror committees, have directly solicited input from the WPMN SG4 and SG7 for the development of these two new work items as they are complementary to documents under development in those two steering groups. One of the Chairs from NIST was nominated in 2010 to represent this ISO work on the WPMN SG7 committee.

3. Information on any risk assessment decisions

EPA has assessed more than 100 nanoscale materials under TSCA since January 2005.

On December 3, 2010, NIOSH released and requested comments on a draft Current Intelligence Bulletin **Occupational Exposure to Carbon Nanotubes and Nanofibres**. The document puts forward a draft Recommended Exposure limit for carbon nanotubes and nanofibres of 0.007 mg/m^3.

4. Information on any developments related to good practice documents

On September 22, 2010, NIOSH and the National Science Foundation Center for High-rate Nanomanufacturing - a collaboration of the University of Massachusetts Lowell, Northeastern University and the University of New Hampshire – formed a formal partnership that will provide companies with practical research and guidance to promote occupational health and safety in nanotechnology (http://www.cdc.gov/niosh/updates/upd-09-22-10.html).

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

In 2010 US EPA entered into an interagency agreement with the US Consumer Products Safety Commission (CPSC) and the US National Institute for Occupational Health and Safety to conduct preliminary research to improve our understanding of children's potential exposures to nanosilver that may be released from consumer products. The focus of the research under this agreement will be to develop tools to categorise and prioritise exposure potential for select children's products containing nanosilver, and to develop approaches and protocols to estimate and predict children's potential exposure pathways for selected product categories. The protocols and tools will be evaluated in pilot tests with selected products.

EPA released in October 2010 a document titled *Nanomaterial Case Studies: Nanoscale Titanium Dioxide in Water Treatment and in Topical Sunscreen*. The case studies incorporate a comprehensive environmental assessment (CEA) framework, which combines a product life-cycle perspective with the risk assessment paradigm. This document will be used as part of a process to identify and prioritise research needs in developing data to inform nanomaterials risk assessment. The final report is available on the NCEA Web site under *Recent Additions* at www.epa.gov/ncea. Also related to its case study effort, EPA held a 5-7 January 2011 workshop using the EPA draft document, *Nanomaterial Case Study: Nanoscale Silver in Disinfectant Spray* (http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=226723) as a starting point for identifying and prioritising possible research directions related to nanoscale silver.

In 2009 the U.S. CPSC developed an inter-agency agreement to review the release of nanoscale TiO2 from aerosol spray products. The work from this study was published in 2010. Chen et al. Inhalation Toxicology, 2010, 1-11. The CPSC and NIOSH will continue to conduct studies on other aerosol products, and refine testing methods.

In 2010, NIOSH researchers have published several leading scientific papers pertaining to occupational health and safety of workers producing or using nanomaterials. These papers include:

"Occupational Exposure Limits for Nanomaterials: State of the Art," Schulte PA., Murashov V., Zumwalde R., Kuempel ED., Geraci C. J Nanoparticle Res, 2010, 12(6), 1971-1987.

A series of papers in the special issue on Human and Environmental Exposure Assessment for Nanomaterials in Int J Occ Env Health, 2010, 16(4).

6. Information on any public/ stakeholder consultation

NIOSH held a public meeting to discuss and obtain comments on a draft Current Intelligence Bulletin **Occupational Exposure to Carbon Nanotubes and Nanofibres** on February 3, 2011 in Cincinnati, USA.

On September 23-24, 2010, NIST hosted the fourth in a series of workshops addressing measurement needs for single wall carbon nanotubes (SWCNTs). The primary focus of this workshop was on SWCNT

chirality population measurements and chirality-dependent properties. Additional details of the workshop can be found at http://www.nist.gov/mml/polymers/complex_fluids/4th-carbon-nanotube-workshop.cfm

EUROPEAN COMMISSION

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

To support the OECD's sponsorship programme and to gain scientific insights into nanomaterials, the Commission's Joint Research Centre (JRC) officially launched its nanomaterials **repository** hosted at the Institute for Health and Consumer Protection (IHCP) in Ispra, Italy.

The repository provides the representative silicon dioxide, titanium dioxide, zinc oxide, cerium dioxide, silver, and MWCNTs to the sponsorship programme as well as several (EU) research projects. The materials from the repository are made available on a case-by-case basis to research projects. It is the intention that each nanomaterial (NM) will have an associated characterisation report, detailing the physico-chemical characterisation of the NM.

In connection with the repository, a scientific database - current working name "NANOhub" - has been developed. It is based on and compatible with IUCLID and templates for the nanospecific end-points in the OECD list have been added. The Database is currently used by some of the consortia in the Sponsorship programme, and some EU research projects.

