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THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY

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CURRENT DEVELOPMENTS ON THE SAFETY OF MANUFACTURED NANOMATERIALS - TOUR DE TABLE

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Series on the Safety of Manufactured Nanomaterials

No. 34

CURRENT DEVELOPMENTS/ACTIVITIES ON THE SAFETY OF MANUFACTURED NANOMATERIALS

Tour de Table at the 9th Meeting of the Working Party on Manufactured Nanomaterials

Paris, France 7-9 December 2011

IOMC

INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

A cooperative agreement among FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD

Environment Directorate

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Paris, 2012

Also published in the Series of Safety of Manufactured Nanomaterials:

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

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

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

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

No. 5, *Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 3rd Meeting of the Working Party on Manufactured Nanomaterials (2008)*

No. 6, *List of Manufactured Nanomaterials and List of Endpoints for Phase One of the OECD Testing Programme (2008)*

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No. 12, *Comparison of Guidance on Selection of Skin Protective Equipment and Respirators for Use in the Workplace: Manufactured Nanomaterials (2009)*

No. 13, *Report of an OECD Workshop on Exposure Assessment and Exposure Mitigation: Manufactured Nanomaterials (2009)*

No. 14, *Guidance Manual for the Testing of Manufactured Nanomaterials: OECD Sponsorship Programme (2009)*

No. 15, *Preliminary Review of OECD Test Guidelines for their Applicability to Manufactured Nanomaterials (2009)*

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No. 17, *Current Development/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 5th Meeting of the Working Party on Manufactured Nanomaterials (2009)*

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No. 21, *Report of the Workshop on Risk Assessment of Manufactured Nanomaterials in a Regulatory Context (2010)*

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)*

No. 29, *Current Development/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 8th Meeting of the Working Party on Manufactured Nanomaterials (2011)*

No. 30, *Regulated Nanomaterials: 2006-2009 (2011)*

No. 31, *Information Gathering Schemes on Nanomaterials: Lessons Learned and Reported Information (2011)*

No. 32, *National Activities on Life Cycle Assessment of Nanomaterials (2011)*

No. 33, *Important Issues on Risk Assessment of Manufactured Nanomaterials (2012)*

ABOUT THE OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 34 industrialised countries in North and South America, Europe and the Asia and Pacific region, as well as the European Commission, meet to co-ordinate and harmonise policies, discuss issues of mutual concern, and work together to respond to international problems. Most of the OECD's work is carried out by more than 200 specialised committees and working groups composed of member country delegates. Observers from several countries with special status at the OECD, and from interested international organisations, attend many of the OECD's workshops and other meetings. Committees and working groups are served by the OECD Secretariat, located in Paris, France, which is organised into directorates and divisions.

The Environment, Health and Safety Division publishes free-of-charge documents in eleven different series: **Testing and Assessment**; **Good Laboratory Practice and Compliance Monitoring**; **Pesticides; 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, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD. 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.

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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 9th Meeting in December 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.

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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 8th meeting held 16-18 March 2011 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 and United Nations Institute for Training and Research (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 9th meeting of the WPMN (December 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 agenda item 4 (the Tour de Table) is to give each delegation the opportunity to describe recent or planned national initiatives and/or events related to the safety of manufactured nanomaterials. This will facilitate the implementation of the projects of the WPMN by allowing delegations to share their experiences and preoccupations with respect to safety, and will identify opportunities for future co-operation and co-ordination.

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(2011)12].

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 8th meeting of the WPMN (March 20110) 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.

Format for the Tour de Table

Highlight of developments since the 8[t] meeting of the WPMN

- Request for information on nanomaterials issued on…..…… (Day/Month/2011)
-

Work completed, underway or planned

(In case of no information under a heading below, please put "None" or delete the heading itself)

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;**
   …….
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.);**
   …….
9. **Information on any development related to exposure measurement and exposure mitigation**
   …….

Additional Information

- Any consideration on the benefits of nanotechnologies;
- Consideration of ethical implications; and
- 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.

RESPONSES FROM DELEGATIONS

AUSTRALIA

Highlight of developments since the 8th meeting of the WPMN

- The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is actively monitoring new chemicals notifications for nanoforms following the introduction of administrative arrangements on 1 January 2011. Concurrently it is also developing options for the regulation of nano-forms of existing chemicals and plans to undertake stakeholder consultations in 2012.

- Safe Work Australia is implementing a Nanotechnology Work Health and Safety Program. Seven research reports and a work health and safety assessment tool for handling engineered nanomaterials have been published. A research report on the *Durability of carbon nanotubes and their potential to cause inflammation* was published in May 2011.

- A Nanoregulation Symposium, organized by the Australian Pesticides and Veterinary Medicines Authority (APVMA) and NICNAS was held in Sydney on 9 November 2011.

- The National Enabling Technologies Strategy Public Awareness and Community Engagement (NETS-PACE) conducted multi-stakeholder workshop that developed the basis of a community engagement framework and principles.

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), is continuing its strategy for the regulation of industrial nanomaterials that received in-principle support of stakeholders from public consultation in 2009/10. Under this strategy, NICNAS uses a working definition for industrial nanomaterials (applicable to this sector only) that was developed in consultation with stakeholders and its Nanotechnology Advisory Group (NAG):

… 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.]

Recognising the need to accommodate future developments in light of the rapid advances in the science, NICNAS will utilise the working definition while keeping abreast of national and international approaches.

NICNAS introduced new administrative arrangements (non legislative) for nanoforms of new chemicals (chemicals that are not on the national inventory) on 1 January 2011. Current compliance monitoring activities will provide NICNAS with information on the extent of industry compliance with these administrative arrangements.

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 reasonably 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. Guidance material on these regulatory arrangements is available here: http://www.nicnas.gov.au/Current_Issues/Nanotechnology/Guidance%20on%20New%20Chemical%20Requirements%20for%20Notification%20of%20Industrial%20Nanomaterials.pdf

NICNAS is also currently examining 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 2012.

More 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 (SWA) has provided information relating to nanomaterials in the model Codes of Practice for; (a) Preparation of Safety Data Sheets for Hazardous Chemicals and (b) Labelling of Workplace Hazardous Chemicals, which were made available on the Safe Work Australia website in September 2011. http://www.safeworkaustralia.gov.au/Legislation/AdministrativeRegulations/Pages/Model%20work%20health%20and%20safety%20Regulations.aspx

For engineered or manufactured nanomaterials, or chemicals containing engineered or manufactured nanomaterials, it is recommended that a Safety Data Sheet (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.

Section 9 of the SDS Code of Practice lists physicochemical parameters for which information on chemicals should be provided in a SDS. In addition to parameters listed in the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), it also lists a number of non-mandatory parameters, specifically relevant to engineered nanomaterials, but also relevant for chemicals more generally.

An Australian paper on SDS and nanomaterials was presented to the UN's Sub-Committee of Experts on the GHS (UNSCEGHS) meeting in December 2010.

As part of the Australian Government's National Enabling Technologies Strategy (NETS) led by the Department of Innovation, Industry, Science and Research, a study is being conducted to assess the feasibility of a nanotechnology product registry for Australia. This is expected to be completed by the end of the year.

2. Developments related to voluntary or stewardship schemes

No developments since the 8th meeting of the WPMN.

3. Information on any risk assessment decisions

Within the industrial chemicals sector, NICNAS has received three applications for substances that are considered to be nanomaterials under its working definition. These were reviewed in accordance with published guidelines (See above for details)

No nanomaterial applications have been received to date in the pesticides or food sectors.

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 Organization for Standardization (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

The Australian Research Council (ARC) is currently providing funding for two projects administered by the Queensland University of Technology that are focussed on the safety of airborne nanoparticles:

- *Detection, characteristics and dynamics of airborne engineered nanoparticles for human exposure assessment*: This project aims to develop an understanding of nanoparticle emission and behaviour in the air, which is needed to control workplace exposure to these particles and minimise the risk to human health.

- *Quantification of airborne engineered nanoparticles: developing a scientific framework to inform their regulation and control*: This work aims to develop a foundation for the quantitative assessment of airborne engineered nanoparticles, which is critical for controlling exposure and minimising health risks.

On 9 November 2011, the Australian Pesticides and Veterinary Medicines Authority (APVMA) and the National Industrial Chemical Notification and Assessment Scheme (NICNAS) held a one day Nanoregulation Symposium in Sydney, Australia. The aim of the symposium was to increase understanding and foster collaborative dialogue between regulators and stakeholders in an international context, with a focus on consolidating current scientific knowledge of health and environmental safety aspects of nanomaterials. Presentations from the day and audio interviews with participants are expected to be placed on the APVMA website before the end of 2011.

NICNAS also 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 totaling 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.

A Nanotechnology Work Health and Safety Program, managed by Safe Work Australia (SWA), is being implemented. The program is Australia-focused, and also contributes to global efforts on nanotechnology work health and safety. The program 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 organizations
- Ensure consistency with international approaches and contributing to international work

Fifteen projects have been commissioned by SWA to progress work in these key areas. Seven research reports have been published, with the following report published since the 8th WPMN Tour de Table report:

- Durability of carbon nanotubes and their potential to cause inflammation

http://www.safeworkaustralia.gov.au/AboutSafeWorkAustralia/WhatWeDo/Publications/Pages/DurabilityCarbonNanotubes.aspx

Further reports will shortly be published.

The work program 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.

SWA 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

Focus is being placed on developing training and guidance materials, including the development of:

- Guide to safe handling and use of carbon nanotubes,
- Nanotechnology work health and safety training course

Food Standards Australia New Zealand (FSANZ) is continuing research into the application of nanotechnologies in food and expects to publish an article in the International Food Risk Analysis Journal in coming months, titled *"Regulation of nanotechnologies in food in Australia and New Zealand"*.

6. Information on any public/ stakeholder consultation

The National Enabling Technologies Strategy has a Stakeholders Advisory Council. As noted in the last Tour de Table, the Advisory council includes representation from industry, researchers, Non-Government Organisations, consumer groups, unions, ethicists, social scientists and an independent chair. The 2nd and 3rd meetings of the council were held in July 2011 and November 2011. They have recommended that the government commission a study to assess the regulatory framework's ability to handle new enabling technologies.

Throughout 2010 and 2011, the National Enabling Technologies Strategy Public Awareness and Community Engagement (NETS-PACE) has been conducting a multi-stakeholder engagement process, to develop a framework for broad community engagement in decision making about science and technology. The framework will provide clarity and guidance about principles, procedures, methods and organisational arrangements to guide NETS-PACE and other relevant organisations in conducting effective community engagement.

The process involved five stakeholder workshops between April 2010 and May 2011 with:

- Public interest, consumer health and trade union organisations
- Researchers (including biophysical scientists, social scientists and community engagement practitioners)
- Industry
- Government
- General Public

It culminated in a multi-stakeholder workshop in August 2011 at which 40 representatives of the different stakeholder groups worked together to develop the basis of the community engagement framework, including a set of principles. The framework is due to be released later in 2011, and the process was awarded the National Core Values Award by the International Association for Public Participation (IAP2).

DIISR also conducted the fifth tracking study into public attitudes towards nanotechnology in 2011, to assess the Australian public's knowledge of and views on nanotechnology. Key findings included:

- understanding of nanotechnology is increasing, with 76% of those surveyed saying they were aware of nanotechnology, compared to 51% in 2005, when the surveys began, and 18% saying they knew in detail what nanotechnology was and how it worked, compared to only 4% in 2005.

- after considering specific benefits and risks, such as those relating to human health and safety or the environment, respondents actually became more excited or hopeful about the technology, increasing their level of support from 84% to 93%/

- improved medical treatments and preventions attracted the highest levels of support (90%) followed by improved technologies for the environment (87%), with the lowest levels of support for using nanotechnology in food (32%) and miniature surveillance devices (32%).

AUSTRIA

Highlight of developments since the 8th meeting of the WPMN

- Implementation of Austrian Nanotechnology Action plan recommendations:

A national EHS programme focusing on nanosafety has released a first call for nanosafety focusing on occupational health and consumer issues research in autumn 2011. This EHS programme is owned by the Federal Ministry of Agriculture, Forestry, Environment and Water Management and is funded by the Federal Ministry of Federal Ministry for Transport, Innovation and Technology, the Federal Ministry of Agriculture, Forestry, Environment and Water Management, the Ministry of Labour, Social Affairs and Consumer Protection, the Federal Ministry of Health, the Federal Ministry for Science and Research, the Workers' Compensation Board and the Chamber of Commerce. The Programme is funded with 440.000 EUR (see http://www.ffg.at/1-ausschreibung-nano-ehs)

- The work on compiling an implementation report on the Austrian Nanotechnology Action plan has started and will be finalised 2012.

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.lebensministerium.at/umwelt/chemikalien/nanotechnologie/nano-aktionsplan.html), 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, contact: Renate.Paumann@lebensministerium.at), Austrian Federal Ministry of Agriculture, Forestry, Environment and Water Management) and elaborated on basis of a broad stakeholder involvement (see also chapter 7). The work for preparing an implementation report will start mid 2011.

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) as well as a position paper: http://www.wien.gv.at/umweltschutz/oekokauf/pdf/nanotech-studie.pdf

2. – 3. (None)

4. Information on any developments related to good practice documents

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**. Building up on this report a **guidance in German language to ensure safe and healthy workplaces regarding nanomaterials** was developed: "Leitfaden für das Risikomanagement beim Umgang mit Nanomaterialien am Arbeitsplatz". The guidance is targeting small and medium enterprises and shall support the central labour inspectorate in advising enterprises dealing with nanomaterials. (http://www.arbeitsinspektion.gv.at/AI/Arbeitsstoffe/nano/default.htm.)

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

At the Centre for Medical Research of Medical University of Graz, **nanotoxicology studies** (cytotoxicity, genotoxicity, impact on macrophage function, intracellular accumulation in lysosoms and cellular effects after long-term exposure) regarding **CNT (SW + MW), SiO2**, and polystyrene are performed (contact: Eleonore Fröhlich, EURO-NanoTOX).

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).

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

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 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.

In the FP7 project **NanoValid** the University of Salzburg is Work Package leader (www.nanovalid.eu)

In the FP7 project **MARINA** Austrian partners from University of Salzburg (contact: Prof. Dr. Christian Huber) and from Department for Environmental Geosciences, University Vienna (contact: Frank von der Kammer) are involved in several workpackages. UNIVIE is involved in material characterization 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 workpackage 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.

