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

Series on the Safety of Manufactured Nanomaterials
No. 26

CURRENT DEVELOPMENTS/ACTIVITIES ON THE SAFETY OF MANUFACTURED NANOMATERIALS

Tour de Table at the 7th Meeting of the Working Party on Manufactured Nanomaterials

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Paris, France 7-9 July 2010

IOMC

INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

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

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

Also published in the Series of Safety of Manufactured Nanomaterials:

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

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

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

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

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ABOUT THE OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 33 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 ten different series: **Testing and Assessment**; **Good Laboratory Practice and Compliance Monitoring**; **Pesticides and Biocides**; **Risk Management**; **Harmonisation of Regulatory Oversight in Biotechnology**; **Safety of Novel Foods and Feeds; Chemical Accidents; Pollutant Release and Transfer Registers; Emission Scenario Documents;** and **Safety of Manufactured Nanomaterials.** More information about the Environment, Health and Safety Programme and EHS publications is available on the OECD's World Wide Web site (www.oecd.org/ehs/).

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

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

This publication is available electronically, at no charge.

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

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FOREWORD

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

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

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

The Working Party endorsed this document at its 7th Meeting in July 2010. This document is published under the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology of the OECD.

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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
- Co-operation on Environmentally Sustainable Use of Nanotechnology

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 6th meeting held 28-30 October 2009 in Paris, France. This document compiles information provided by member countries and other delegations on current developments on the safety of manufactured nanomaterials (section I) in their countries or organisations. There are also written reports on current activities related to nanotechnologies/ nanomaterials in other International Organisations including the International Organisation for Standardisation, the Food and Agriculture Organisation of the United Nations and the World Health Organisation (section II).

This is intended to provide delegations and other stakeholders with a "snapshot" of information on activities related to manufactured nanomaterials, as well as other activities on nanotechnologies, at the national and international level. This "snapshot" was current at the time of the 7th meeting of the WPMN (July 2010).

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 3 (the Tour de Table) is to give each delegation the opportunity to describe recent or planned national initiatives and/or events related to the safety of nanomaterials. This will facilitate the implementation of the projects of the WPMN by allowing delegations to share their experiences and preoccupations with respect to safety, and will identify opportunities for future co-operation and co-ordination.

At the previous meetings of the WPMN, delegations provided written submissions in advance of the meeting and highlighted (in their interventions) points that were not already included in their written submissions. The WPMN agreed that these reports were informative and recommended that they are made available publicly. These reports have been declassified by the Chemicals Committee and are publicly available as publications in the series on *the Safety of Manufactured Nanomaterials* [ENV/JM/MONO(2010)4].

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 6th meeting of the WPMN (October 2009) might wish to simply review their previous submission and update it as needed. Information submitted could be supported by any supplementary information, or supporting documentation, especially if it was available in electronic form including links to website.

1) Firstly, please provide a list of the latest developments in your country and organisation since the 6th meeting of the WPMN (October 2009) as highlights to appear at the top of your document:

Highlight of developments since the 6th meeting of the WPMN

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

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

Work completed, underway or planned

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

Additional Information

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

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

RESPONSES FROM DELEGATIONS

AUSTRALIA

Highlight of developments since the 6th meeting of the WPMN

- Following public consultation on a proposal for regulatory reform of industrial nanomaterials, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is finalising its reform package taking into account stakeholder views. Implementation will be commenced in 2010 and is expected to be undertaken in a staged manner.
- Safe Work Australia is implementing a Nanotechnology Work Health and Safety Program. Two research reports were published in November 2009. Safe Work Australia has also commissioned NICNAS to undertake a health hazard assessment of carbon nanotubes.
- The Australian Pesticides and Veterinary Medicines Authority (APVMA) conducted workshops to consider the toxicological and environmental data requirements for ag-vet chemical products.
- Completion of a review by the Department of the Environment, Water, Heritage and the Arts (DEHWA) of the scientific literature relevant to the environmental fate of manufactured nanomaterials.