DG RTD NMP initiative EU Nanosafety cluster also continues their activities. More details at:
www.nanosafetycluster.eu
The second edition of the "*Compendium of Projects in the European NanoSafety Cluster"* is available:
http://www.nanosafetycluster.eu/home/european-nanosafety-cluster-compendium.html
The 2010 version is at:
ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/compendium-nanosafety-cluster2010_en.pdf

7th EU Research Framework Programme (FP7)
New projects that have received funding from the fourth call for proposals are, by topic:
i) Reference Methods for Managing the Risk of Engineered Nanoparticles; Large-scale integrating Collaborative Projects

- **MARINA:** "Managing Risks of Nanoparticles"
- **NANOVALID:** Development of reference methods for hazard identification, risk assessment and LCA of engineered nanomaterials
- Modelling toxicity behaviour of engineered nanoparticles; Collaborative Projects
- **ModNanoTox:** Modelling nanoparticle toxicity: principles, methods, novel approaches
- **NanoTransKinetics**: Modelling the basis and kinetics of nanoparticle cellular interaction and transport

ii) Coordination of national programmes on nanotechnologies, including nanotoxicology Coordination actions, ERA-NET

- **SIINN: S**afe **I**mplementation of **I**nnovative **N**anoscience and **N**anotechnology

iii) Research Infrastructures for processing, analysis and characterisation (physico-chemical properties, health and environmental impact) of engineered nanomaterials, nanoparticles and nanostructures:

- **QNano**: A pan-European infrastructure for quality in nanomaterials safety testing

Under the fifth call for proposals the following topics have been addressed:

- NMP.2011.1.3-2 Worker protection and exposure risk management strategies for nanomaterial production, use and disposal
- NMP.2011.1.3-1 New methods for measuring, detection and identification of nanoparticles in products and/or in the environment
- NMP.2011.1.3-3 Intelligent testing strategies for nanomaterials impact and exposure – towards regulation and clustering of materials

Examples of recent results of the EC-funded research programmes are:

- Official opening of the Nanomaterials Repository, holding and making available materials used in the OECD Sponsorship programme, by the EC's Joint Research Centre, Institute for Health and Consumer Protection.
- Release of the colloidal silica certified reference material ERM-FD100 for quality assurance in particle size measurements by the EC's Joint Research Centre, Institute for Reference Materials and Measurements.
- Introductory Guide to Nanometrology, P.-E. Hansen et al., www.co-nanomet.eu

2. Ongoing Regulatory Considerations

Definition of Nanomaterials

On 24 April 2009 the European Parliament called for the introduction of a comprehensive science-based definition of nanomaterials in Union legislation as part of nano-specific amendments to relevant horizontal and sectoral legislation. Further, they called on the Commission to promote the adoption of a harmonised definition of nanomaterial at the international level and to adapt the relevant European legislative framework accordingly.

Pursuant to this, the Commission invited the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) to provide scientific input on elements to consider when developing a definition of the term "nanomaterial" for regulatory purposes.

The opinion "Scientific basis for the definition of the term 'Nanomaterial'" was adopted for public consultation on 6 July 2010. SCENIHR concluded that:

- Size is universally applicable to nanomaterials and is a key element to a definition. A defined size range would facilitate a uniform interpretation.
- The lower limit was proposed at 1 nm.
- An upper limit of 100 nm is commonly used by general consensus but there is no scientific evidence to qualify the appropriateness of this value. The use of a single upper limit value might be too limiting for the classification of nanomaterials and a differentiated approach might be more appropriate.
- For regulatory purposes, the number size distribution should also be considered using the mean size and its standard deviation to refine the definition.

In addition the SCENIHR identified certain specific cases where the application of the definition can be facilitated by using the volume specific surface area as proxy for the internal or surface structure.

Following this the Commission is now working on a Commission Recommendation on the definition of the term “nanomaterial”.

A first draft was submitted to a public consultation in October – November last year. Based on the 195 contributions received during the consultation, on other definitions emerging and evolving

internationally, on the Reference Report of the EC Joint Research Centre (JRC), and on the final opinion of SCENIHR, the Commission Services are now further considering this issue.

The full SCENIHR opinion can be found at:
http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_032.pdf
The full JRC Reference Report can be found at:
http://ec.europa.eu/dgs/jrc/index.cfm?id=2540
The full Commission consultation can be found at:
http://ec.europa.eu/environment/consultations/nanomaterials.htm

Worker protection

The European Commission service responsible for workers protection is Directorate General Employment, Social Affairs and Inclusion (DG EMPL). The EU Agency for Safety and Health at Work (OSHA) in Bilbao, Spain, also holds responsibilities concerning awareness raising and dissemination of information.

The current Commission initiatives on workers protection arising from the use of nanomaterials and/or nanotechnology in the workplace can be summarised as follows:

1. Preparatory work is ongoing to launch a call for tender (2nd quarter 2011) with a view to having a study elaborated and finalised by the end of 2012. The study will look, inter alia, into:
   a) The types, uses and likely exposures and which workers are more likely to be exposed as well as future exposure trends based on current knowledge.
   b) The information requirements for risk assessment and what are the more significant gaps relative to workplace risk assessment needs.
   c) Identification of types and effectiveness of risk management measures relevant in this context.
   d) Based on current knowledge, and to the extent possible, identification of whether the mode of action of nanomaterials is similar or different from traditional work based chemicals *e.g.* is there an increased risk from the dermal and inhalation exposure routes.
   e) State of the art regulating measurement and monitoring *e.g.* have national or other Occupational Exposure Limits setting bodies any standards in place and whether there are associated measurement methodologies.

   Conclusions from the work may be used to assess the appropriateness of current Occupational Safety and Health legislation to protect workers from potential risks posed by nanomaterials and/or nanotechnology in EU workplaces.

2. Furthermore, DG EMPL has introduced the issue of nanomaterials, in terms of risk assessment and management at EU workplaces, in the framework of the Advisory Committee on Safety and Health at Work's activities and in particular its Working Party on Chemicals in the form of an opinion request.

   The aim of this initiative is to prepare guidance explaining occupational health and safety requirements when handling or using nanomaterials, based on the requirements of Directive 98/24/EC on chemical agents.