EURO-NanoTOX is an open virtual national platform which is co-ordinated by the BioNanoNet Forschungsgesellschaft mbH. It elaborates strategies to conduct standardised toxicological on nanostructered material. See: http://www.euro-nanotox.at/

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

A Scientific Symposium of the Austrian Society of Toxicology (ASTOX) and the Emerging Field Oxidative Stress and DNA Stability (ANTIOX) with **Nanotoxicology** as a main conference subject has taken place on 24.-25th of November 2011 in Vienna.

7. Information on any public/ stakeholder consultation

As a measure of implementation of the Austrian Nanotechnology Action plan 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. Currently the setup of a national website for the public including chances and risks of nanomaterials is in progress.

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.

In the **Sparkling Science project "Nanomaterials – Possibilities and Risks of a New Dimension",** sponsored by the Federal Ministry of Science and Research, first results reveal a low information status on nano-products among young people as well as a not balanced information regarding risks and possibilities in media and school books. The project is lead-managed by the Austrian Environment Agency (contact: Simone Mühlegger), four Austrian schools, three research institutions and an environmental education partner are included (see also: http://www.sparklingscience.at/en/projekte/401-nanomaterialien-chancen-und-risiken-einer-neuen-dimension)

Greenpeace has launched an **online petition against the use of nanotechnology in sunscreens** http://www.greenpeace.org/austria/de/themen/konsum/Was-wir-tun/sonnencreme/

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. Austrian partner is IFZ-Inter-University Research Centre for Technology, Work and Culture Graz (contact: Manfred Klade; http://www.seberoc.info/home0.0.html)

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.

Austria is partner of the **ERA-net SIINN** ("Safe implementation of innovative Nanoscience and Nanotechnolgies") and workpakage leader of WP3 ("Risk assessment and life cycle validation"). The ERA-Net will coordinate European activities in the area of Nano-EHS and will implement joint calls for research projects.

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 workpackage **"How to foster the responsible use of nanotech and manage associated risks".**

The project "**NanoSan - Application of nanoscale zero-valent iron (nZVI)** for in situ remediation of groundwater contaminated by chlorinated solvents" focuses on improving nZVI particles properties with respect to sufficient longevity, reactivity, and in-depth understanding of their mobility under hydrogeological conditions typically accounted in coarse-grained, alpine, highly productive porous aquifers and under corresponding water chemical conditions. The project is led by the Department for Environmental Geosciences, University Vienna (project partner: Austrian Institute of Technology GmbH (AIT),Health&Environment Department) and funded by the Federal Ministry of Agriculture, Forestry, Environment and Water Management (BMLFUW). Management by Kommunalkredit Public Consulting GmbH.

9. Information on any development related to exposure measurement and exposure mitigation

A **conference** regarding nanotechnology and **occupational health** took place on 7th of December 2011 in Vienna at the Austrian Academy of Sciences. (http://nanotrust.ac.at/nano11/)

Additional Information

- Consideration of ethical implications;

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 Conference on **(Nano-)Silver in Medical and Consumer Products** –Miracle Drug Against Germs Or Threat For Our Health and Environment?" organised by the Institute for Sustainable Healthcare in collaboration with the University Hospital Uppsala, Sweden took place on 9th June, 2011, in Vienna: http://www.inges.at/silbertagung.htm.

CANADA

Highlights of Developments since the 8th Meeting of the Working Party on Manufactured Nanomaterials

The following activities have taken place since the 8th meeting of the Organization for Economic Cooperation and Development (OECD) Working Party on Manufactured Nanomaterials (WPMN) in March 2011:

- Health Canada has revised the *Interim Policy Statement on Health Canada's Working Definition for Nanomaterials* (Interim Policy Statement) based on stakeholders' feedback, developments in international norms, evolving scientific evidence and regulatory program needs. In October, 2011, the revised *Policy Statement on Health Canada's Working Definition for Nanomaterial* was published on Health Canada's website. This Working Definition will continue to be updated as the body of scientific evidence and international norms progress. Health Canada's response to stakeholders' comments resulting from the Interim Policy Statement public consultation, as well as a set of frequently asked questions are also posted on Health Canada's website.

- Canada participates in a Joint Working Group (Joint WG), under the International Co-operation on Cosmetic Regulation (ICCR), on safety approaches to nanomaterials in cosmetics.

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 October, 2011, Health Canada published a revised Policy Statement based on stakeholder feedback, as well as developments in international norms, evolving scientific evidence and regulatory program needs. The *Policy Statement on Health Canada's Working Definition for Nanomaterial* (Working Definition) which is available on Health Canada's website, will continue to be updated as the body of scientific evidence and international norms progress. Health Canada's responses to stakeholders' comments and a set of frequently asked questions are also posted on Health Canada's website.

B. Discussions at the 4th annual meeting of International Cooperation on Cosmetic Regulation (ICCR-4) in Canada on cosmetics and cosmetic-like drug/quasi-drug products led to the formation of a new Joint Industry/Regulator Working Group. Canada is participating in the Joint WG which is a follow up from the previous ICCR Ad Hoc Nano Working Group that developed criteria for identification of nanomaterials within the context of cosmetic regulation. 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 nanometers in the final formulation and is sufficiently stable and persistent in biological media to allow for the potential of interaction with biological systems.

The purpose of the Joint WG is to examine the existing safety approaches for applicability to nanomaterials in use by (or relevant to) activities within the cosmetic industry. The main task of the Joint WG is to carry out a review of the existing safety approaches, and to identify any specific

aspects relevant to consumer safety that should be taken into consideration in relation to the use of nanomaterials in cosmetics.

The Joint WG will aim to produce a document that will be aimed at providing guidance and help to those intending to use or assess nanomaterials in a cosmetic product in the form of an expert view on important safety aspects for consideration in an industry or regulatory setting. It is, however, not the intention of the Joint WG to focus exclusively on regulatory (mandatory) safety testing, or to develop any strict pathway or protocol, although it will take a brief account of the current requirements for safety assessment under the existing regulatory frameworks within the ICCR jurisdictions.

2. Developments related to voluntary or stewardship schemes.

None

3. Information on any Risk Assessment Decisions.

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

- *Industrial or commercial chemicals:* Since March 2011, an additional five notifications have been received for nano-related assessment under the *Canadian Environmental Protection Act, 1999* (CEPA 1999). The Significant New Activity (SNAc) provisions of CEPA 1999 have been applied to these notifications, requiring the submission of additional information and assessment prior to use of the substances at the nanoscale or in other nanoscale applications.

- *Pharmaceuticals:* A number of nanotechnology based products in the areas of medical devices and drugs are currently under review by 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 fertilizers, veterinary biologics, or animal feed have been received to date.

4. Information on any Developments Related to Good Practice Documents.

A. The Canadian Standards Association (CSA) Technical Committee on Nanotechnologies - Occupational Health and Safety has completed a draft national standard (CSA Z12885) to provide guidance for workers, entitled "Nanotechnologies — Exposure control program for engineered nanomaterials in occupational settings" This document is largely based on the published international ISO Technical Report, ISO/TR 12885:2008 entitled "Health & Safety Practices in Occupational Settings relevant to Nanotechnologies". The CSA Z12885 standard has completed the public review process and is proceeding to ballot, with completion anticipated in mid-2012.

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 Organization for Standardization/Technical Committee 229 (ISO/TC229) Nanotechnologies, facilitated by CSA Standards. This includes active participation on terminology,

nomenclature, measurement, characterization, material specification and health, safety, environmental aspects of nanotechnologies standards under development.

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 has begun a research project to investigate the toxicity of surface-modified silica nanoparticles. The aim of the project is to investigate the importance of size and surface modification to the toxicity of silica nanoparticles. Silica nanoparticles are being modified to most closely resemble those for which notifications for assessment have been received by the New Substances Program.

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 TiO2, ZnO and Ag. The projects examined fate both in the aqueous and the subsurface compartments and include establishing methodologies for suspension and physical-chemical characterization 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) characterization in complex media; (3) methods for biological effects testing; and (4) establishing collaborative dialogue between key stakeholders.

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 C60 fullerenes). Testing includes pulmonary and cardiovascular injury; reproductive, developmental and transgenerational effects; exposure and tissue penetration, interactive effects with microorganisms, immune defenses, 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, harmonizing and standardizing 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, and ecosystem level effects studies of silver nanoparticles.

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 and responses have been collected.

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 consultations.**

None.

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

None.

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.)**

Canada is engaged in a project lead by the International Life Sciences Institute (ILSI) to look at releases of nanomaterials from industrial matrices (e.g., coatings). The purposes of this project are to develop information on different test methodologies and nanomaterials used to study releases from matrices, and to develop standard methodologies (validated through round-robin testing) to quantify releases of nanomaterials from a matrix. At present, the Steering Committee for the project has selected the nanomaterial to be studied (MWCNT) and is requesting input from manufacturers and processors to select the polymeric matrix to be used. Government agencies in the United States, Non-Governmental Organizations and Industry are also engaged in the project. Additional information can be found at http://www.ilsi.org/ResearchFoundation/Pages/NanoRelease1.aspx.

9. **Information on any development related to exposure measurement and exposure mitigation**

None

Additional Information

None

CZECH REPUBLIC

Highlights of developments since the 8th meeting of the WPMN

- Ministry of the Environment of the Czech Republic has launched a working group to prepare a national strategy for environmentally safe handling of nanomaterials and nanotechnologies

- Various individual individual research projects addressing environmental health and safety aspects of nanomaterials, funded by national grant agencies, are underway in the Czech Republic

- Meetings, seminars and short courses dedicated to nanosafety issues have been organized by various institutions. These include Ministry of the Environment (Nanomaterials and nanotechnologies in energetics, June 2011); National Institute of Public Health, Prague (Occupational health aspects of nanomaterials, 21.6.2011); Technology Centre of the Czech Academy of Sciences (several short conferences addressing also nanosafety issues); Czech Technology Platform on Industrial Safety, etc.

- NanoOstrava 2011 conference with a section Environmental and health risks of nanomaterials was held on April 27-29, 2011, in Ostrava

- NanoCon 2011 conference with a section Protection of health and environment & toxicity of nanomaterials was held on September 21-23, 2011, in Brno

Work completed, underway or planned

1.-5. (None)

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

- Ministry of the Environment of the Czech Republic has launched a working group to prepare a national strategy for environmentally safe handling of nanomaterials and nanotechnologies

- Ministry of Labour and Social Affairs together with Occupational Safety Research Institute http://www.vubp.cz has launched a project HC213/11 "Analysis of contamination of working environment by nanoparticles and determining the effectiveness of personal protective equipment to protect respiratory system against the influence of nanoparticles at the workplace"

- Various individual research projects addressing environmental health and safety aspects of nanomaterials, funded by national grant agencies, are underway in the Czech Republic

7.- 8. (None)

9. Information on any development related to exposure measurement and exposure mitigation

Exposures to nanoaerosols in workplaces are occasionally monitored on a commercial basis with the results kept confidential.

DENMARK

Highlight of developments since the 8th meeting of the WPMN

- Funding for establishing a Danish Center for Nano Safety in 2012 (se below under section 9)

- Funding for establishing a register for registration of products containing nanomaterials (section 1 below).

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;**

   Recently the Danish Government has allocated funding for establishing activities aimed at gaining clarity about the consequences for consumers and the environment due to the use of nanomaterials. The activities include the establishment of database on products with nanomaterials. At present the Danish EPA is in a planning phase in order to investigate the various possibilities for establishing such a database.

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

   None

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

   The Danish Environmental Protection Agency (EPA) has ordered withdrawal of a specific spray sealing product marketed as a nanoproduct from the market. The spray product in itself did not contain nanomaterials but generated a nanolayer on the treated surfaces and produced reactive nanosized aerosols during spraying.

   The product has been notified to the European RAPEX system: http://ec.europa.eu/consumers/dyna/rapex/create_rapex.cfm?rx_id=298 (see 42-1057/10).

   The withdrawal was due to very high toxicity by inhalational exposure to mice, see publication: http://toxsci.oxfordjournals.org/content/116/1/216.full.pdf+html.

   Further work is now going on in order to identify spray products with similar high inhalational toxicity.

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

   The Danish industrial trade organisation has issued guidance on how to handle nanomaterials in the occupational environment. Most of the material is in Danish language; however an English version of "Nanoparticles in the working environment" in laboratories is available at; http://www.i-bar.dk/Vejledninger%20mm/Liste/~/media/Industrien/PDF/NANO%20NY%202011/LAB/Lab_pjece_english_2version.ashx

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

   None

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

   The Danish EPA has recently published two reports concerning human health and environmental assessment of nanomaterials.

   In one of the projects work was initiated for developing a screening tool (called "NanoRiskCat") for exposure and hazard assessment of products containing nanomaterials. However, further work and

development has to be done in order to improve the screening procedure and develop a more practical and user friendly screening tool: http://www.mst.dk/Publikationer/Publications/2011/12/978-87-92779-11-3.htm.

In another project seven widely used nanomaterials were evaluated in relation to uses and environmental and human health hazard and risk in order to create a common basis and understanding of the current knowledge concerning these nanomaterials: http://www.mst.dk/Publikationer/Publications/2011/08/978-87-92779-09-0.htm

Further projects from the Danish EPA are underway: one project concerning characterisation, use and evaluation of CNTs and one project on nanosilver in textiles where products containing nano-silver is analysed and assessed in relation to the potential of environmental and human health risk.

A further project examines various spray products used for nano-coating in relation to the inhalational toxicity in mice in order to create a better understanding of hazards and risks and to identify products of concern on the market.

7. Information on any public/ stakeholder consultation;

In November 2011 the Danish Europe Movement together with Confederation of Danish Industry and The Danish Consumer Council organised an open conference in the Danish Parliament building regarding health and nanotechnology. At this meeting the Danish Minister of Environment announced the funding of the new Danish Government for establishing a nano-register. Benefits as well as knowledge gaps and potential risks in relation to nanotechnology were further discussed at the conference.

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.);

The former Danish Government has funded a Center for Nano Safety for a period of 3 years. The center will be established by the Danish Working Environment Authority in 2012 and the work will focus on projects on various issues such as: measurements and exposure assessment of nanoparticles in the occupational environment; mitigation and risk reduction measures, and risk assessment of specific uses of nanomaterials.

9. Information on any development related to exposure measurement and exposure mitigation

The National Research Centre for Working Environment has recently published their work regarding Comparison of dust released from sanding conventional and nanoparticle-doped wall and wood coatings. The addition of engineered nanoparticles to the products only vaguely affected the geometric mean diameters of the particle modes in the sanding dust when compared to their reference products, see: http://www.nature.com/jes/journal/v21/n4/full/jes201032a.html

Additional Information

- Any consideration on the benefits of nanotechnologies;
- Consideration of ethical implications; and
- 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.