Work completed, underway or planned

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

The Australian government regulator for industrial nanomaterials, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) held public consultations on a discussion paper for a *Proposal for Regulatory Reform of Industrial Nanomaterials*. The proposed package was developed in consultation with NICNAS's external Nanotechnology Advisory Group (NAG). NICNAS has established this group to advise on nanotechnology related issues. The committee composes of representatives from industry, community and academic sectors. In developing the strategy, NICNAS reviewed its existing regulatory framework and administrative processes in light of the unique challenges posed by these novel materials. The resulting proposal provides for the use of best available scientific evidence in NICNAS's risk assessments and the ability to review decisions as new information becomes available. Under the proposal, the health and environmental impacts of nanomaterials will be assessed by NICNAS pre-market on a case-by-case basis to ensure that appropriate risk assessments are conducted and controls recommended when required.

Overall the proposed reforms aim to ensure safe and sustainable use of these substances through appropriate regulatory oversight, industry cooperation and community confidence the strategy will be supported by comprehensive communication/outreach activities. (See *6. Information on any public/ stakeholder consultation* for more information on this consultation activity.)

NICNAS, with further consultation with the NAG will further refine its regulatory strategy taking into account stakeholder feedback. NICNAS intends to publish these submissions with responses to issues

raised in the near future. In general this feedback indicates strong support for the regulatory proposal. The final reform package is to be implemented in stages and NICNAS will be conducting further stakeholder consultation as required, and undertaking the necessary regulatory impact assessment, prior to implementation.

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is receiving an increasing number of enquiries regarding agvet nanoproducts from the agvet chemical industry. The majority of products are in still in R&D and, to date, only one nanoproduct has been approved for marketing. In order to track nanoproducts under evaluation or approved by the APVMA, a modified application form will be routinely used as from 1 July 2010. It will be complemented by an electronic search facility for nanoscaled product applications and approvals, to be commissioned at the same time.

Safe Work Australia has commissioned NICNAS to undertake a formal health hazard assessment of carbon nanotubes for health hazard classification, and to provide effective guidance for organisations, has commissioned CSIRO to develop a guide on safe handling and disposal for carbon nanotubes.

Safe Work Australia is also currently in the process of revising the Code of Practice for Safety Data Sheets (SDS). In the section which lists physicochemical parameters for which information on chemicals should be provided, Safe Work Australia is proposing the addition of a number of non-mandatory parameters, specifically relevant to engineered nanomaterials (but also relevant for some other chemicals). This document has been available for public comment. A paper on this matter was presented to the Sub-Committee of Experts on the Globally Harmonised System of Classification and Labelling of Chemicals (UNSCEGHS) meeting in December 2009. Safe Work Australia is also considering the addition of a section on engineered nanomaterials to the Approved Criteria for the Classification of Hazardous Chemicals.

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

2. Developments related to voluntary or stewardship schemes

No developments since the 6th meeting of the WPMN.

3. Information on any risk assessment decisions

4. Information on any developments related to good practice documents

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

NT-001 is also represented on the ISO TC229 HSE Working Group, which coordinates the development of international HSE related nanotechnology standards, and on 4 project groups:

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

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

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

NICNAS is progressing its comprehensive technical 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;
- reviewing data requirements for NICNAS assessments and benchmarking risk assessment methodology for nanomaterials that meet international best practice;
- leveraging linkages between national and international agencies that are working in the same area to maximise efficiency of research;
- continue to lead the OECD WPMN project on a database of environment, health and safety (EHS) research into manufactured nanomaterials;
- continuing participation in ISO TC229, through the Standards Australia Nanotechnology Committee (NT-001) to facilitate reliable characterisation and testing of nanomaterials; and
- developing information products for use by industry and community on nanomaterials.

An Australian consortium is participating in the Sponsorship Programme for the Safety Testing Manufactured Nanomaterials. Australia is co-sponsoring testing of cerium oxide, zinc oxide and silver nano-particles. The Commonwealth Scientific and Industrial Research Organisation (CSIRO) lead this consortium with the National Measurement Institute and the Royal Melbourne Institute for Technology.