   Such guidance will contribute to increasing the effectiveness of workplace controls to protect workers from exposure to specific engineered nanomaterials and/or nanotechnologies in EU workplaces.

   The draft Opinion, which will include the guide, is expected to be adopted by the Advisory Committee in 2012.

3. DG EMPL will give consideration to requesting a more robust involvement of OSHA with a view to raising awareness and/or disseminating information, as appropriate, in relation to nanomaterials and/or nanotechnology in EU workplaces. OSHA has already provided two things:

   i) publication of a literature review on Workplace exposure to nanoparticles in 2009, available at: (http://osha.europa.eu/en/publications/literature_reviews/workplace_exposure_to_nanoparticles/view)

   ii) a (non-exhaustive) list of some major information sources with regard to occupational safety and health (OSH) and nanomaterials, including examples of risk assessment tools and guidance developed in some EU Member States (annexed).

4. Similarly, DG EMPL will continue to inform the EU SCOEL (Scientific Committee on Occupational Exposure Limits) about the current debate on nanomaterials. The SCOEL should ensure that their methodology remains appropriate when addressing the evaluation of nanomaterials and to consider how information is presented in SCOEL Recommendations, particularly where different physical forms of the same substance/compound may exist *e.g.* TiO2. When requested, SCOEL is expected to review existing data on a chemical in the form of a nanomaterial, which may produce different effects from those of the bulk material and may also be solid enough to allow for the establishment of an OEL.

Other work

- The REACH Implementation Projects on Nanomaterials are now entering their final phase. The next steps include a review by the Commission and presentation to the authorities as well as ECHA.
- The JRC is organising a "Joint JRC Nano-event and 2nd ENPRA Stakeholder Workshop: Challenges of Regulation and Risk Assessment of Nanomaterials" in May 2011. The workshop will provide a forum for discussing recent scientific development on Risk Assessment of nanomaterials as well as relevant regulatory frameworks for assessing risk from nanomaterials.
- A workshop entitled “Bridging NanoEHS Research Efforts: A Joint US-EU Workshop”, was organised on March 10-11, 2011 in Washington, DC, under the Science and Technology Cooperation agreement between the EU and the US. It allowed US and EU researchers to share their expertise, also with the regulators, on several fields related to managing the risks related to nanotechnology.

  The two sides agreed to continue the scientific dialogue that will lead to more effective collaboration between US and EU, through active discussion about Environmental Health and Safety questions for nano-enabled products, encouraging joint programs of work that would leverage resources and establishing communities of research practice, including identification of key points of contact / interest groups / themes between key US and EU researchers and key US and EU funding sources for near-term and future collaborations.

  http://www.nano.gov/html/meetings/us-eu/index.html

BUSINESS AND INDUSTRY ADVISORY COMMITTEE (BIAC)

PART I: ACC

The American Chemistry Council Nanotechnology Panel participates in national and international forums to promote scientifically sound approaches to nanotechnology policy and support research needed to assess and manage potential health and environmental risks associated with the responsible development of nanoscale materials. While the Panel continues to be an active participant in international discussions such as the WPMN and ISO TTG 229, this update focuses largely on the Panel's domestic activities.

The Panel continues its support of the research coordinated by the U.S. National Nanotechnology Initiative (NNI) and has provided input to recent consultations on both the NNI's 2011 strategic plan and EHS research strategy. ACC and the Panel continue to support the modernisation of the Toxic Substances Control Act (TSCA) in a manner consistent with ACC's *10 Principles for Modernising TSCA* (http://www.americanchemistry.com/s_acc/sec_mediakits.asp?CID=2178&DID=9938). In the meantime, the Panel anticipates that EPA's Office of Pollution Prevention and Toxics will soon move forward with plans to exercise its existing regulatory powers under TSCA to collect data, implement test rules, and issue a generic "significant new use rule" for nanomaterials

(See: http://www.epa.gov/oppt/nano/#existingmaterials for more information). The Panel is also in discussions with EPA's Office of Pesticide Programs on approaches for gathering information on pesticides that contain nanomaterials under the Federal Insecticide, Fungicide, and Rodenticide Act.

At the state level, the Panel continues to engage the California Department of Toxic Substances Control (DTSC) on its implementation of the state's Safer Consumer Product Alternatives (SCPA) Act and its recent nanomaterials data call-in. In November 2010, the Panel and other industry stakeholders submitted comments to DTSC articulating concerns with the nanomaterial-specific language in proposed regulations under SPCA. The timing for finalising the SCPA regulation is uncertain. In its December 2010, data call-in, DTSC requested information on analytical test methods for detecting nano cerium oxide, nano silver, nano titanium dioxide, nano zero valent iron, nano zinc oxide, and quantum dots in water, air, soil, sediment, sludge, and chemical waste. California companies and universities that received the data call-in letters have one year to respond.

On the research front, the Panel is a co-sponsor of the NanoRelease project (http://www.ilsi.org/ResearchFoundation/Pages/NanoRelease1.aspx) coordinated by the International Life Sciences Institute's Research Foundation (ILSI-RF). The purpose of the NanoRelease project is to identify available methods for evaluating the release of nanomaterials from matrices, to identify gaps where new methods are needed, and to eventually fill some of the gaps by testing and evaluating selected methods. The project Steering Committee has chosen "solids" (including coatings) as the first type of matrix to be assessed and is discussing which nanomaterials to evaluate. The project will develop state-of-the-science reports describing what is known and what research gaps exist and aims to identify broadly accepted methods that can inform the need for risk management measures in occupational, consumer, and environmental contexts. Other project co-sponsors include EPA, Environment Canada, Health Canada, the U.S. National Institute for Standards and Technology, and other industry associations. Labour unions, consumer advocates, and other federal agencies participate either through the project Steering Committee or in an advisory capacity.