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 has been 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 2011 established a formal discussion forum on nanotechnology under the Ministry of Social Affairs and Health in order to follow and participate in the national and international discussions.

In October 2011 Finland (and Finnish Safety and Chemicals Agency) organized a Nordic Workshop on nanomaterial safety and especially regulatory issues as one project of their chairmanship of the Nordic Council of Ministers. The meeting identified areas of cooperation which would enhance the Nordic participation and input in OECD and EU regulatory work.

2.– 4. (None)

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) program 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 fiber based products with nanocellulose4. The E15 million program develops and demonstrates new types of products, but carries out also safety assessment of nanocellulose applications and studies their life-cycle.

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

Finnish Institute of Occupational Health has established Nanosafety Research Centre as of January 1, 2011. The centre has resources of 21.2 person years some 42 individuals working in different capacities for the Centre. The Centre 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 characterization and risk assessment of engineered nanomaterials, and prepares guidance on safe use of engineered nanomaterials in workplaces.

A part of the Centre's networking activities is being a member of a recently established network of nanosafety activities in Finland. The network was established by the Ministry of Social Affairs and Health, and is coordinated by it. It includes representation from all governmental sectors dealing with nanosafety in Finland, also the representation of those research institutes which work under different ministries represented in the network. The Nanosafety Research Centre is a part of this network and as a member of a preparatory working group of the network prepares operationalization of the network activities.

The Nanosafety Research Centre is also active in the Finnish-RUSNANO collaboration in issues related to nanosafety and standardization.

The Centre is currently Coordination the NanoSafete Cluster that includes all research projects funded from the EU FP6 and FP7. The Centre is also coordinating, together with the NanoSafety Cluster, and for the Commission, two documents: Vision for Nanosafety 2015-2020, and a Strategic Research Agenda on Nanosafety 2015-2010. Presumably both are a part of preparation of the 8th Framework Programme for Research and Innovation of the EU.

The Centre will also organize, on a request of the EU Commission, an EU-USA Nanosafety workshop jointly organized by the EU Commission and the US Government (NNI) in Helsinki on April 19-20, 2012. The Venue of the Congress is Congress Centre Paasitorni in Helsinki. The workshop is by invitation (the Commission and NNI) and the number of expected participants is 100-120.

The Centre also organizes an International Congress on Safe Nanomaterials and Nanotechnologies (SENN2012, see www.senn2012.fi) on October 28-31, 2012. The venue of this event is Marina Congress Centre in Helsinki. Some 300 participants are expected.

The Centre also coordinates FP7 funded research project NANODEVICE (EU contribution of 9.5 million euros and totally 26 partners in addition to the coordinator). The Centre is also responsible for the Coordination of a new ERANET project (not yet started but already accepted for funding) on industrial safety. The title of the ERANET Project is SAF€RA, and is has a budget of 1.5 million euros and has some 18 partners.

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 " *Inflammatory 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.
- European Commission 7thFramework project "Scale-up nanoparticles in modern papermaking

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

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 Workpackage 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 workpackage on dissemination and exploitation: social-ecological analysis of nanopatterning and related applications with a consortium of 20 European partners coordinated by VTT Finland.

The Technological Research Centre of Finland VTT is participating in:

- Recently established network on nanosafety activities in Finland, coordinated by the Ministry of Health and Social Affairs.
- European Commission 7th Framework Programme NanoSustain project (Development of sustainable solutions for nanotechnology-based products based on hazard characterization and LCA), in work on ecotoxicology and on recycling and final treatment of nanotechnology-based products.
- European Commission 7th Framework Programme MARINA project (Managing Risks of Nanoparticles), in the workpackages on monitoring and assessment of occupational exposure.

The laboratory of the Finnish Environment Institute (SYKE) has started studies on aquatic exposure concentrating especially on nanomaterial detection and characterization. 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 characterization 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”.

7. - 9. (None)

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**

The interministerial decree (Environment, Health and Labour, Agriculture, Defence, Justice) relating to the annual declaration of market-traded nanoscale substances, issued pursuant to Article L, 523-4 of the Environmental Code, was notified to the European Commission and prompted not a detailed opinion but observations from the Commission, as well as from Germany and the United Kingdom, to which the French authorities have responded. These observations concern the scope of application, the declaration threshold, the definition, the notion of "importer", the content of the declaration, the declaration in the framework of research, the number of enterprises, laboratories, substances, mixtures and articles covered by the declaration and development, as well as the impact study.

The text of the decree (in the European Union's various official languages – the French version being authentic) is available at the following Internet addresses, in English and French respectively:

http://ec.europa.eu/enterprise/tris/pisa/app/search/index.cfm?fuseaction=pisa_notif_overview&sNlang=EN&iyear=2011&inum=307&iBack=17&lang=en (in English)

http://ec.europa.eu/enterprise/tris/pisa/app/search/index.cfm?fuseaction=pisa_notif_overview&iYear=2011&inum=307&lang=FR&sNLang=FR (in French)

It should be noted that the threshold above which a declaration must be filed has been raised from 10 g/year (as indicated at the previous Tour de Table) to 100 g/year.

2. - 5. (No information)

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

NANOGENOTOX meets the objectives in terms of the safety of manufactured nanomaterials laid down in the 2009 work plan of the Programme of Community Action in the Field of Health (ref.: Decision No. 1350/2007/EC).

For the record, the primary purpose of this three-year programme is to provide the European Commission with a robust and reliable method for detecting the potential genotoxicity of manufactured nanomaterials (MNs), which could then trigger a risk of cancer or toxicity to human reproduction.

At the present time, characterisation tests are practically completed, and standardised measuring protocols are being drawn up. Toxicokinetic and in vitro studies are far advanced. In vivo studies will begin soon, as will a round robin test (an inter-laboratory test to validate the trial method) concerning the in vitro tests.

Stakeholders consultation in respect of the NANOGENOTOX joint action

An initial stakeholders consultation took place between October 2010 and January 2011. Its objectives were to:

- identify the key concerns regarding the aims and outputs of the project;
- bring the project to the attention of key concerned actors/stakeholders;
- establish contacts in order to facilitate and orient further dissemination activities.

Nineteen persons, selected from five broad categories of European-level stakeholders (industrial firms, trade unions, EU competent authorities, NGOs and the scientific community), took part in the consultation by responding to a detailed questionnaire. The consultation report was posted in April 2011 on the nanogenotox.eu website.

A second phase of the consultation will take place in early May 2012 in Brussels, in the form of a mini-conference open to all. The aim here, in the presence of representatives of stakeholders and project partners, will be to take stock of the initial progress of NANOGENOTOX and to discuss the dissemination and use of future findings and the organisation of the final conference, to be held in early 2013.

7. Information on any public/ stakeholder consultation

None

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.)

The French National Institute for Industrial and Environmental Risks (INERIS) has conducted a study on socio-economic analysis in REACH and its adequacy and adjustment requirements in the case of nanomaterials. This will be available very soon on the INERIS Internet site: http://www.ineris.fr/.

9. Information on any development related to exposure measurement and exposure mitigation

None

Additional Information

The European Committee for Standardization (Technical Committee 352) has approved a proposal from the French Association for Standardisation (AFNOR) regarding the management of uncertainty with respect to products derived from nanotechnologies (or incorporating nanomaterials).

GERMANY

Highlight of developments since the 8t meeting of the WPMN

A) Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU)

- Preparation of the NanoDialog: NanoDialog is an Expert Dialogue (ED) on issues relating to nanotechnology. There are 4 ED planned by the BMU. The first one is aimed at the "risk management in the nano world" and will take place on December 1st and 2nd, 2011.

- The German Advisory Council on the Environment (SRU) published its special report on "Precautionary Strategies for managing Nanomaterials" in September 2011

Work completed, underway or planned

- See Highlights
- English versions of reports of NanoKommission are available online: http://www.bmu.de/english/nanotechnology/nanodialog/doc/47547.php

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 Environment Agency (Umweltbundesamt, UBA):

(1) Federal Environment Agency (Umweltbundesamt, UBA): *Legal questions regarding the application of the substance definition to nanomaterials within the framework of the REACH Regulation:* Currently it is discussed whether and how to adapt the existing chemical legislation (e.g. the European REACH Regulation) to the particular characteristics that are exhibited by nanomaterials. One core question is the applicability and the possible problems of the application respectively of the substance definition. Therefore, the German Federal Environment Agency conducts a project which analyzes whether the application of the existing substance definition and the requirements that result from the substance identification take account of the differences of bulk and nanomaterials sufficiently. Furthermore, it will be analyzed whether an adaptation of the substance definition is necessary or if the adaptation of the guidance documents is sufficient. Additionally, the project will include an analysis of different possibilities for the regulation of nanomaterials within the REACH framework.

2. - 4. (None)

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

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

(1) BfR participates in the Coordination and Support Action QNano which is coordinated by Ireland for integrating activities within the 7th European Framework Programme in different work packages. In WP JRA 5, BfR is lead in the advancement of in vitro methods in nanotoxicology. The aim is to promote the development of *in vitro*, alternative methods for hazard characterisation of manufactured nanomaterials.

(2) BfR participates in methods development for in vitro genotoxicity analysis in the FP-7-EU- Nanogenotox consortium (www.nanogenotox.eu) coordinated by France.

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

A) Federal Environment Agency (Umweltbundesamt, UBA):

(1) *Ecotoxicological investigation of nanogold:* As direct support of the Global-NanoMaPPP public private partnership, Germany funds research performed by the Fraunhofer Institute for Molecular Biology and Applied Ecology (IME). Global-NanoMaPPP addresses safety issues of nanomaterials in collaboration between scientists, industry, public authorities and other stakeholders. For the research project at the Fraunhofer IME the nanogold NM 330

(and NM-330DIS as dispersion control) of the NM-Series of representative manufactured nanomaterials (JRC repository) was selected in order to address the aquatic toxicology of nanogold. The following OECD test guidelines will be applied: OECD 201 (Freshwater Algae and Cyanobacteria, Growth Inhibition Test, 2006), Draft Test Guideline on "Fish Embryo Toxicity Test"Draft New Guideline (May 2006), OECD 219 (Sediment-Water Chironomid Toxicity Using Spiked Water, 2004).

(2) *Environmental assessment of nano-sized titanium dioxide: Analysis of studies regarding ecotoxicology and environmental fate:* This expert`s report will focus on the analysis of existing literature regarding the selected reference and alternate materials within the OECD Sponsorship Programme. Furthermore the analysis will also include study reports performed within the TiO2 Sponsorship Programme which are provided in the TiO2 installation at NANOhub. The analysis will concentrate on assessing the quality and reliability of the studies. For this aim the Klimisch Code for reliability (Klimisch et al. 1997) will be applied. The following questions will be answered: Are the presented information complete and comprehensive? Is the methodology adequately described? Is the sample preparation sufficiently described? Is the material well characterized? Are the results and conclusion plausible? In addition to this analysis the appropriateness of the chosen methods and selected endpoints for assessing environmental fate and effects will be elaborated. Based on the results of the assessment key studies as well as supporting studies will be selected and conclusions regarding the ecotoxicological potential and the environmental fate will be drawn.

(3) *Study on potential environmental impacts due to nanowaste disposal in different types of waste treatment plants:* It will be analyzed if the disposal of so called nanowaste in a waste incineration plant, in a mechanical-biological-treatment plant, in a anaerobic digestion plant and in a composting plant causes the release of nanoparticles into the environment. One result should be a mass balance and an evaluation of the allocation of nanoparticles during the processes. The study will be a basis for a guidance for the handling of nanowaste.

(4) *Investigation of the fate of synthetic, inorganic nanoparticles (NP) during sediment passage under near-natural conditions.* In the frame of this study, the risk associated with breakthrough of four nanoparticles (TiO_2, Sb_2O_5, Ag(0), CeO_2) during natural drinking water treatment methods such as river bank filtration, artificial groundwater recharge and slow sand filtration was assessed. The NP were suspended in the supernatant of a water-saturated sediment column (1 m length) implemented into a slow sand filtration pond. The column was fed with surrounding surface water and sampled in various depths (20 cm, 40 cm, 60 cm, 80 cm) as well as at the outflow. Besides, various aggregation experiments with NP in the water were conducted to elucidate possible hydrochemical effects on NP size distribution. Results of the experiments will help to gain a better understanding on the fate of NP in both water and sediment.

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

(1) Within the research programmes of the Federal Ministry of Education and Research a project called “NanoGEM” (Nanostructured Materials - Health, Exposure and Material properties), BfR participates in risk evaluation and experimental analysis of modes of action of manufactured nanomaterials. For further information please refer to http://www.nanogem.de.

7. Information on any public/ stakeholder consultation;

None

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.);

A) Federal Environment Agency (Umweltbundesamt, UBA):

(1) *Analysis and strategic management of sustainability potentials of nanoproducts*: On behalf of Federal Ministry of Environment and Federal Environment Agency, the Institute for Applied Ecology (Öko-Institut e.V.) has developed a general assessment system for evaluation of sustainability aspects of nanotechnology based products. It is intended that assessment tool will serve as a basis for strategic optimization of products. BASF and Nanogate have participated in the project. The project is finished. It is intended that the results will be published soon.

(2) *Investigation of the impacts of selected nanotechnology based products on the resource and energy demand*: Often nanotechnology based products contain scarce metals and precious metals which are functional active nano components. The products show some opportunities in comparison with conventional applications (i.e. saving of energy and resources). On behalf of Federal Ministry of Environment and Federal Environment Agency the Institute for Applied Ecology (Öko-Institut e.V.) focuses on the analysis of the relevance of an increased demand of energy and resources in the production on nano materials in products. Applying special evaluation criteria it should be assessed if a higher use of resources can cause a relevant environmental problem or if the availability of the resources is crucial. It is intended that the results of the project support the assessment of sustainabilty of nanotechnology based. The project has started in September 2011. It will end in March 2013.