Since the 6th meeting of the WPMN, the National Measurement Institute has received and distributed test materials to participating research organisations, and has also distributed standard samples of latex and gold nanoparticles for qualification, verification and calibration of instruments. The Australian government recently provided funds to the Consortium, part of which enabled CSIRO to host a workshop in May 2010 to support interactions and knowledge-sharing amongst active members of the Australian Consortium and Australian regulators.

An inter-Agency model of engagement for developing data requirements for agvet nanoproducts has been rolled out by the Australian Pesticides and Veterinary Medicines Authority (APVMA). As a first step, workshops have been conducted to consider the toxicological and environmental data requirements for agvet chemical products. The workshops considered specific nanoproducts and how their properties might potentially impact on human health or the environment; and the need for additional studies to address specific concerns.

In the longer term, it is proposed that checklists will be developed containing issues that may need to be addressed. These checklists will form one component to allow for a tiered approach to the risk assessment of agvet nanoproducts.

The APVMA has also appointed a Science Fellow in the field of nanoscience to complement its existing Science Fellows Program. Capacity building through the provision of staff training in nanotechnology-related areas was also enhanced through the establishment of a Nanotechnology Awareness Forum in early 2010.

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 2008 project grant round, for funding commencing in 2010. From this funding round, 20 projects, totaling over $8.7 million over the life of the projects, will be funded. Research supported by NHMRC is aims to increase knowledge of the effects, potential applications and hazards of nanomaterials, and may complement and inform regulatory regimes. More information about research grants and policies is available at: http://www.nhmrc.gov.au/grants/apply/research.htm Nanotechnology and health was also identified as a strategic plan issue under the 2009 project grant round, for funding commencing in 2011. Applications opened on 8 December 2009 and closed on 17 March 2010.

The Department of the Environment, Water, Heritage and the Arts (DEHWA) has completed a technical review on the environmental fate of manufactured nanomaterials to inform its risk assessment methodologies and provide scientific advice to regulatory agencies. The review is available on the following website: http://www.environment.gov.au/settlements/biotechnology/publications/index.html.

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

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

Eleven projects have been commissioned by Safe Work Australia to progress work in these key areas. Two research reports were published in November 2009:

- *Engineered Nanomaterials: A review of the toxicology and health hazards*
- *Engineered Nanomaterials: Evidence on the effectiveness of workplace controls to prevent exposure*

Further research reports will shortly be published.

The work programme is supported by two reference groups:

- Nanotechnology OHS 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 OHS Measurement Reference Group. The role of the group is to help ensure the safe development and use of nanotechnology in Australian workplaces, by facilitating the development of suitable methods for assessing emissions of nanoparticles, and exposure levels in workplaces. Members are nanoparticle measurement experts, occupational hygienists, nanotechnology risk managers and work health and safety regulators.

6. Information on any public/ stakeholder consultation

In November 2009, NICNAS commenced a public consultation on its regulatory reform proposal for industrial nanomaterials that ran until 12 February 2010. Face to face meetings were held and NICNAS invited comment from all stakeholders in the form of written submissions. A feedback questionnaire and a business impact survey were developed to facilitate written feedback. NICNAS will be consulting with its Nanotechnology Advisory Group on the results of the consultation and considering comments in development of the final reform package.

In addition to consultation activity, NICNAS continues to engage with stakeholders on industrial nanomaterials through periodically updated website, newsletter and fact sheets. NICNAS is preparing, for publication, the outcomes of a 2nd voluntary Call for Information that took place in 2008 (closed 23 January 2009). The voluntary call aimed to gauge the extent of nanomaterial introduction into Australia and to ascertain what categories of physicochemical and toxicological data are held on each nanomaterial.