PART II: CEFIC

Highlights

- Active contribution of industry to national and international regulatory initiatives to effectively manage nanomaterials and nanotechnologies.

- Cefic is an active participant in the REACH Implementation Project aimed to evaluate the current guidance to the regulation with regards to Nanomaterials.
- Last year, Cefic published a Guidance describing how companies can apply the principles underpinning Responsible Care to their production and handling of nanomaterials.
- 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 and sustainable 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 strive for that our nanomaterials, products and technologies are researched, designed, manufactured and used safely and responsibly throughout their entire life cycle. We continuously initiate dialogues 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.

At the end of 2009 the first out of three REACH Implementation Projects started, aimed to evaluate the applicability of existing guidance with regards to nanomaterials. This first project addresses how to conclude on Substance ID and sameness with the purpose of forming SIEFs (substance information exchange forum) ahead of registration. The other two projects, which concern guidance on information requirement and how to conduct a chemical safety report, started in January 2010. All projects are now in their final stage and are foreseen to be finalised before the summer.

In addition, Cefic and its members continue to 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 overall provisions of REACH and its guidance documents could be applied to nanomaterials.

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. At the international level, Cefic works through the ICCA (International Council of Chemical Associations) to contribute to initiatives at the global level.

Together with ICCA, Cefic developed and agreed on a definition for nanomaterials (http://www.icca-chem.org/ICCADocs/Oct-2010_ICCA-Core-Elements-of-a-Regulatory-Definition-of-Manufactured-Nanomaterials.pdf).

Research programmes 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. As a first 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. This project has started in 2010 – after a delay due to agreements needed on the reference material- and is now in the experimental phase. The finalisation is expected by end of 2011.

In order to address regulatory and public concerns, industry is evaluating, in a second Cefic-LRI research project, the ecological risks that may be 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 nanoparticles 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. The project is well underway and expected to be completed by summer 2011.

Both projects are contributions of Cefic (via BIAC) to the Sponsorship Programme of the OECD Working Party of Manufactured Nanomaterials.

Finally, a third Cefic-LRI project has been launched on testing and assessment of reproductive toxicity of Nanomaterials. The overall objective of this proposal is to analyse 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 research is being led by Dr J. van de Sandt at TNO, in a consortium with BASF. 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? The project passed the suspension and aerosol characterisation initial stage and 2nd-generation study is underway.

Stakeholder Engagement

To draw on the strength of speaking on behalf of the entire industry, Cefic initiated last year an Industry Platform with participants from the supply chain. It has been proven a success and has achieved a better coherency between different sectors but also allowed for a better alerting system on sector specific regulatory activities.

Cefic has also identified a need to improve our way of communication to ensure more balanced messages which also include nanomaterials' environmental and societal benefits. This work will be carried out with the help of case studies, and illustrated by a number of workshops but also by a more detailed leaflet. The objective of the work which will be finished by the end of the year is to serve as basic information set for further discussions with policy makers and stakeholders.

Cefic will also continue to progress with development of industry specific guidance on best practices where the Responsible Care Guidance (http://www.cefic.org/Policy-Centre/Environment--health/Nanomaterials/) issued last year will form an important part. In addition, Cefic will also actively participate to a project related to risk management and occupational safety within the 7th Framework Program under the ownership of DG RTD, European Commission.

PART III: JCIA

The Japan Chemical Industry Association (New Topics Working Group) is committed to the ongoing development of the nanotechnology industry, particularly with respect to safe and secure nanomaterial

evaluation techniques for use in Japan and internationally, based on the Action Plan set out in the *Nanomaterial Opinion Statement*, issued in July 2008.

The major initiatives undertaken this year are listed below.

1. June 2010

The Working Group discussed the RoHS issue in Europe (the listing of nano silver and long CNTs) and consulted with NBCI (the Nanotechnology Business Creation Initiative) under the guidance of JCIA in order to draft a public statement to be submitted to the European Parliament. The Working Group introduced parties related to Cefic to NBCI and requested their cooperation when submitting the statement to the Parliament. The listing of nano silver and long CNTs was eventually postponed.

2. July 2010

The Working Group explained the importance of nanomaterial safety studies for business development in the chemical industry to NBCI, whose major concern is the business development of nanotechnology. Accordingly, NBCI organised a Nanomaterial Study Group in order to collect information from safety studies and to provide the information to NBCI member companies.

Two members of the Working Group also signed up to BIAC in Paris, through Nippon Keidanren, in order to join the OECD WPMN meeting.

3. November 2010

The Working Group and the NBCI Nanomaterial Study Group jointly discussed the nanomaterial definition proposed by the EU in order to identify the scientific issues involved and summarised the views presented. An expert member of the Working Group was sent to participate in the Study Meeting hastily held in Brussels at the end of November to discuss the definition of nanomaterials, and, as an ICCA member, greatly contributed to the development of that definition.

4. November 2010

The Working Group participated in the formulation of basic guidelines for the Nanomaterial Industry-Government Study Group organised under the auspices of the Ministry of Economy, Trade and Industry, and recommended member companies for the Study Group. In addition to the members of four chemical companies, two JCIA members joined the group's first meeting and took an active part in the discussions for the healthy business development of nanomaterials as chemical industry representatives.