9. Information on any development related to exposure measurement and exposure mitigation

A) Federal Institute for Occupational Safety and Health (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, BAuA):

(1) In autumn, a working group consisting of institutes and institutions from research, chemical industry, social accident insurance and government published a pragmatic approach for the measurement of inhalative exposure to nanomaterials. The approach is applicable both in commercial production operations and R&D laboratories and pilot plants. The tiered approach and thus the present document focuses on a size range from 1 nm to 100 nm and is designed to support assessment of health risks from solid, particulate substances released as nanoscale aerosol from engineered nanomaterials in routine workplace operations. Therefore, aerosols containing nano-objects and their nanoscale aggregates and agglomerates are targeted by this approach. Members of the group are: Institute of Energy and Environmental Technology e.V. (IUTA); Federal Institute for Occupational Safety and Health (BAuA); German Social Accident Insurance Institution for the Raw Materials and Chemical Industry (BG RCI); German Chemical Industry Association (VCI); Institute for Occupational Safety and Health of the DGUV (IFA) Research Group Mechanical Process Engineering; and Institute of Process Engineering and Environmental Technology, Technical University Dresden (TUD).

Tiered Approach to an Exposure Measurement and Assessment of Nanoscale Aerosols Released from Engineered Nanomaterials in Workplace Operations (PDF-Datei, 2 MB)

Additional Information

None

IRELAND

Highlight of developments since the 8t meeting of the WPMN

- The Irish Health & Safety Authority issued a request for information on nanomaterials on the 28th September 2011 *via* a web survey:

  http://www.hsa.ie/eng/Your_Industry/Chemicals/Nanotechnology/Nanotechnology_Survey/

Work completed, underway or planned

Ireland is participating in a relevant ERANeT (see point 6 below).

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;**

   Ireland participated directly in the European Commission's REACH Implementation Project on Nanomaterials 1 (RIP_oN 1) on Substance Identity. It is foreseen that the report will be forwarded to the European Chemicals Agency (ECHA) shortly. In addition, it is anticipated that ECHA will keep the REACH and CLP Competent Authorities (CARACAL) and the Competent Authorities subgroup on Nanotechnology informed of developments and issues arising on an ongoing basis. It is also anticipated that any policy recommendations arising from this work area will be referred to CARACAL for agreement and decision. Ireland will follow these discussions closely.

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;**

   The Irish Health & Safety Authority published an information sheet on considerations for handling nanomaterials in the workplace.

   http://www.hsa.ie/eng/Publications_and_Forms/Publications/Chemical_and_Hazardous_Substances/Nanoparticles%20Information%20Sheet.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;**

Ireland is participating in the SIINN ERA-NET (*Safe Implementation of Innovative Nanoscience and Nanotechnology*); Science Foundation Ireland is the national representative. The primary aim of SIINN is to promote the rapid transfer of the results of nanoscience and nanotechnology research into industrial application by helping to create the conditions necessary for such technology transfer. In order to strengthen the European Research Area and to coordinate nanoscience and nanotechnology related R&D work, the project will bring together a broad network of ministries, funding agencies, academic and industrial institutions to create a sustainable transnational programme of joint R&D in nanoscience and nanotechnology.

The Irish Department of Agriculture, Food and the Marine is funding a research project that aims to develop methodologies for the development of 'smart' packaging materials by incorporation of antimicrobial/antibacterial nanoparticles into conventional polymers, with the potential to develop active antibacterial packaging to extend the quality, safety and shelf-life of many forms of food products. Aspects of the project relating to human health and environmental safety aspects include the following:

- An examination of the effects of nanoparticle application to packaging materials through physical and functionality testing of these packaging materials.
- An examination of the possibility for nanoparticle migration to food surfaces by exposing food samples to different contact times and temperatures. Samples will subsequently be examined for attachment/migration of nanoparticles onto various food products.
- An assessment of the potential attachment or migration of particles into the food product.
- An assessment of the potential human exposure levels to nanoparticles and additionally, the potential change in microbial risk to consumers, resulting from the use of nanoparticles in food packaging applications.

7. Information on any public/ stakeholder consultation;

The Irish Health & Safety Authority issued a request for information on nanomaterials on 28th September 2011 via a web survey.

http://www.hsa.ie/eng/Your_Industry/Chemicals/Nanotechnology/Nanotechnology_Survey/

The survey will remain open until December 2011 and aims to collect detailed information on **the types of nanomaterials being produced and/or used in Ireland and the corresponding safety measures being used by Irish industry/academia when handling these materials.**

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.);

A number of Ireland's research laboratories and nano-initiatives will be in involved in submitting a number of proposals to the following NMP topics with a stage 1 deadline of November 8: (the details of the specific projects are not yet public domain):

- Engineered nanomaterial interactions with living systems and/or the environment
- Modelling toxicity behaviour of engineered nanoparticles

- Regulatory testing of nanomaterials

Department of Agriculture, Food and the Marine: See item 6 above.

9. Information on any development related to exposure measurement and exposure mitigation;

Additional Information

- Any consideration on the benefits of nanotechnologies;

The Irish Department of Agriculture, Food and the Marine are funding a research project that aims to examine consumer and industry acceptability of novel technologies and one of the technologies chosen is nanotechnology. This research provides some insights into Irish consumer acceptance of food related applications of nanotechnology and details the determining factors framing consumers' attitudes. Key issues investigated include consumers' awareness of and attitudes towards nanotechnology, the subjective values (including perceived risk-benefit trade-offs) that frame these attitudes and the influence of new information on consumers' attitudes and acceptance.

ITALY

Highlight of developments since the 8t meeting of the WPMN

- The Italian Society for Environmental Mutagenesis has organized a Symposium entitled "Nanomaterials: new opportunities for medicine and new challenges for toxicity assessment" in the frame of its 19th Annual Congress (Parma, 28-30 September, 2011)

- The Italian Society of In Vitro Toxicology, in the frame of its 20th anniversary congress, has organized a session on "In vitro Nanotoxicology: Achievements and Future Challenges" (Rome, 19-21 October, 2011).

- A session on Responsible Development and Nano Toxicology is planned during the International Conference NanotechItaly 2011, jointly organized by AIRI/Nanotec IT, Veneto Nanotech, National Research Council and Italian Institute of Technology, in collaboration with Federchimica, Politecnico of Torino (Latemar Research) and Assobiotec-Federchimica (Venice 23-25 November, 2011).

- The National Institute of Health (Istituto Superiore di Sanità, ISS) is organizing a session on "Nanomaterials health and environment" in the frame of the National Congress on Health and Environment in Italy (Rome, 5-6 December, 2011).

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;

Third National Conference on REACH legislation to be held in Rome on November 14, 2011. The event is jointly organized by the Ministry of Economic Development, the Ministry of Environment, the Centre for Chemical Substances of the National Institute of Health, the Institute for Environmental Protection and Research and the Italian National Agency for New Technologies, Energy and

Sustainable Economic Development. Among other topics it will address new emerging issues related to the application of the REACH legislation to nanomaterials.

2. – 5. (None)

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

The National Institute of Health (Istituto Superiore di Sanità, ISS) is participating, as additional partner, to the QNano project, the European Union-funded infrastructure for nanomaterial safety testing. In particular, the Environmental and Primary Prevention Department of ISS will be involved in the JRA5 component: Development of alternative testing strategies.

Environmental and Primary Prevention Department and the National Centre for Chemicals of ISS are involved in a two years project funded by the Italian Ministry of Health on "Sviluppo e implementazione di metodi validati e/o alternativi per la determinazione delle caratteristiche fisico-chimiche e della potenziale attività geno/tossicologica di nanomateriali rilevanti per applicazioni industriali".

7. Information on any public/ stakeholder consultation;

None

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.);

The Life Cycle Assessment and Ecodesign Laboratory of ENEA participates with its expertise on the combination of LCA and Risk Assessment methodologies to the EU projects: NANOHEX for research and development of nanofluid coolants and LAMP for research and development of a new method to produce quantum dots with high performing light-emitting properties.

9. Information on any development related to exposure measurement and exposure mitigation

None

Additional Information

None

JAPAN

Highlight of developments since the 8t meeting of the WPMN

- Ministry of Economy, Trade and Industry (METI) launched a five-year programme for the "Development of Innovative methodology for Safety Assessment of Industrial Nanomaterials" in September, 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. (September/2011)

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 8th WPMN.

2. Developments related to voluntary or stewardship schemes;

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 8th 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 FY 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

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

Exposure to Chemical Substances Posing 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 characterization). Until the end of October 2011, sixteen documents developed by TC229 had been published. With regard to the items proposed and led by JISC, ISO TS 10868 "Nanotechnologies –- Characterization of single wall carbon nanotubes using ultraviolet-visible-near infrared (UV-Vis-NIR) absorption spectroscopy", was published 17 August and ISO TR 10929 "Nanotechnologies –- Characterization of multiwall carbon nanotube samples", was registered for formal approval on 4 October. Moreover, the latest new work item, Technical Specification "Nanotechnologies - Nanoparticles in powder form: Characteristics and measurements" was approved as a new project on 10 May.

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

No significant change after the 8th WPMN.

6. 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

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

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 website8. The final Risk assessment reports on three nanomaterials are envisaged at the end of the project in mid-2011. After that, NEDO/AIST held a two-day international symposium in Tokyo on 29-30 September 2011 to explain the achievements of the programme.

METI launched a five-year programme for the "Development of Innovative methodology for Safety Assessment of Industrial Nanomaterials" in September, 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 FY2011, 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). Thirteen-week inhalation study is on-going now (FY 2011) as the preliminary studies for two-year inhalation study of MWCNT, .

The National Institute of Occupational Safety and Health Japan (JNIOSH) conducted 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 conducted a one-year research project on "Behaviour of Nanomaterials in the Workplace" and National Institute of Occupational Safety and Health Japan (JNIOSH) was chosen to perform this project in FY2010. This project includes the research on behaviour of several nanomaterials both in workplace and in an experimental chamber. For subject materials, CNTs, nano-silica and TiO2 were chosen for both fields. Difficulties of detection of nanomaterial pariticles in real workplaces was

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

observed even if such particles were detected in experimental chambers. Applicability of present analytical methods to work environment control was analyzed.

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

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.

7. 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 public9.

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.)

9. 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	286
Research project on the potential hazards, etc. of nanomaterials	MHLW	111
Food nanotechnology project	MAFF*	98
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	27

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

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

KOREA

Highlight of developments since the 8th meeting of the WPMN

- The Korean government has established the 'National Nano-safety Master Plan (2012~2016)' on nanomaterials, nanotechnology, nanoproducts and occupational safety. For this plan, Ministry of Environment (MOE), Ministry of Education, Science and Technology (MEST), Ministry of Knowledge and Economy (MKE), Ministry of Employment and Labour (MOEL) and Korea Food and Drug Administration (KFDA) worked together.

- 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 the 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 was published as Korean Standard on 12 May 2011.

- 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

MOE has developed the guidance on the occupational safety management for nanomaterials.

MKE is 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. This guidance was published as Korean Standard on 12 May 2011.

2. Developments related to voluntary or stewardship schemes

MOE initiated the project which is a 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 #5 this year including risk assessment, but these are still in the initial stage.

KATS (The Korean Agency for Technology and Standards, an affiliated body of MKE) 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's review. KATS is developing the reference doses of silver nanoparticles for workers and consumers. The draft provisional reference doses have been presented in OECD WPMN SG8 meeting in Aug, 2011.

4. Information on any developments related to good practice documents

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

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

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

Ministry of Environment (MOE)

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 rats, bacteria, yeast and fish' to develop alternative methods for nanotoxicity tests.

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 on nanomaterials and cumulate the data related to physico-chemical properties, eco-toxicity, environmental fate and human-health in order to contribute to decision making since 2007.

MOE and NIER launched the project for a survey on the production, use, import and export volumes, use pattern and the information on manufactured nanomaterials in order to establish inventory for nanomaterials. NIER organized the Nanomaterial Risk Expert Committee and held the fifth meeting in Oct, 2011. This committee handles the nanomaterial safety issues, such as reviewing of the project planning on the nanomaterial safety assessment.

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

Ministry of Education, Science and Technology (MEST)

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

KRISS (Korea Research Institute of Standard Science, 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 Characterization Techniques for Nanomaterials Safety (2009 – 2015)" was launched.

This project is composed of four parts; i) physic-chemical property characterization of nanoparticles such as silver, gold, titanium dioxide, polystyrene, silicon dioxide, CNTs and quantum dot has been conducted in order to develop their CRMs, ii) Surface structures and its compositions are studied using XPS, MALDI-ToF, ToF-SIMS etc. iii) 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 development. iv) The studies on the transport and potential transformation of nanomaterials (ADME) are underway.

In 2011, MEST/NRF (National Research Foundation of Korea) launched two projects under the category of Green Nanotechnology to monitor the changes in physicochemical properties of

nanomaterials with living cells and the environmental fate of one dimensional nanomaterials. These are five year projects (2011-2016) with aims to develop measurement techniques for intracellular nanoparticle SiO2, or CNT tracking and further detection of one dimensional nanomaterials in the environments. The research results are expected to contribute to understanding the relationship between the physicochemical properties of nanomaterials and living bodies as monitoring the property changes in the environments. Also it is expected to develop standard operation procedures (SOP) and test guidelines for evaluating environmental toxicity of nanomaterials through these projects.

Ministry of Knowledge and Economy (MKE)

MKE in collaboration with 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 characterization, 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.

KATS has been developing national standards to ensure safety and support marketing of consumer products containing silver nanomaterials and CNTs. Guidelines for exposure monitoring, characterization, 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’s 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 provisional reference doses have been presented at OECD WPMN SG8 meeting in Aug, 2011.

Korea Food & Drug Administration (KFDA)

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

Test materials such as SiO2, silver, gold and ZnO have been used to prepare guidelines for safety evaluation.. 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 mainly conduct studies on the selected nanomaterials, such as SiO2 and ZnO to get the information on physico-chemical properties, kinetics, and toxicity.

Ministry of Employment and Labor (MOEL)

MOEL has actively participated in the 'National Nano-safety Strategic Plan (2011~2015)' especially on occupational safety in the workplace.

KOSHA (Korea Occupational Safety and Health Agency, a subsidiary body of MOEL) has conducted the project concerning the risk assessment and management of nanomaterials in the workplace. Hazard of ultrafine dust generated from the workplace has been evaluated to study the connection between the dust and the increasing occupational disease. The inhalation exposure test of nano scaled carbon black dust has been conducted to assess its health effect. Also, surveillance of the workplace treating nanomaterials has been carried out under the relevant guideline published in 2008, to monitor the effectiveness of safety management tool including personal protective equipment and ventilation system.

MOEL provides useful information on typical nanomaterials such as titanium dioxide and CNT(Carbon Nano Tube) for the evaluation of occupational exposure with respect to particle sizes, mass, surface area and concentrations, suggesting that surface area monitor can be used for monitoring nanomaterials due to its correlation with other nanomaterial monitors and economic issues. Also, control measures for reducing exposure to nanomaterials as well as nanoband tool and general guidelines were established in 2010.

6. Information on any public/ stakeholder consultation

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

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

NETHERLANDS

Highlight of developments since the 8^{t} meeting of the WPMN

- The Netherlands has hosted and organised a fruitful horizontal meeting on inhalation testing of nanomaterials.
- A new research and innovation program on nano- and microtechnology was started in the Netherlands (NanoNextNL).

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 Dutch government focuses its efforts for regulatory developments on EU regulation to ensure a coherent legal framework on the risk assessment and management of nanomaterials (*e.g.* by active involvement in the REACH implementation plans on nanomaterials and SCENIHR discussions on the definition). In February 2011 the Dutch government called upon the European Commission for progress in managing nanomaterials (*i.e.* decide on a definition, finalize the REACH implementation

plans on nanomaterials, and get clarity on which criteria are needed to assess whether a nanomaterial exposes specific risks).

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

   Within the REACH process the Netherlands has proposed one nanomaterial for substance evaluation. As soon as the list for substance evaluation is adopted by the Member State Committee the Netherlands will start to work on this nanomaterial.

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

   Facilitated by the Dutch Ministry of Social Affairs and Employment and supported by trade unions and the Confederation of Netherlands Industry and Employers nano reference values were derived as provisional alternative for health based recommended occupational exposure limits or derived no-effect levels and their practice and feasibility for precautionary risk management were assessed. The English report is available at the SG8 section in OECD's Clearspace.

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

   The Dutch National Institute for Public Health and the Environment (RIVM) participates actively in the EU funded projects MARINA and NanoSafety Cluster, both of which will contribute to Integrated Testing Strategies and/or Alternative test methods.

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

   - NanoNextNL is the name of the new research and innovation program on nano- and microtechnology in the Netherlands. It has a budget of 250 M€, 125 M€ from government, the other half from universities, research institutes and the business community. In total over 110 partners participate, including more than 80 companies (about 70 small/medium enterprises). Research will be done along the following lines: energy, nanomedicine, clean water, food, beyond Moore ('nano-electronics'), nanomaterials, bio-nano, nanofabrication and sensors & actuators. Beside these lines an integrated line covering Risk Analysis and Technology Assessment is formulated. The basic thought behind this integrated line is to turn information on risks into (pivotal) information that stimulates technological and economical development of nanotechnology. Therefore this line covers both links to the relevant technical lines, as well as risk research of a more generic nature. NanoNextNL will started in 2011 and runs until 2016.

   - The Dutch National Institute for Public Health and the Environment (RIVM) participates actively in NanoImpactNet, an EU funded network that promotes knowledge and protocol exchange. Participation includes contributions to annual conferences, workshops and training schools for young researchers.

   - The Netherlands (RIVM) has coordinated inhalation studies on cerium oxide within the OECD Sponsorship Programme for the Testing of Manufactured Nanomaterials including studies on the biodistribution of these nanomaterials.

   - The Netherlands (RIVM) has performed studies in volunteers on the biodistribution of nano-sized gold particles in collaboration with the University of Edinburgh.

6. Information on any public/ stakeholder consultation;

The Dutch Committee on the *Societal Dialogue on Nanotechnology* was installed in 2009 to organize the societal dialogue on nanotechnology in The Netherlands. In the last two years the committee funded 35 nano-dialogue projects. These varied both in audience (from high school students till young parents), manifestation (from theatre till You Tube movies) and participating organizations (*e.g.* knowledge institutes, companies, NGO's). In January 2011 the committee published its final report. It concluded that Dutch citizens want a responsible development of nanotechnology, just as the government. Dutch citizens have a carefully balanced opinion on both the positive possibilities and the possible negative consequences of nanotechnology. The current absence of practical experience with nanotechnology in the general public indicates that their opinion may change once more products enter the market. Well-balanced information, both on positive aspects and on risks can help the acceptance of new technologies. More information can be found on http://www.nanopodium.nl/CieMDN/english (mainly in Dutch).

Additional Information

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

  KIR-nano aims at observing and monitoring the potential risks of nanotechnology, gathering relevant scientific literature, generating overviews of relevant legislation, and advising and informing governmental bodies and professionals. These activities are always performed from a risk assessment viewpoint. Its signalling function is put into practice by participating in national and international networks (*e.g.* OECD-WPMN, REACH CASG-Nano, ISO, SCENIHR, ILSI, EFSA, SETAC, WHO/FAO, ETP NanoMedicine) and bringing experts together into national expert panels on different topics (environment, food, consumer products, medical applications, and workers). In addition, KIR-nano is involved in the EU FP-7 projects EU-ObservatoryNano and NanoImpactNet. In this way, KIR-nano acts as an information exchange platform without performing research itself. KIR-nano regularly publishes newsletters in Dutch directed at professionals and regulators but publicly available (www.rivm.nl).

- **Nanomaterials in Consumer Products**

  The Dutch National Institute for Public Health and the Environment (RIVM) in corporation with MESA+ has examined 22 consumer products for the presence of nanomaterials (2011, RIVM Report 320029001, www.rivm.nl). Products with a 'nano' claim do not necessarily contain nanomaterials and *vice versa*. The main conclusion was that measurement techniques should be improved to verify these results. In addition research institute RIKILT detected nanomaterials in 5 of the 15 tested cosmetics products (RIKILT Report 2011.009, www.rikilt.wur.nl; in Dutch only). Their conclusion was that currently consumer products may contain nanomaterials, but whether these pose a risk is still uncertain.

- **Dutch worker exposure to nanomaterials.**

  The Dutch research institute TNO conducted a survey of workplace exposure to nanoparticles in a large number of Dutch industries The results of the survey serve as a basis for large-scale study of exposure to nanoparticles in Dutch workers that was recently launched at TNO.. Their main conclusion was that many Dutch people are potentially exposed to nanoparticles in the workplace. The full report is only available in Dutch (TNO-rapport V9300, www.tno.nl).

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;**

   In Poland there is an obligation (imposed by article 15 of the Act on Chemical Substances and its Mixtures of 25 February 2011) which stays that a natural or legal person that manufactures a dangerous mixture or hazardous mixture in the territory of the Republic of Poland, and a natural or legal person that imports such a mixture to the territory of the Republic of Poland, shall notify the Inspector for Chemical substances of this mixture. Currentlywe are expanding the database of dangerous preparations and it will be possible, on a voluntary basis, to submit information about nano in dangerous preparations.

2. – 5. (None)

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

   - **New polymeric and carbon materials, which protect against the nanoparticles with harmful properties and against specific vapours and gases, are being developed by the researchers from the Central Institute of Labour Protection-National Research Institute** (CIOP-PIB). In contrast to the conventional filtering-absorbing materials, new fabrics will stop not only vapour and gas, but even the smallest particles of sizes ranging from 1 to 100 nanometers (1 nanometer is one millionth of a millimetre).

   - Scientists received over PLN 6.5 million from the Operational Program Innovative Economy for their research project "Innovative polymeric and carbon materials protecting against nanoparticles, vapours and gases". The funds were granted under the competition organised by the Ministry of Science and Higher Education. The project began in May 2009 and will continue until June 2013.

   - In addition, the project of BioNanoPark is implemented by Technopark Lodz. As part of this investment Molecular and Nanostructural Biophysics Laboratories will be created. One of the main tasks of these laboratories will be the assessment of nanostructures impact on human health and the environment. Laboratories are planned to be open by the end of 2012. In general, in Poland in recent years 3 large nanotechnology centers have been created: in Lodz, Szczecin and Gdansk.

7. **Information on any public/ stakeholder consultation; (**None)

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.);**

   The Central Institute for Labour Protection has been realizing the project no OPIE 01.01.02-10-018/09-01 “Innovative polymer and carbon materials for respiratory protection against nanoparticles, vapors and gases.” Period: 01.05.2009 r. - 30.06.2013 on The project is implemented under the Operational Programme Innovative Economy OPIE, 2007-2013Priority 1: "Research and development of new technologies"Measure 1.1: "Support for scientific research for the economy knowledge-basedAction 1.1.2: "The strategic research programs and work development Project leader: Central

Institute for Labour Protection - National Research Institute CIOP-PIBProject 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 vapors and gases.

9. Information on any development related to exposure measurement and exposure mitigation

None

Additional Information

- In May 2011 in Lodz has been signed an agreement between 5 Polish voivodships to establish a consortium of bioregions. The aim of this initiative is to promote mutual cooperation in the field of bio and nanotechnology and related industries and services, and in particular to:
  - work together to create good conditions for business activity
  - cooperate to facilitate the development and commercialization of innovative products
  - work together to facilitate closer cooperation between the world of science and business
  - cooperate in the development of educational activities in the field of bio and nanotechnology
  - initiate and support joint projects in the field of bio and nonotechnology
  - inform each other about conferences and seminars
- On 9th and 10th of November 2011, in Hotel Andels in Lodz, The European Economic Forum will take a place. During the forum the potentials of the regions in the field of bio and nanotechnology will be presented. One of the topics which will be discussed is "*The role of Central European Consortium of Bioregions in the development of bio and nanotechnology in Central and Eastern Europe*. Moreover, at the same time, it is planned to sign a letter of intent between Poland, Lithuania, Latvia, Czech Republic, Slovakia and Hungary to establish bioregions of Central and Eastern Europe.
- Furthermore, currently European Centre of Bio and Nanotechnology is being built in Lodz. ECBNT is formed by Technical University of Lodz as innovative institution in Poland and will follow the leading European standards. Centre will conduct research in accordance with scientific studies tendency of world leading research institutes and research priorities of EU Framework Programme.
- In addition, an Polish-Norwegian project was finished by the end of last year. The overall objective of this project is to elucidate understanding of the nature of measured comparative responses induced by nanoparticles in various biological models. The latter are investigated at different

levels of organization (from molecules to individuals) from which the potential hazards to human health can be determined by observation, modeling and data interpolation.

The project consortium consists of five academic and research partners from Norway and Poland Project details:

Research area: Healthcare
Project Reference: PNRF-122-AI-1/07
Start date: 2008-12-31
End date: 2010-12-31
Total amount: 1 609 230.00 Euro

SOUTH AFRICA

Work completed, underway or planned

1. – 2. (None)

3. Information on any risk assessment decisions;

The Department of Science and Technology (DST) in South Africa has initiated research platform for Health and Safety Risk Assessment Research in the country. The initiative describes the DST's strategy for supporting research in investigating the possible adverse effects of nanotechnologies may have on human health and the environmental. It also aims at developing nanotechnology sustainably in its applications in South Africa

4. – 9. (None)

Additional Information

- Any consideration on the benefits of nanotechnologies;
- Consideration of ethical implications; and
- 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.

SPAIN

The Spanish Ministry of Environment and Marine and Rural Affairs finances the work carried out in the Framework of the OECD WPMN Sponsorship Program to Test Manufactured Nanomaterials with the technical support of the Spanish "Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria (INIA)" by cosponsoring the testing of three types of nanomaterials (Titanium dioxide, Cerium Oxide and Dendrimers).

Highlight of developments since the 8t meeting of the WPMN

- Development of a robust method to measure concentrations of metal nanoparticles in biological samples
- Development of a robust method to measure concentrations of dendrimer nanoparticles in biological samples is underway and is expected to be completed shortly
- Submission of results produced during the project to a peer reviewed journal
- Preparing further results for submission in 2 cases

Work completed, underway or planned

- Finalized 1st stage toxicological and ecotoxicological testing of two nanoparticles (CeO2 and TiO2)
- Beginning of 2nd stage testing (CeO2 and TiO2)
- Finalizing toxicological testing of dendrimer nanoparticles 1st stage

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;

Spain is actively participating in REACH Competent Authority Subgroup on Nanomaterials (CASG-Nano) that works in the development of technical guidance related to substance identification, information requirements and chemical safety assessment and how to apply the regulation on nanomaterials.

2. – 8. (None)

9. Information on any development related to exposure measurement and exposure mitigation

Development of a robust method to measure concentrations of metal nanoparticles in biological samples

Development of a robust method to measure concentrations of dendrimer nanoparticles in biological samples is underway and is expected to be completed shortly

Additional Information

None

SWITZERLAND

Highlight of developments since the 8t meeting of the WPMN

- New web application of the Precautionary Matrix for Synthetic Nanomaterials is online since September 2011 (see item 2a).
- An interim report about the status of implementation of the Swiss action plan "Synthetic nanomaterials" will be presented to the federal council of Switzerland in January 2012 (see item 2b).
- The Federal offices involved with implementing the Swiss action plan are currently compiling a joint web site on nanotechnology, which will go online by end of 2011.

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;

Switzerland is preparing a guidance document explaining the requirements for self-supervision by manufacturers and importers regarding synthetic nanomaterials under the existing Swiss chemicals law. This guidance document is expected to be released for public review by spring 2012.

2. Developments related to voluntary or stewardship schemes;

a) An updated version of the Precautionary Matrix for Synthetic Nanomaterials has been released on July 14, 2011. The new version has been reworked and refined in several details, in particular regarding the environmental aspects. By end of September 2011, a fully interactive web application of the Precautionary matrix has been launched. The web application of the precautionary matrix furthermore allows to down-, upload and edit individual data files. Link to the Precautionary Matrix:

http://www.bag.admin.ch/themen/chemikalien/00228/00510/05626/index.html?lang=en

Link to the new web application:

http://www.bag.admin.ch/themen/chemikalien/00228/00510/12290/index.html?lang=en

(Web site available in German, French, Italian and English)

b) The Federal authorities involved with implementing the Swiss action plan "Synthetic Nanomaterials" from April 9, 2008 will present to the federal council of Switzerland an interim report in January 2012. This report will summarise the activities, results, as well as future perspectives and regulatory requirements for synthetic nanomaterials in Switzerland.

c) As a side-project of the action plan, a nanotechnology teaching platform aiming at high school and professional school level has been established under the name "Swiss Nano-Cube". Link to the web site: http://www.swissnanocube.ch/en/home/

1. (Web site available in German, French, Italian and English; some parts of the site may not be fully translated)

d) The Federal offices involved with implementing the Swiss action plan are currently compiling a joint web site on nanotechnology (presumably www.nano-info.ch), which will go online by end of 2011.

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

The National Research Programme NRP 64 "Opportunities and risks of Nanotechnologies" has been underway since December 2010. The total funding amounts CHF 12 million, and the proceedings of NRP 64 are to be expected by 2016.