5. December 2010

Representatives from the Working Group served on the TC 229 International Committee held in Malaysia and contributed to the standardisation of the TiO_2 specifications proposed by China.

6. The Working Group has actively contributed to a project of the Japanese National Committee for ISO/TC229, an OECD follow-up group, since September 2008. This year, in particular, the Working Group contributed to the development of a counterargument regarding voting for ISO nano-labelling.

7. The Working Group held for JCIA members and user companies three lectures on international nanomaterial trends as follows:

May 12: NBCI

October 29: Japan Auto Parts Industries Association

December 10: Japan Automobile Manufacturers Association

A total of slightly less than 100 participants attended these lectures.

PART IV: NIA

The Nanotechnology Industries Association (NIA) provides the Lead Sponsor to the OECD WPMN Sponsorship of ZnO, as well as the Co-Lead Sponsor to the OECD WPMN Sponsorship of CeO_2, through coordination of ***PROSPEcT*** (*i.e. Ecotoxicology Test Protocols for Representative Nanomaterials in Support of the OECD Sponsorship Programme*), a Public-Private-Partnership between the UK Government and several industrial NIA members (PPP duration: 3 years; started: 1st January 2009; total value: GBP 3.7 Million).[15]

In January 2011, PROSPEcT delivered an interim report to the UK Government; a sanitised version of this report will be made available to the OECD Sponsorship Programme in time for the 8th WPMN.

PROSPEcT, in collaboration with the CeO_2- and ZnO-Sponsorship Partners, developed and published a number of dispersion- and sample-preparation protocols, which have been discussed and highlighted at a number of nanomaterial (eco)toxicology workshops (including OECD WPMN SG7), and are now being included in the OECD WPMN collection of recommended dispersion protocols.

PROSPEcT formally finishes in December 2011. In the last project year, PROSPEcT will deliver prototypes of particle elimination instruments, as well as real-time in-situ tracing technology.

NIA has co-authored a report on nano-Silver characterisation, in the course of materials and data-provision to the European Commission (JRC) NM-Series of Representative Manufactured Nanomaterials.

During the 7th WPMN (July 2010), the NIA took on Lead-Sponsorship for nano-Clay. In September 2010, a privately funded project started, aiming to investigate the physchem properties of a nano-Clay sample (bentonite), as well as its eco-toxicology, environmental fate and transport/migration behaviour.

Towards the end of 2010, the NIA, in collaboration with various public partners, started the creation of a new PPP, following the success of the PROSPEcT Project, but including a broader range of OECD WPMN (R)NMs. In January 2011, a draft budget of EURO 4.4 Million had been earmarked for this project (negotiations continue).

(Other) NIA Projects:

Safety Assessment:

1. In late 2010, the NIA participated in the conduct ***NanoImaging - Detection of Engineered Nanomaterials in the Environment: Available techniques and potential for applied techniques from nanomedicine and nanotoxicology***. This project was funded by the UK Department for Environment, Food and Rural Affairs (DEFRA) and the resulting report will be published by DEFRA.[16]

2. In November 2010, the project on ***Development of Exposure Scenarios for Manufactured Nanomaterials (NANEX)***, (European Commission, FP7), in which the NIA was a partner, finished. The aim of the NANEX project was to develop a catalogue of generic and specific exposure scenarios for manufactured nanomaterials (MNMs) relevant for human exposure taking account of the entire lifecycle of these materials. NIA provided real-life exposure scenarios to the project.[17]

[15] Follow this link for more information on PROSPEcT: http://www.nanotechia.org/content/activities2/current-projects/prospectproject20090101/ or http://www.nanotechia-prospect.org/home/home

[16] Follow this link for more information on NanoImaging: http://www.nanotechia.org/nia-activities/nia-projects

[17] Follow this link for more information on NANEX: http://www.nanotechia.org/content/activities2/current-projects/niaprojectnanex/

3. Since January 2010, the NIA conducts ***REACH Implementation Plans on Nanomaterials (RIP-oNs):[18] Scientific and technical Support on Nanomaterials.***

   RIP-oN2:'Specific advice on fulfilling information requirements for nanomaterials under REACH"[19],

   This project aims to:

   - Develop specific advice on how REACH information requirements on intrinsic properties of nanomaterials can be fulfilled. This should address and advise on the appropriateness of the relevant test methods (including dosimetry) for nanomaterials, and outline, when relevant, possible specific testing strategies.
   - Develop advice on the information that is needed for safety evaluation and risk management of nanomaterials and in particular if information is needed beyond or in addition to the current information requirements listed in REACH Annexes VI-X.

   RIP-oN3:'Specific advice on exposure assessment and Hazard/Risk Characterisation for nanomaterials under REACH"[20]

   The project addresses exposure assessment and hazard/risk characterisation for nanomaterials within REACH. It aims to:

   - Develop advice on how to do exposure assessment for nanomaterials within the REACH context. This shall be the main focus of the project and shall cover:
     - development of Exposure Scenarios;
     - evaluation of operational conditions and risk management/mitigation measures; and
     - exposure estimation.
   - Develop ideas on how to conduct hazard and risk characterisation for nanomaterials. The latter will involve threshold/non-threshold considerations.

The projects are expected to finish in April 2010.