4. 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.)

a) Some of the ongoing research projects of the NRP 64 (see above) are also focussing on life cycle aspects.

b) The Centre for Technology Assessment TA-SWISS has started an overview study "Nanomaterials: Effects on Environment and Health", which runs from September 2011 until end 2012.

http://www.ta-swiss.ch/en/projects/nanotechnologies/nano-and-environment/

In particular, this study aims at identifying and assessing the benefit-risk ratio of a number of nanomaterials applications within the societal, economical and environmental context of Switzerland.

Additional Information

- Switzerland has proposed the addition of activities on the environmentally sound management of nanotechnology and manufactured nanomaterials to the Global Plan of Action of SAICM (Strategic Approach to International Chemicals Management). Additional information can be found on the SAICM web site:

  http://www.saicm.org/documents/OEWG/Meeting%20documents/OEWG1%208_GPA%20Additions%20E.pdf

- Additional Information on the Swiss action plan "Synthetic Nanomaterials" can be found on the website of the Federal Office for the Environment FOEN:

  http://www.bafu.admin.ch/chemikalien/01389/01393/01394/index.html?lang=en

(Web site available in German, French, Italian and English, however some sub-pages or documents may not be available in all these languages)

THAILAND

Highlight of developments since the 7th meeting of the WPMN

- Since the 8th meeting of WPMN, a number of nano-safety development and activities have taken place in Thailand.

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

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

The National Nanotechnology Center (NANOTEC) has established:

- National Nanosafety Strategic Plan which has already been approved by the Executive Board Committee of NANOTEC and the Board of National Science and Technology Development Agency (NSTDA)
- Nanotechnology Information Center of Thailand (NICT) at Chulalongkorn University
- "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
- National Nano-safety Guideline compliance with laboratory and industrial protocol
- Nanosafety training program with UNITAR.
- 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.
- Nanotoxicity and ecotoxicity research program of nanosilver, TiO_2, fly ash particles
- Collaborative research programs with the Swiss Federal Institute for Materials Testing and Research (EMPA)
- Participation as part of the Thai Delegation in the ISO/TC229 Nanotechnologies standard development activities
- 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 program.
3. Standardize 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 Nanotechnology Information Center of Thailand (NICT) in collaboration with Chulalongkorn University. NICT 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, NICT is expected to become an independent agency in order to boost its credibility as an impartial organization.

Thai Industrial Standard Institute (TISI)

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

Chulalongkorn University

In addition to the scientific and technological components, the Center for Innovative Nanotechnology (CIN) of Chulalongkorn University has two built-in programs or units that cover the topics of nanosafety and nanoethics, respectively. The nanosafety program, led by Dr. Lerson Tanasugarn, is preparing the budget for funding in 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 activites have been conducted by NANOTEC. They were National Nano-safety Strategic Plan Assembly Forum, and the establishment of Nanotechnology Information Center of Thailand, in collaboration with Chulalongkorn University. The nano-label, so called Nano-Q, have been initiated and planned to approve some nanoproducts in the end of 2011 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 organizations such as OECD and ISO TC 229.

Back in 2004, the newly drafted NANOTEC strategic plan called for a national policy body to handle nanosafety issues. This established policy body then initiated a drafting of a nanosafety and nanoethics guideline in 2005.

NANOTEC consequently commissioned Chulalongkorn University to prepare a nano-safety status report in 2007. The main objective of this exercise was to gather international information on all aspects of nanosafety and nanoethics. Data sources include university centers that receive US government grants related to nanosafety/ nanoethics, independent policy research institutes, independent academics, e.g. in South America, and international organizations such as OECD, ISO, and APO (Asian Productivity Organization). In addition, this exercise attempted to familiarize a dozen of experts in various fields with the foundation and features of nanotechnology. These experts from the fields of environmental law, consumer protection law, economics, and political science, would become invaluable resource persons and reviewers of the national nanosafety guideline.

2. Developments related to voluntary or stewardship schemes

Stewardship schemes are being studied in parallel with the nanosafety guideline development effort and the nano-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 programs or strategies designed to address human health and/ or environmental safety aspects of nanomaterials

During the past few years, NANOTEC as a funding agency has urged researchers to add the safety aspects to all nanomaterial R&D grant proposals. For example, nanoparticle-coated fabrics under development were subject to wash-water contamination tests. Nano-titanium dioxide (TiO2) coated fish tanks were tested for toxicity to fish. Skin creams containing titanium dioxide nanoparticles were also tested for skin penetration through a model (pig) skin. Ecotoxicity of nanosilver in waste water was also tested. More comprehensive nanomaterial safety data resulting from program specifically designed to address the human health and environmental safety aspects should be available through NANOTEC after such research works are completed.

6. Information on any public/ stakeholder consultation.

NANOTEC has regularly organized nanosafety public seminars, assembly forum, and international conferences including NanoThailand, the largest international conference and exhibition of nanotechnology in Thailand, nanosafety session was included.

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

UNITED KINGDOM

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 that has been running for over a year and will complete shortly. Sponsors are in discussion about how best to make the project's report available publicly. The project looked at how the current EU Chemicals Regulation (REACH) 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

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.

A revision of the first UK nanotechnology terminology document (ref PAS71) – vocabulary – nanoparticles, first published in June 2005 has been completed. An updated August 2011 version is available at http://shop.bsigroup.com/en/ProductDetail/?pid=000000000030214797

Two new standards documents are being developed by the BSI: A guide to disposal of wastes containing manufactured nanoscale materials; and A guide to the detection and identification of manufactured nanomaterials in complex matrices

Work through the National Physical Laboratory (NPL) continues for standardisation for airborne nanoparticle number concentration in ISO TC24;BSI – NTI/1: 3 ISO and 1 PAS published since March. Ambient air quality measurements carried out for Defra as part of the particle network.

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

A. Phase 2 of the Environmental Nanoscience

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, has selected two 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. A third collaborative project has also been funded looking mainly at airborne exposures to nanomaterials with a focus on human health. In addition, researchers will be asked to develop novel techniques for detection and characterisation of nanomaterials in complex environmental and biological systems. The projects have been underway for about 1 year and are progressing well. Total funding is in the region of $8M. Awards to the following projects were made:

- **NanoBEE** (Manufactured nanoparticle bioavailability and environmental exposure)
- **TINE** (Transatlantic Initiative for Nanotechnology and the Environment)
- **RAMNUC** (Risk Assessment of Manufactured Nanomaterials in Consumer Products)

B. 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. The results of this study will be published in late 2011.

C. FABLE project funded under Environmental Exposure and Health Initiative (NERC)

FABLE (From Airborne Exposures to Biological Effects) is one of a number of studies being funded under the Environmenttal Exposure and Health Initiative (EEHI). This study will focus on 3 nanoparticulate metals (cerium, zinc and vanadium) found in vehicle exhausts. These will be investigated for their potential to impact on human and environmental health. It is anticipated that this

study will make a major step-change in the assessment of risks from NPs. The study will use these real life levels (rather than the usual approach of using high concentrations) in a series of lab experiments to define where these NPs go once breathed in and what damage they might do. It is anticipated that this work will identify the processes which occur upon exposure to nanoparticles (e.g. inflammation) and consequently will allow "safe" levels / limits of exposure to be established.

D. The Engineering and Physical Sciences Research Council (EPSRC)

EPSRC 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.

EPSRC 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.

E. NPL have completed a Technology Strategy Board (TSB) feasibility project investigating the selective capture of nanoparticles from waste water.

F. The Department of Health has 4 ongoing projects totaling £1m looking at:

- Nanoparticles and Antherothrombosis
- Carbon nanotubes asbestsos/fibre structure activity relationship;
- In Vivo Safety and Particokinetics of inhaled nanomedicines
- Risk Assessment for Manufactured Nanoparticles used in Consumer Products.

G. Imperial college are leading on RESAC (Respiratory effects of silver and carbon nanomaterials), a project focussed on interactions of silver and carbon nanomaterials with the lung. This will include analysis of particles, tubes and wires in order to fully expose the impact of shape on pulmonary effects.

H. The Risk Assessment for Manufactured Nanoparticles used in Consumer Products (RAMNUC) study

It aims to undertake a detailed experimental investigation of potential exposure arising from nano-consumer products (cleaners/air fresheners) in a controlled environment and measuring the airborne particulates. The study will also be examining Cerium Oxide used as a fuel additive.

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

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 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 toolkit can be accessed **by clicking here**)

9. Information on any development related to exposure measurement and exposure mitigation

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) commissioned a monitoring and modelling study to ascertain likely environmental exposure to nanosilver in the UK aquatic environment. This study undertook monitoring to measure concentrations at 6 'typical' UK sewage treatment plants (STP). The results were 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. The results of this study are available by clicking below.

http://randd.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&ProjectID=17267&FromSearch=Y&Publisher=1&SearchText=cb0433&SortString=ProjectCode&SortOrder=Asc&Paging=10#Description

UNITED STATES

Highlight of developments since the 8th meeting of the WPMN

- EPA Office of Pesticide Programs has published a notice in its Federal Register announcing how EPA plans to determine which pesticide products currently on the market contain nanoscale materials. The Food and Drug Administration (FDA) announced availability of a draft guidance for industry entitled ''Considering Whether an FDA–Regulated Product Involves the Application of Nanotechnology'' on June 14, 2011. On April 17, 2011, NIOSH released "Current Intelligence Bulletin 63: Occupational Exposure to Titanium Dioxide (http://www.cdc.gov/niosh/docs/2011-160/).

- The Food and Drug Administration (FDA) announced availability of a draft guidance for industry entitled ''Considering Whether an FDA–Regulated Product Involves the Application of Nanotechnology'' on June 14, 2011. The guidance is intended to provide industry with FDA's current thinking on whether FDA-regulated products contain nanomaterials or otherwise involve the application of nanotechnology. The guidance is intended to be broadly applicable to all FDA-regulated products, with the understanding that additional guidance may be articulated for specific product areas, as appropriate in the future.

- EPA Office of Pesticide Programs published a notice in the Federal Register on June 11, 2011 announcing how EPA plans to determine which pesticide products currently on the market contain nanoscale materials. This notice also contains a policy stating that EPA will consider any product identified as containing nanoscale materials as a new active ingredient for purposes of the pesticide laws.

- EPA Office of Pesticides Programs has received applications to register antimicrobial pesticides containing nanoscale silver. These applications 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. Currently, EPA is deliberating on whether or not to register these products using toxicity data for analogous forms of nanosilver available in the scientific literature. As a condition of registration, EPA is proposing to require additional product chemistry, toxicology, exposure, and environmental data to confirm these products will not cause unreasonable adverse effects to human health and the environment

- On May 6, 2011, EPA issued a significant new use rule (SNUR) for a multiwalled carbon nanotube. EPA had previously issued SNURs for other carbon nanotubes on September 17, 2010. EPA has received premanufacture notifications for other carbon nanotubes and is developing proposed SNURs for those chemical substances B7to be issued later this 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 has assessed more than 120 nanoscale materials under TSCA since January 2005.

- Beginning October 2011, EPA's nanomaterials research activities will be located within EPA's new Chemical Safety for Sustainability research program. This move will enable closer coordination of EPA's nanomaterials research with other EPA chemicals-related research that relates to EHS issues, such as life-cycle assessment, inherent chemical properties, and green chemistry. Additional information may be found at http://epa.gov/research/priorities/chemicalsafety.htm.

- On April 17, 2011, NIOSH released "Current Intelligence Bulletin 63: Occupational Exposure to Titanium Dioxide (http://www.cdc.gov/niosh/docs/2011-160/).

- NIOSH co-sponsored the 5th International Conference on Nanotechnology-Occupational and Environmental Health, which was held on Aug. 9-12, 2011, in Boston, Mass. More information is available at www.uml.edu/nano/nanoehs/Conferences.html. 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

- In March 2011, NIOSH invited comments on the types of research relevant to hazard identification and risk management that it should consider in updating its strategic plan on nanotechnology research. http://edocket.access.gpo.gov/2011/2011-5110.htm

- On February 28-March 1, 2011, NIST hosted a workshop on carbon nanomaterials, held under the auspices of the National Nanotechnology Initiative (NNI) Signature Initiative on Sustainable Manufacturing. The workshop focused on technical barriers to manufacturing carbon nanomaterials and issues concerning environmental, health, and safety of these materials. Additional information on the workshop can be found at http://www.nist.gov/cnst/thenewsteel.cfm

- The National Cancer Institute (NCI) of the National Institutes of Health (NIH) funds a variety of groups that use nanotechnology to improve cancer-related outcomes. In particular, the NCI funds the Alliance for Nanotechnology in Cancer (ANC) which is a targeted funding initiative to create a network of investigators and institutions that will serve as nanomedical research hubs as well as become models for future research groups to form transdisciplinary projects. The first phase of the ANC (2005-10) funded eight large centers and twelve research projects and resulted in over 1,000 publications, 250 patent disclosures, and 50 spin off companies. The current Phase II (2010-15) seeks to build upon these successes while expanding a significant training effort. (website: http://nano.cancer.gov/)

- A component of the NCI-ANC is the intramural Nanotechnology Characterization Laboratory (NCL) at NCI-Frederick SAIC. The NCL provides a free service for the cancer nanotechnology community (domestic and international) including academia, government, as well as small and large business concerns. Since 2005 it has conducted its preclinical assay cascade on close to 300 nanoparticles with intended use for cancer treatment, imaging, and/or diagnostics and published extensively on thematic observations. This assay cascade examines the physical character, in vitro activity, and in vivo toxicity to thoroughly characterize these particles for biological use. This work has been instrumental in several Investigational New Drug (IND) filings with the US-FDA. (website: http://ncl.cancer.gov/) (Email: ncl@mail.nih.gov)

EUROPEAN COMMISSION (EC)

Highlight of developments since the 8th meeting of the WPMN

- The European Commission adopted on 20 October 2011 a Recommendation on the definition of a nanomaterial. The Recommendation is designed to be used as the common reference defining nanomaterials when they are subject to requirements under EU regulations. For further details see heading 1 below.

- The Commission concluded in summer 2011 a two-year long REACH Implementation Project on Nanomaterials (RIPoN) providing thorough recommendations on how companies and ECHA should tackle nanomaterials when a nanomaterial is being registered under REACH. Final reports are available here:

- http://ec.europa.eu/environment/chemicals/nanotech/index.htm#ripon

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. i) Definition of nanomaterials

The European Commission adopted on 20 October a Recommendation on the definition of a nanomaterial (696/2011). The core terms of the definition reads:

1. "Nanomaterial" means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm.

In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %.