Regulatory Assessment:

In 2010, the NIA held a workshop entitled '***REACHing Nanomaterials'***, which discussed the following topics:

- How are nanomaterials regulated in the absence of nano-specific provisions under REACH?
- What is the state of play on the EU nano-definition & what can we expect from the 'REACH Implementation Plans on Nanomaterials'?
- How can companies fulfil current compliance and prepare for future regulation?

Benefits of Nanotechnologies:

1. In the 2nd half of 2010, the NIA was participating in a project entitled ***'Valuing Nanotechnologies - Methodology for estimating, in monetary terms, the benefits of nanotechnology'.***[21]

[18] *RIP-oN1: 'Substance Identification of Nanomaterials':* this RIP-oN is conducted by the IHCP (JRC) under consultation of additional experts.

[19] Follow this link to find out more about RIP-oN2: http://www.nanotechia.org/content/activities2/current-projects/niaprojectripons/niaprojectripon2/

[20] Follow this link to find out more about RIP-oN3: http://www.nanotechia.org/content/activities2/current-projects/niaprojectripons/niaprojectripon3/

[21] Follow this link to find out more about the 'Valuing Nanotechnologies'-Project: http://www.nanotechia.org/content/activities2/current-projects/valuenanotech20100400/

This project aimed to develop a methodology to quantify the value of nanotechnology in comparison to conventional products.

The Project generated a variety of reports, guidelines and tools for policy makers, governments and companies utilising nanotechnology; all of these have been published by DEFRA and are also available from the NIA website.[22]

Commercialisation:

1. In the summer of 2010, the NIA-supported project on ***Best Practices for IPR and Technology Transfer in Nanotechnology Developments*** finished.[23]

The Nano2Market project aimed to develop and provide guidelines for technology transfer, rules for IPR and license agreements and license models in nanotechnology development projects.

The Project results were presented to the 7th WPN.

Market-Specific R&D:

1. The NIA continues to conduct a research project entitled '***Transforming the future of heat management (NanoHex)'***. The world's largest collaborative project for the research and development of nanofluid coolants, NanoHex comprises of a consortium of 12 leading European companies and research centres. It has been funded by a €8.3 million 'Seventh Framework Programme' grant, together with investment from the consortium themselves.

   Using promising research results from previous work by the consortium, NanoHex aims to develop and optimise the processes for the production of high performance nanofluid coolants for use in industrial heat management. As well as an analytical model that will predict the nanofluid's thermal performance; something that has not yet been achieved.

Governance of Nanotechnologies:

Since 2006, the NIA is instrumental in the development and promotion of the '***Responsible Nano Code'***.[24]

Forecast of Emerging Technologies:

In 2011, the NIA will publish a new version of its '***Forecast of Emerging Technologies'***.[25]

Nanotechnology Norms and Standards:

The NIA is a member of the UK BSI (British Standards Institution) (i.e. BSI NTI/1) and the European Committee for Standardisation (CEN TC/352).[26] The NIA furthermore provided evidence to the ISO/TC 194 committee on the needs for standardisation.

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[22] Follow this to find out more about the output of ValueNano:

and: http://www.nanotechia.co.uk/global-news/estimating-in-monetary-terms-the-benefits-of-nanotechnology

[23] Follow these links to find out more about the Nano2Market project: http://www.nanotechia.org/content/activities2/current-projects/niaprojectnano2market/ or http://www.nano2market.eu/

[24] Follow this link to find out more about the *Responsible Nano Code*: http://www.nanotechia.org/content/activities2/responsible-nano-code/

[25] Follow this link to find out more about teh NIA Forecast of Emerging Technologies: http://www.nanotechia.org/content/activities2/techforesight/

Contributions to the WPN:

The NIA provides the BIAC Co-Lead representative to the WPN. At the beginning of February 2011, the NIA participated in the ***WPN Bureau Workshop*** on *'Building a Strategic Framework for the OECD Working Party on Nanotechnology'.*

Publications (since last report – i.e. after May 2010):

1. **Consultation Responses & Evidence (interactive list):**[27]

   - ***January 2011:***

     NIA Comments submitted to CEN/TC 352 on *CEN ISO/TS 13830:2010 Guidance on the labelling of manufactured nano-objects and products containing manufactured nano-objects* Registered NIA Members can download the full NIA Comments by following the link listed under the NIA Committee on 'Standardisation' page

   - ***November 2010:***

     NIA Comments and Evidence in Response to the European Commission's Public Consultation on a *Proposal for a Commission Definition of the Term "Nanomaterial"*.

   - ***November 2010:***

     NIA Comments on proposed *California DTSC '**Green Chemistry Regulation**'*

   - ***September 2010:***

     NIA Comments submitted to the *Public Consultation on the proposed SCENIHR Opinion on **'Scientific Definition on the Term 'Nanomaterial''***

2. **Statements & Opinions :**[28]

   - ***November 2010:***

     NIA Position on nano-specific Provisions in the Revision of the ***Novel Foods Regulation*** *((EC) No 258/97)*

PART V: VCI

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

Principle documents:

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

Regulatory documents:

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[26] Follow this link to download find out more about the NIA's work in Norms and Standardisation: http://www.nanotechia.org/nia-activities/standards---nanotechnology

[27] Follow this link for a full list of NIA Consultation Responses & Evidence: http://www.nanotechia.org/content/publications/consultation/

[28] Follow this link for a full list of NIA Statements & Opinions: http://www.nanotechia.org/content/publications/statements/

- 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 Recovery and Disposal of Waste containing nanomaterials
- 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
- Results of 10 years Research in Nanosafety (Working title; the German version will be published in Feb/March 2011, an English version is going to follow.)