2. By derogation from point 2, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials.

The Recommendation and a question and answer document can be found here: http://ec.europa.eu/environment/chemicals/nanotech/index.htm#definition

The definition will primarily be used to identify materials for which special provisions (concerning for example risk assessment or ingredient labelling) might apply. Those special provisions are not part of the definition but of specific legislation in which the definition will be used.

Nanomaterials are not intrinsically hazardous but there may be a need to take into account specific considerations in their risk assessment. Therefore one purpose of the definition is to provide clear and unambiguous criteria to identify materials for which such considerations apply. It is only the results of the risk assessment that will determine whether the nanomaterial is hazardous and whether or not further action is justified.

Today there are several pieces of EU legislation and technical guidance documents that support the implementation of legislation, which contain specific references to nanomaterials. To ensure conformity across legislative areas, where the same materials are often used in different contexts, the purpose of the Recommendation is to provide a coherent cross-cutting reference. Therefore another basic purpose is to ensure that a material which is considered as a nanomaterial in one sector will also have the same classification if used in another. Definitions so far used in EU legislation have not been subject to the same level of detailed scrutiny as the present Recommendation. The EU co-legislators already acknowledged this when e.g. the Cosmetics Regulation was adopted, by allowing later adaptation of the definition through the comitology procedure. The Recommendation will be used as the basis for this adaptation.

Why not use existing international definitions?

Several countries, both inside and outside the EU, as well as international organisations, have used working definitions. All these have been carefully scrutinised. There is variability between the different working definitions and most of them are not as precise as the present Recommendation.

Most non-EU countries generally use their definitions in a different regulatory context mainly to identify individual substances on a case by case basis, which then may be subject to specific data provision or risk assessment obligations. In the EU, provisions in individual pieces of legislation (e.g. ingredient labelling, prior notification and authorisation etc.) apply directly to all producers of products containing nanomaterials. Therefore, much more precision is required to provide legal clarity.

The Commission has taken the ISO (International Organisation for Standardisation) term "nanomaterial" as the basis for its definition but has made a number of modifications which were deemed necessary to ensure its practical application in a regulatory context.

Notably the reference to "approximately" when referring to the size range is not appropriate in a legislative context. Moreover, contrary to ISO terminology, the Commission definition of "nanomaterial" is limited to materials consisting of particles (excluding non-particular materials such as proteins or micelles as present for example in mayonnaise), and excludes nanostructured materials (i.e. solid products, parts or components) with an internal or surface structure in the range between 1-100 nm, such as computer chips).

Is it really possible to have only one single definition?

The Recommendation offers a common understanding of the term "nanomaterial" to avoid confusion on terminology and inconsistency between different pieces of legislation. This does not mean that specific legislation needs to apply to all nanomaterials, or that there could not be legislation covering similar materials outside the definition. Since the definition is broad in its coverage, further sector specific qualifiers may be needed in order to identify more precisely those materials that should potentially be subject to specific legislative requirements or policy attention.

Why must the particle distribution be measured in number and not by mass which is commonly used?

The amount of nanoparticles in a material can be determined based on mass (weight of nanoparticles to total weight of material) or based on the numbers (number of nanoparticles to total number of particles, "number size distribution"). There is a correspondence between the two measures for every material, but size and mass distribution are not directly convertible.

The Scientific Committee (SCHENIR) argued in its opinion that "a low mass concentration of nanoparticles in a product may still represent a high number of particles and a mass based distribution can be skewed by the presence of relatively few large and thus heavy particles". Therefore it considered number size distribution as a more relevant metric for possible effects of nanoparticles than mass concentration.

The Commission considers this reasoning as relevant and decided to follow this choice of metrics. Further work is certainly needed on the metrological aspects. The Commission intends to start work to provide practical guidance on measurement methods. This issue is also likely to be one of the subjects to be studied in further detail as part of the review planned for 2014.

Are aggregates and agglomerates of nanoparticles nanomaterials?

The short answer is 'yes'. Agglomerated or aggregated particles may exhibit the same properties as unbound particles. Moreover, there can be cases during the life-cycle of a nanomaterial where the particles are released from weakly bound agglomerates or under certain conditions even from more strongly bound aggregates. The definition in the Recommendation therefore includes particles in agglomerates or aggregates whenever the constituent particles are in the size range 1 nm - 100 nm.

This inclusion is in conformity with the scientific advice the Commission has received as well as the general international understanding e.g. in the works of ISO.

3. ii) 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.

Work is ongoing to undertake a study, elaborated and finalised by the end of 2012, which 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.

The call for tender was successfully launched with four offers being received. The process of choosing a contractor is underway and a contract is expected to be signed in 2011 still.

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

7th EU Research Framework Programme (FP7)

- The projects MARINA, NANOVALID, MODNANOTOX and NANOTRANSKINETICS are launched on 1st November 2011.

- New proposed projects selected under the fifth call for proposals are currently in negotiation, by topic:

4. i) New methods for measuring, detection and identification of nanoparticles in products and/or in the environment; projects targeting SMEs

- INSTANT: "Innovative Sensor for the fast Analysis of Nanoparticles in Selected Target Products

- SMART-NANO: "Sensitive Measurement, detection, and identification of engineered nanoparticles in complex matrices"

5. ii) Worker protection and exposure risk management strategies for nanomaterial production, use and disposal, Small focused projects

- Sanowork: "Safe Nano Worker Exposure Scenarios"
- Nanomicex: "Mitigation of risk and control of exposure in nanotechnology based inks and pigments"
- Scaffold: "Innovative strategies, methods and tools for occupational risks management of manufactured nanomaterials (MNMs) in the construction industry"

6. iii) Intelligent testing strategies for nanomaterials impact and exposure – towards regulation and clustering of materials; Coordination and support action

- ITS-Nano: “Intelligent Testing Strategy for Engineered Nanomaterials”

- Under the sixth call for proposals the following topics have been addressed:

- NMP.2012.1.3-1 Systematic investigations of the mechanisms and effects of engineered nanomaterial interactions with living systems and/or the environment.
- NMP.2012.1.3-2 Modelling toxicity behaviour of engineered nanoparticles
- NMP.2012.1.3-3 Regulatory testing of nanomaterials

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

- 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 nanosafety cluster is preparing a "nano-EHS research strategy for 2015-2020".

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

This EU FP7 NanoValid project will run for four years with the aim of developing a set of reference methods and materials for hazard identification, risk assessment, and life cycle analysis of engineered nanomaterials. The kick-off meeting took place in Rome on 1 November 2011. Further information can be found at the project website: http://www.nanovalid.eu/

9. Information on any development related to exposure measurement and exposure mitigation

An International Workshop on 'Nano Reference Values as provisional substitutes for OELs and DNELs for nanoparticles' took place on 29th September, 2011 at The Hague, Netherlands.

This is an initiative of IVAM University of Amsterdam, the Dutch Trade Unions and Dutch Employers Organization. They have kindly given permission to send the relevant information for the purposes of a submission to the OECD WPMN SG8.

Thus, copies of the following papers will be forwarded to SG8 members:

- A paper titled 'Nano Reference Values as provisional alternative for HBR-OELs or DNELs - practice and feasibility for precautionary risk management'.
- The respective presentation made by Pieter van Broekhuizen of the University of Amsterdam.

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 on the Panel's domestic activities.

In April the Panel submitted comments to the National Institute of Occupational Health and Safety (NIOSH) with comments on its strategic plan for nanotechnology research. The Panel recommended that NIOSH focus its efforts on questions of exposure assessment, risk characterization, and risk management. The Panel believed NIOSH's plans regarding hazard assessment of nanomaterials was duplicative and should be left to the numerous federal and international agencies already focusing on that subject.

In August the Panel submitted comments to the U.S. EPA Office of Pesticide Programs on its preferred approach for gathering information on pesticide products (active and inert ingredients) that contain nanomaterials under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Panel disagreed with EPA's analysis and offered substantial comments on alternative approaches.

In August the Panel also submitted comments to the U.S. Food and Drug Administration (FDA) on its draft guidance to industry on how FDA will determine whether FDA-regulated products contain nanomaterials or otherwise involve the application of nanotechnology. The Panel largely supported FDA's approach, but made a number of recommendations to focus and further clarify the guidance.

In addition to providing agencies with guidance on specific proposals, the Panel continues to engage EPA's Office of Pollution Prevention and Toxics on its plans to exercise its existing regulatory powers under the Toxic Substances Control Act (TSCA) to require reporting of certain information, implement test rules, and issue a generic "significant new use rule," or "SNUR," for nanomaterials (see http://www.epa.gov/oppt/nano/#existingmaterials). The reporting rule would require that persons who manufacture nanoscale materials notify EPA of certain information including production volume, methods of manufacture and processing, exposure and release information, and available health and safety data. The test rule is expected to apply to specific multiwall carbon nanotubes, certain clays, alumina, and spray-applied nanomaterials and will require material characterization data, as well as testing for health effects, ecological effects, and environmental fate. The SNUR would require persons who intend to manufacture, import, or process certain nanomaterials for an activity that is designated as a significant new use by the proposed rule to notify EPA at least 90 days before commencing that activity.

The Panel continues its support of the research coordinated by the U.S. National Nanotechnology Initiative (NNI) and participated in a public webinar announcing the NNI's 2011 EHS research strategy (http://www.nano.gov/node/681). The NNI has released a set of reports that are the result of a series of workshops focusing on various issues in the nanotechnology environmental, health, and safety (EHS) arena (http://www.nano.gov/node/647). The reports cover human health, environmental health, exposure, and legal and ethical dimensions of nanotechnology.

Other activities of note include being interviewed by the U.S. Government Accountability Office regarding an investigation into the U.S. government's investments in nanotechnology EHS research, and participating in a meeting with U.S. Department of Agriculture (USDA) Officials about a recommendation from an advisory group that would have banned nanomaterials from USDA-certified organic foods. At the level of individual states, there has been little activity since the last WPMN meeting.

The Panel continues to co-sponsor the NanoRelease project coordinated by the International Life Sciences Institute's Research Foundation

(ILSI-RF; http://www.ilsi.org/ResearchFoundation/Pages/NanoRelease1.aspx).

In addition to our sponsorship, ACC Nanotechnology Panel members serve on the project's steering committee. The purpose of the 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.

After considerable discussion, the project's steering committee selected MWCNTs embedded within polymer matrices as the first nanomaterial to carry forward to the next phases of the project. The next steps include recruiting experts to develop white papers on several topics, convening a workshop to gather feedback on the resulting documents, writing a state-of-the-science document, and creating the work plan for the next phase of the project. That phase will consist of testing and methods development using an inter-laboratory testing approach. US and Canadian government, industry, and academic laboratories will be convened using a "cooperative research and development agreement" approach often used by US government agencies to enable technology transfer between public and private sectors.

Other project co-sponsors include U.S. EPA, Environment Canada, Health Canada, Society of Chemical Manufacturers and Affiliates, U.S. National Institute of Standards and Technology, The Adhesive and Sealant Council, and the American Cleaning Institute. Labor unions, consumer advocates, and other U.S. government 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 finalised before the summer and available on http://ec.europa.eu/environment/chemicals/nanotech/index.htm#ripon. Cefic welcomes the reports as the final outcome of an extensive evaluation of not only existing REACH guidance but also several hundred scientific reports to ensure nanomaterials are appropriately addressed. In the end, the reports confirm Cefic's views that in general the REACH guidance is applicable to nanomaterials with only few amendments needed. We are now looking forward to ECHA's work in incorporating the conclusions from the RIP-oN2 and 3 in the existing guidance to REACH.

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.

On October 18, the European Commission adopted its long-awaited recommendation for a definition of the term "nanomaterial". Cefic welcomes these efforts to develop a regulatory definition for nanomaterials to help provide legal certainty and consistency, but is concerned that the Commission's recommendation is too broad in scope and therefore difficult to integrate into existing legislation in a meaningful way.

In particular, Cefic supports the initiative to develop a scientifically balanced definition of the term "nanomaterial" to help provide legal certainty and consistency for industry as well as for policy and law makers. Cefic fears implementing the proposed definition will add unnecessary burden for companies, leading to added costs and less efficient use of resources. In addition, its current form would define as nanomaterials some decades-old substances such as mineral pigments used in paints and other everyday products. The chemical industry is also concerned by the lack of standardised measurement techniques, which are important for legal certainty.

Last year, Cefic together with ICCA, 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). Cefic will now continue to offer the experience of the chemical industry to illustrate the practical consequences of the definition proposals under discussion based on real materials.

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

Through its Long-range Research Initiative (LRI), Cefic sponsors health and environment safety research on nanomaterials. 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 finalization 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 Program 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 analyze the suitability of current OECD guidelines to assess the reproductive toxicity of nanomaterials. Using two reference materials present on the OECD list of 'representative manufactured nanomaterials for testing' (1), nano silicium dioxide and nano zinc oxide, the ability of current reproductive toxicity OECD guidelines to identify hazard associated with nanomaterials will be tested in this project. The 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 characterization 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 a 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 nanomaterial evaluation techniques for use inside and outside Japan 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. January 2011

With a view to consulting with experts in Japan and overseas about a newspaper article in the Nikkei newspaper dated November 8, 2010 entitled "Silica and titanium dioxide nanoparticles cause pregnancy complications in mice (2011, 4. nature nanotechnology)," the Working Group visited a research laboratory once (January 12) and attended research report meetings twice (February 10 and June 7) in order to discuss issues of interpretation in accordance with the protocol.

The New Topics Working Group Committee plans to prepare an opinion statement by the end of this year and to release the statement to member companies on JCIA's website as an official statement from the association.

2. April 2011

The Working Group visited nanomaterial analysis experts at the AIST's National Metrology Institute of Japan in order to study current R&D trends regarding systems for the measurement of average nanomaterial particle diameters and average particle diameter distributions.

It was discovered that measurement systems are not readily available for practical use.

The Working Group explained the need for such measurement systems to the experts (a definition of nanomaterials is likely to be established by the EU by the end of this year).

3. May 2011

Working Group members attended the 12th TC 229 International Committee Conference held in St. Petersburg, Russia and discussed at the meeting of Working Group 3 (environment and safety) the problems of the industry regarding SDS (Safety Data Sheets) in order to highlight the need to accelerate development.

At the meeting of Working Group 4 (materials standards), our Working Group members proposed a new approach to the standards proposed by China (creating general standards instead of specific standards for silica or titanium oxide).