These documents have been discussed with the public as well as with national and European authorities and have been received very well by the OECD Working Party on Manufactured Nanomaterials (WPMN). Updates of some documents are in preparation.

In addition to these activities VCI is currently compiling information on nanoparticle exposure at the workplace and in the environment. This information aims at deriving best practices for exposition measurement and is intended to be published at scientific and political level.

Furthermore VCI has supported and sponsored the international workshop on “Workplace aerosols” held in Karlsruhe, Germany in June 2010.

Together with its sector groups VCI will present in the first half of 2011 the results of 10 years of research on the safety of nanomaterials and on potential release of nanoparticles from end products. The projects refer to nanomaterials with wider commercial application in different areas and on topics of high scientific priority. Some results of safety research have already been published further publications are in preparation.

In 2006, VCI and the German Federal Institute of Occupational safety and health (BAuA) had conducted a first survey on how industry is dealing with nanomaterials in workplace safety. This survey is now being carefully reviewed and currently reissued by BAuA with an extended scope. The process is assisted by VCI. First results are planned to be deliverable in 2011.

On the political level, the German chemical industry is deeply engaged in the second phase of the dialogue activities, called “Nano-Dialog”, with the German government. The process has been finalised in February 2011. The results of these activities will be fed into the international discussion.

Furthermore the German chemical industry is engaged in the preparation of a Workshop on standardisation of nanotechnologies that is foreseen to be held in May 2011 in Berlin, Germany.

More information is available at www.vci.de

TRADE AND UNION ADVISORY COMMITTEE (TUAC)

Highlights of developments since the 7th meeting of the WPMN

1. The European Trade Union Confederation (ETUC) has contributed to the consultation from the European Commission on a proposal for a definition of the term "nanomaterial".[29]

The ETUC considers that the definition should cover all nanomaterials and in particular those with a size smaller than 1 nanometre (nm) such as fullerenes. The criteria used for the definition should capture as much material as possible about which there is already concern, while avoiding materials that do not give rise to nano-scale-related concerns.

The ETUC has developed a flow diagram to distinguish a substance in the nano-form from the bulk form. The ETUC proposal helps also to decide in which respect a nanomaterial should be considered as a different substance in case of surface modifications.

In particular with regard to the definition of nanomaterials, it should enable and support the generation of information and its dissemination in the supply chain in such a way that workers and consumers are informed when nanomaterials constitute an integral part of a substance (or a mixture) and whether nanomaterials can be released from related products.

2. The ETUC developed the 2nd Resolution on Nanotechnologies and Nanomaterials adopted on its Executive Committee the 1st and 2nd of December 2010.[30] The resolution is a result of the work done by the ETUC Working Group on Nanotechnologies and of the discussion during the seminar *Nanotechnologies in national and European trade union strategies* organised by the ETUI on 19-22 October.

The aim of the resolution is to call for the protection of workers potentially exposed to nanomaterials in all sectors.

One of the ETUC's demands is the development of concrete measures in the workplace to identify who is exposed, to what extent and to what type of nanomaterials, and which prevention measures to install to avoid exposure.

It particularly addresses the concern that little emphasis is being placed on the social and ethical issues related to nanotechnologies and how they should be used to contribute to human well-being and the development of socially just societies.

The ETUI is looking forward for future co-operation.

[29] ETUC (2010) Definition of substances in nano- form http://www.etuc.org/IMG/pdf/REACH_nanosubstance_definition_ETUC_concept.pdf

[30] ETUC (2010) 2nd Resolution on Nanotechnologies and Nanomaterials

http://www.etuc.org/a/8047

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

THE INTERNATIONAL ORGANISATION FOR STANDARDISATION TECHNICAL COMMITTEE- NANOTECHNOLOGIES (ISO/TC 229)

The International Organisation for Standardisation Technical Committee (ISO/TC) 229 - Nanotechnologies - was established in June 2005 with a UK secretariat and chair. It has held eleven meetings to date, with the most recent being in Kuala Lumpur, Malaysia, in December 2010. The next meeting will be in May 2011 in St Petersburg, Russia. The committee currently has 44 members - 36 "P" and 8 "O". Eleven documents have been published to date – five terminology (WG1), two measurement and characterisation (WG2), and four health, safety and environment (WG3) – with a further 33 documents currently under development (see document 'ISO TC 229 project summaries 11.01.24', available at https://community.oecd.org/docs/DOC-17057). The publications most relevant to the WPMN since its last meeting, in July 2010, are ISO 10801:2010 - Nanotechnologies - Generation of metal nanoparticles for inhalation toxicity testing using the evaporation/condensation method, ISO 10808:2010 - Nanotechnologies - Characterisation of nanoparticles in inhalation exposure chambers for inhalation toxicity testing, and ISO TS 80004-1 - Nanotechnologies – Vocabulary Part 1: Core terms.

The TC structure consists of 4 working groups (WG), the first two of which are Joint Working Groups (JWG) with IEC/TC 113 (Nanotechnology standardisation for electrical and electronic products and systems): Terminology and Nomenclature (JWG1, convened by Canada); Measurement and Characterisation (JWG2, convened by Japan); Health, Safety and Environment Aspects of Nanotechnologies (WG3, convened by USA), and Material Specifications (WG4, convened by China).

The committee has Task Groups that are developing recommendations for 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. TC 229 also works closely with the CEN (European Committee for Standardisation) TC in the area (TC 352 – Nanotechnologies, chaired by France), 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, ECOS, ETUI, IUPAC and with VAMAS.

Given the number of ISO and other committees and working parties with an interest in nanotechnologies standardisation, and in particular in the development of test methods for measurement and characterisation, the committee has establish a Nanotechnology Liaison Coordination Group to ensure coordination of activities and harmonisation 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 summarised below:

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

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

Acceptance requires

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

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

ISO standards are voluntary. As a non-governmental organisation, 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.

Recent ISO publications of interest to members of the WPMN:

- ISO 10801:2010 – Nanotechnologies - Generation of metal nanoparticles for inhalation toxicity testing using the evaporation/condensation method
- ISO 10801:2010 – Nanotechnologies – Characterization of nanparticles in inhalation exposure chambers for inhalation toxicity testing
- ISO TS 80004-1 – Nanotechnologies – Vocabulary Part 1 – Core Terms

Relevant documents currently under ballot:

- ISO DTS 80004-4 – Nanotechnologies – Vocabulary Part 4 – Nanostructured materials.

Documents about to be submitted for ballot:

- ISO DTR 13014 – Nanotechnologies – Guidance on physico-chemical characterization for manufactured nano-objects submitted for toxicity testing (3 month ballot should start by mid-April)

Members wishing to comment on documents under ballot can do this either through the liaison between the WPMN and ISO TC 229 (contact the secretariat) or, if they wish to influence the outcome of the ballot, through their national standards body mirror committee – contact details for which are available through the password protected website.

Further details on ISO TC 229 can be found at http://www.iso.org/iso/standards_development/technical_committees/list_of_iso_technical_committees/iso_technical_committee.htm?commid=381983 , and on ISO at http://www.iso.org

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

Highlight of developments since the 7th meeting of the WPMN

1. Final Report: International Conference on Food and Agriculture Applications of Nanotechnologies - NANOAGRI 2010 - June 20-25 2010 - Sao Pedro, Brazil
2. WHO Guidelines: "Protecting Workers from Potential Risks of Manufactured Nanomaterials"
3. FAO/WHO Electronic expert discussion group on nanomaterials used in food sector

Activities on health and environmental safety aspects of manufactured nanomaterials

1. Final Report: International Conference on Food and Agriculture Applications of Nanotechnologies - NANOAGRI 2010 - June 20-25 2010 - Sao Pedro, Brazil

The Government of Brazil, in collaboration with the Food and Agriculture Organisation of the United Nations (FAO), organised an international conference as forum for discussion on emerging nanotechnologies with the potential to provide significant benefits in food, water and agriculture. FAO jointly hosted with EFSA, IUFoST and OECD, three technical roundtable sessions with 22 experts coming from academia, private sector, governmental organisations, international organisations, and NGOs to facilitate exchange of views among stakeholder groups and to seek opportunities for collaboration in areas that are of particular interest to developing countries. The outcomes of the Conference are going to be used as base for future work activities, including the facilitation of partnerships and collaborations between countries on nano applications of common interest; the contribution to an international exchange of information on issues of global relevance related to nanotechnologies; and a coordinated effort to review and define the tiered approach for assessing the risks of nanotechnologies. The report of the Round Table sessions is available at: ftp://ftp.fao.org/ag/agn/agns/NANOAGRI_2010.pdf .

2. WHO Guidelines: "Protecting Workers from Potential Risks of Manufactured Nanomaterials"

WHO is developing Guidelines to "Protecting Workers from Potential Risks of Manufactured Nanomaterials" (WHO/NANOH). These Guidelines aim to facilitate improvements in occupational health and safety of workers potentially exposed to nanomaterials in a broad range of manufacturing and social environments. WHO is in the process of identifying scientific knowledge and expertise on nanomaterials and health to contribute to this initiative. Relevant scientific publications, submissions from experts

wishing to participate in the development of these guidelines and declarations of interest in supporting this project through other contributions can be sent to nanohealth@who.int. Further information about this project is available at http://www.who.int/occupational_health/topics/nanotechnologies/en/.

3. FAO/WHO Electronic expert discussion group on nanomaterials used in food sector

As was reported to the last session, FAO and WHO held an expert meeting on the application of nanotechnologies in the food and agriculture sectors: potential food safety implications (http://www.who.int/foodsafety/fs_management/meetings/nano_june09/en/index.html). One of the recommended follow-up items for FAO/WHO was to review the risk assessment strategies 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. In addition, at the 33rd Session of Codex Alimentarius Commission (July 2010), the Commission discussed the possible establishment of a Task Force on the topic of nanotechnology, however, the Commission was informed of the outcome of the above mentioned FAO/WHO expert meeting, thus agreed that there was no need to establish a Task Force for the time being. The Commission encouraged FAO and WHO to continue working on this matter. Thurs FAO/WHO established an electronic expert discussion group to seek further scientific advice from experts on the development of a tiered risk assessment approach for application of nanotechnologies to food and feed. In light of this the specific objectives are as follows:

- To develop a decision tool to support identification of the appropriate risk assessment approach of nanomaterial categories; and
- To review the current risk assessment approaches that are used by FAO/WHO, including the decision tree approaches that JECFA is currently developing, in order to address the specific emerging issues associated with the application of nanotechnologies in food and feed.

For more information contact Masami Takeuchi (masami.takeuchi@fao.org) at FAO or Kazuko Fukushima (fukushimaka@who.int) at WHO.