4. July 2011

The Working Group attended a briefing for the AIST's project entitled "Research and Development of Nanoparticle Characterization Methods" and identified issues in the report on how to deal with NOAEC (No Observed Adverse Effect Concentration) when evaluating of titanium oxide. The final briefing is scheduled to be held as an international symposium in Tokyo on September 29 and 30. The Working Group Committee plans to send four committee members to the symposium for participate in detailed discussions.

5. Since September 2008

The Working Group has actively contributed to the Japanese National Nanotechnology Standardization Committee Project, which was set up by AIST, an OECD follow-up group. This was the last fiscal year of our second term of office, which lasted for four years (two terms), and we were reappointed as a committee member.

PART IV: NIA

Through the coordination of the PROSPEcT (i.e. Ecotoxicology Test Protocols for Representative Nanomaterials in Support of the OECD Sponsorship Programme) project, the Nanotechnology Industries Association (NIA) provides the Lead Sponsor to the OECD WPMN Sponsorship of nano-ZnO, as well as the Co-Lead Sponsor to the OECD WPMN Sponsorship of nano-CeO2. PROSPEcT is a Public-Private-Partnership (PPP) (value: GBP 3.7 Million) between the UK Government and several industrial NIA members; the PPP was originally set up to run for three years (from 1st January 2009 until 31st December 2011), but received a 6 months extension in order to conduct in-depth research into phenomena observed earlier in the project.10

The NIA provides the Lead Sponsor to the OECD WPMN Sponsorship of **nano-Clay** through the project **RefNanoCLAYM** (i.e. Lead-Sponsorship, Characterisation and Testing of Reference Nanoclay Materials within the OECD Sponsorship Programme) – a Public-Private-Partnership (PPP) (value: EURO 245 000) between governmental test laboratories and NIA members (duration: 3 months, start date: 1st September 2010).[11]

On the 1st July 2011, the NIA launched the **Global-NanoMaPPP** (i.e. Global PPP for the Integrated Measurement and Testing of Representative NanoMaterials in Support of the OECD Sponsorship Programme) – an international Public-Private-Partnership (PPP) (value: EURO 4.6 Million). The Global-NanoMaPPP provides continuing Sponsorship and Contribution of the following OECD WPMN nanomaterials: **nano-ZnO**, **nano-CeO_2**, **MWCNT**, **SWCNT**, **nano-clay**, **nano-silver**, **nano-Gold**, as well as **nano-$BaSO_4$**.[12]

The *Global-NanoMaPPP* furthermore provides stewardship of data collection and data review in the ***NANOhub*** (*i.e.* IUCLID-based database adopted by the OECD WPMN for the collection of data generated during the OECD WPMN Sponsorship Programme) for the above mentioned nanomaterial types.

10 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

11 Follow this link for more information on *RefNanoCLAYM* : http://www.nanotechia.org/nia-activities/nia-projects/nia-projects-refnanoclaym

12 Follow this link for more information on the *Global-NanoMaPPP*: http://www.nanotechia.org/nia-activities/nia-projects/nia-projects-globalnanomappp

(Other) NIA Projects:

Safety Assessment:

1. The ***REACH Implementation Plans on Nanomaterials (RIP-oNs):[13] Scientific and technical Support on Nanomaterials*** concluded in September 2011.

RIP-oN2: 'Specific advice on fulfilling information requirements for nanomaterials under REACH'14'

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'[15]

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.

2. On the 1st November 2011, the FP7 project ***MARINA - Managing Risks of Nanoparticles*** commenced:[16]

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

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

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

16 Follow this link for more information on MARINA: http://www.nanotechia.org/nia-activities/nia-projects/nia-project-marina

MARINA will address the four central themes for the Risk Assessment and Management of Nanomaterials: Materials, Exposure, Hazard, and Risk. In MARINA we will develop beyond-stateof- the-art referential tools from each of these themes and integrate them into a Risk Management Toolbox and Strategy for both human and environmental health. Specifically, MARINA will use and develop:

- a well-tested set of reference nanomaterials with thoroughly validated referential characterisation methods,
- methods to further understand the properties, interaction, exposure, and fate of ENM in relation to human health and the quality of the environment,
- validated, harmonised, and standardised reference methods for hazard assessment for both human health and environment culminating in an integrated/intelligent testing strategy, and
- risk assessment tools by combining elements of (i), (ii) and (iii); strategies for monitoring ENM exposure for human health and environment (including estimating the size and possible pollution scenario caused by massive release, e.g. explosion or environmental spillage), and integrate them into a risk management toolbox and strategy for risk reduction.

Regulatory Assessment:

On the 30th November 2011, the NIA held a workshop entitled ***'Defining Nano!? - Compliance Requirements & Market Impact of the EU Definition of 'Nanomaterials'-***, during which the following questions were discussed:

- Which market sectors utilising nanotechnologies will be affected by additional regulatory compliance?
- What is the economic impact on current and future applications of nanotechnologies?
- How will the EU definition be implemented (in European legislation and in the EU Member States)?
- What can companies do in the short term, in order to offset the cost of long-term compliance?

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 Standardization (CEN TC/352).17 The NIA furthermore provides expert evidence to several ISO/TC 229 committee projects, as well as nano-specific evidence to the ISO/TC 194 committee.

Contributions to the WPN:

The NIA provides the BIAC Co-Lead representative to the WPN.

Publications (since last report – i.e. after January 2011):

1. Consultation Responses & Evidence (interactive list):[18]

17 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

- ***February 2011:***

NIA Opinion on French Government *'Decree regarding the annual mandatory reporting of nanoparticulate substances placed on the market' ('décret relatif à la déclaration annuelle des substances à l'état nanoparticulaire mises sur le marché')*

- ***February 2011:***

NIA Comment on *EFSA Draft Scientific Opinion* on ***Guidance on risk assessment concerning potential risks arising from applications of nanoscience and nanotechnologies to food and feed***

PART V: VCI

The German chemical industry is committed 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 – over the years - issued a 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:

- 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 nanosafety research (The German version was published in October 2011; an English translation is currently being prepared.)

18Follow this link for a full list of NIA Consultation Responses & Evidence: http://www.nanotechia.org/content/publications/consultation/

These documents have been discussed with the public as well as with national and European authorities, and were also communicated to the OECD Working Party on Manufactured Nanomaterials (WPMN). Updates of some documents are in preparation.

Information on developments related to exposure measurement and exposure mitigation

In 2011, a special focus was given on workplace safety – also as VCI contribution to SG 9 of the WPMN. VCI, the German Federal Institute of Occupational safety and health (BAuA), the German Social Accident Insurance Institution for the Raw Materials and Chemical Industry (BG RCI), and the Federal Institute for Occupational Safety and Health (IFA) of the German Social Accident Insurance (DGUV) jointly evaluated actual experiences and took them as the basis for a joint strategy paper on a "Tiered Approach to an Exposure Measurement and Assessment of Nanoscale Aerosols Released from Engineered Nanomaterials in Workplace Operations". This information aimed at deriving best practices for exposition measurement and is currently communicated at scientific and political level.

In order to enable a better overview of existing findings on the handling and use of nanomaterials and wishing to share this knowledge with all stakeholders in science, industry and public bodies, the VCI also supported a scientific review article by the Institute of Energy and Environmental Technology (IUTA) at Duisburg University and the Institute of Process Engineering and Environmental Technology at TU Dresden. The article "Nanoparticle Exposure at Nanotechnology Workplaces" came out in August 2011 in the journal "Particle & Fibre Toxicology".

In 2006, VCI and the German Federal Institute of Occupational safety and health (BAuA) had conducted a first survey on how industry is handling nanomaterials at the workplace. This survey is currently, with VCI's support and with an extended scope, repeated by BAuA. First results are planned to be communicated by end of 2011.

Further VCI activities

VCI was engaged in the political discussion on the EU definition of nanomaterials and is currently supportive in the establishment of suitable analytical methods for this definition.

Together with the German Society for Chemical Engineering and Biotechnology (DECHEMA) VCI has published in October 2011 a brochure with the results of 10 years of nanomaterials safety research and on potential releases of nanoparticles from end products.

The German chemical industry has been deeply engaged in the second phase of the German *"Nano-Dialog"* initiated by the German government.

Furthermore the German chemical industry is engaged in the process of implementation REACH, e.g. in the RIPoNs, and in sector specific legislation addressing nanomaterials.

More information is available at www.vci.de

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 Standardization Technical Committee (ISO/TC) 229 - Nanotechnologies - was established in June 2005 with a UK secretariat and chair. It has held twelve meetings to date, with the most recent being in St Petersburg, Russia, in May 2011. The next meeting will be in November 2011 in Johannesburg, South Africa. The committee currently has 44 members - 34 "P" and 10 "O". Fifteen documents have been published to date – six terminology (WG1), four measurement and characterization (WG2), and five health, safety and environment (WG3) – with a further 29 documents currently under development – see http://www.iso.org/iso/standards_development/technical_committees/list_of_iso_technical_committees/iso_technical_committee.htm?commid=381983 .

The publication most relevant to the WPMN since its last meeting, in March 2011, is ISO/TR 13121:2011 - Nanotechnologies -- Nanomaterial risk evaluation. Two documents that will be of interest to members of the WPMN are currently under ballot within the committee: DTS 12901-1 Nanotechnologies - Guidelines for occupational risk management applied to engineered nanomaterials —Part 1: Principles and approaches, with a closing date 12th January 2012; and DTR 13329 Nanotechnologies - Safety Data Sheet (SDS) preparation for manufactured nanomaterials, with a closing date 26th January 2012. Members of the WPMN who wish to comment on either or both of these documents are encouraged to do so either through their national member body of ISO/TC 229 or through the liaison between the WPMN and ISO/TC 229.

ISO/TC 229 recently completed its second survey of members needs, the results of which will be presented at the next meeting of the committee, 14th to 18th November in South Africa. This survey will help to inform the committee's business plan and standards roadmap for the next three years.

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. The relationship between TC/ 229 and the WPMN is governed by the terms of the 'ISO/TC 229 – OECD WPMN coordination paper – version 2, February 2009'.

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

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

- a national body;
- the secretariat of that technical committee or subcommittee;
- another technical committee or subcommittee;

- an organization in liaison;
- the technical management board or one of its advisory groups;
- the Chief Executive Officer.

Acceptance requires

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

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

ISO standards can support regulation and legislation by, for example, providing validated and verifiable measurement methods for demonstrating compliance with regulatory requirements. However, whilst TC 229 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.

Further details about 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 about ISO at http://www.iso.org

THE UNITED NATIONS INSTITUTE FOR TRAINING AND RESEARCH (UNITAR)

The mandate for UNITAR to work alongside OECD in this specific area of international awareness raising comes from resolution II/4 of the second session of the International Conference on Chemicals Management in 2009, as well as a 2009 OECD Joint meeting request to undertake awareness raising and other related activities in developing countries regarding the potential risks and benefits of nano.

7. 1. Second round of regional nano workshops

As you know, a first round of regional nano awareness raising workshops took place in 2009 and 2010, and I believe my predecessor, Craig Boljkovac, whom many of you know, already reported to you on this first round of workshops in 2010.

Subsequently, during this year, UNITAR organized a second round of regional workshops, with the support of Switzerland including:

- Africa: Nairobi, 5 and 6 April 2011; 86 participants;
- Latin America and the Caribbean: Panama City, 31 May and 1 June 2011; 55 participants;
- Central and Eastern Europe: Lodz, 27 and 28 June 2011; 26 participants;

- Asia and the Pacific: Beijing, 6 and 7 September 2011; 66 participants.

All of these workshops were followed by SAICM regional meetings.

The outcomes of this second round of regional workshops included:

- discussion among Governments and key stakeholders on the inclusion of nanotechnology and manufactured nanomaterials in the Global Plan of Action of SAICM,

- consideration of regional perspectives in preparation for further discussions on nanotechnology at the first meeting of the Open-ended Working Group of SAICM and the third session of the International Conference on Chemicals Management; and

- additional and more detailed input provided by participants on nanotechnology use and initiatives in their countries and organizations.

The workshop materials are available on the UNITAR website. UNITAR's view, and I believe the view of many of the countries and stakeholders in the regions, was that these regional nano workshops provided a major service in terms of providing information about nano to these regions that many not have otherwise been so easily accessible, as well as providing these regions an opportunity to consider their views regarding nano, in particular in relation to the SAICM process. UNITAR again would like to thank all the donors and supporters of both rounds of the regional workshops for making this possible.

8. 2. Pilot projects

The WPMN has also been informed previously that UNITAR, with the support of Switzerland, is initiating national pilot projects on nano during 2011. The purpose of these pilot projects is to assist three non-OECD countries to develop programmatic capacities to tackle nanotechnology issues at the national level. UNITAR is developing guidance and training materials to ensure that the participating countries are aware of the current state of the nanotechnology field and possible actions that can be taken at the national level. To initiate the development of guidance, a draft outline of a national nanotechnology profile, or assessment, was developed and presented for comment at the regional workshops. The 3 countries involved are: Thailand, Nigeria, and (subject to confirmation) Uruguay. Lessons learned from these projects will be presented to the International Conference on Chemicals Management at its third session, in September 2012.

9. 3. SAICM-related activities

As most of you know, nano is considered as an ''emerging issue'' in the SAICM process. ICCM-2 of SAICM requested that a report on nano be developed by the SAICM Secretariat, and this report was recently made available at the first meeting of SAICM's Open Ended Working Group, in Belgrade, Serbia, held 15-18 November 2011.

In addition, at the Belgrade meeting, UNITAR and the OECD presented a document regarding progress made in regards to nano, in particular focusing on information regarding the work to contribute to the implementation of ICCM-2 resolution II/4 E, such as the two rounds of regional workshops, progress related to country level activities, and progress related to the programme on the environmental, health and safety considerations of manufactured nanomaterials. Both of these reports are available on the SAICM secretariat website.

All SAICM-related discussions have also been shared with our partners in the Inter-Organization Programme for the Sound Management of Chemicals (IOMC).

10. 4. 2010 survey results

The WPMN will recall that the issue of a questionnaire on nanomaterials was discussed at your seventh meeting. UNITAR invited interested delegations to respond to the questionnaire to identify information on legislation and national governance, as well as experience in raising awareness. The purpose of the questionnaire was to gather relevant information that can be shared with developing countries and countries with economies in transition. The questionnaires were circulated to countries in July 2010 and the responses were compiled afterwards. A total of 12 OECD and non-OECD countries replied to the questionnaire, and a summary of the results has been recently posted on the UNITAR website: www.unitar.org/cwm/nano/pilot-projects (towards bottom of page) or http://www.unitar.org/cwm/sites/unitar.org.cwm/files/nano%20survey%20summary.pdf