The APVMA continues to provide guidance to the Industry in relation to the registration of nanoproducts. In early 2010, a presentation entitled 'Developing an understanding of nanotoxicology' was delivered at the APVMA Science Fellows Symposium. The presentation served to balance the benefits and potential risks of nanoproducts likely to be used in the agricultural and animal health sectors. APVMA has published three papers relating to nanotechnology on its website, including the APVMA strategies for improving the regulation of agvet chemicals and chemical products containing nanomaterials.

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

AUSTRIA

Highlight of developments since the 6th meeting of the WPMN

➢ The **Austrian Nanotechnology Action Plan** was adopted on 2nd March 2010 by the Austrian government (English and German version can be downloaded on http://www.umweltnet.at/article/articleview/81646/1/7033/) The action plan was lead-managed by the Federal Ministry of Agriculture, Forestry, Environment and Water Management (BMLFUW) and elaborated on basis of a broad stakeholder involvement (five ministries, NGOs, Environment Agency Austria, Chamber of Commerce, Companies representatives, research institutions….). A public consultation was launched for 3 weeks in autumn 2009. The action plan includes about 50 measures which will be implemented by Austrian stakeholders on national, EU and international level till 2012.

The measures focus; 1) on making use of potential benefits of nanotechnology (such as for Austrian SMEs or environmental technologies); 2) on risk/safety aspects (such as bundling of resources in field of

EHS / EHS-programme including workplace safety); and 3) on increasing cooperation and communication between stakeholders including providing specific information for targeted groups (workers, public…).

- With regard to workplace safety it can especially mentioned that the central labour inspectorate (part of the Federal Ministry of Labour, Social Affairs and Consumer Protection) mandated a project investigating Austrian **nano-workplaces**. The aim was to get a preliminary overview on different **uses and risk management applied:** A final report in German can be found under http://www.arbeitsinspektion.gv.at/AI/Arbeitsstoffe/nano/default.htm. A new project was recently started to **develop the guidance for preliminary risk management**. It will follow the precautionary principle and ensure safe and healthy workplaces regarding nanomaterials. The guidance is targeting small and medium enterprises and shall support the central labour inspectorate in advising enterprises dealing with nanomaterials. The guidance shall be available in early autumn 2010.

Work completed, underway or planned

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

No national Austrian laws/regulations are planned at the time being. The Austrian Nanotechnology Action plan, however, includes measures/guidelines how to contribute to EHS-developments on EU and international level. This includes recommendations for stakeholders which line to take on specific aspects such as labelling, register, definitions, safety data sheet, etc. as well as recommendations how to contribute to the closing of gaps in the field of hazard and risk.

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.

A **conference** on **"Approaches to risk assessment and risk management of nanotechnologies"** will take place on September 23th in Vienna at the premises of the Austrian Academy of Sciences. The conference is dedicated to explore the room for manoeuvre in a situation characterized by a need for action given insufficient knowledge.(See also http://nanotrust.ac.at/nano10/) The conference is free of charge but there is a limited number of anticipants. Please, register via e-mail at: tamail@oeaw.ac.at.

2. Developments related to voluntary or stewardship schemes

No information provided.

3. Information on any risk assessment decisions

No information provided.

4. Information on any developments related to good practice documents

No information provided.

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

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

Toxicological Investigation of Nanoparticles - Effects On Human Cells" by Seibersdorf Labor GmbH, Toxicology (a subsidiary of the AIT Austrian Institute of Technology, formerly known as Austrian Research Centres, member of EURO-NanoTOX). The aim was the establishment of an in-vitro test system to reveal the potential risk to human health of **nanoparticles at the workplace**.

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

See also **EURO-NanoTOX** in section 6.

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

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

A brochure for **"Assessment of Toxicological Effects by in-vitro and in-vivo Assays and open flow microperfusion"** was released by the national platform EURO-NanoTOX, which is co-ordinated by the BioNanoNet Forschungsgesellschaft mbH. The expertise-folder is revised each year. For the actual version see: http://www.euro-nanotox.at/images/stories/folder_euronanotox_webversion.pdf

At the Centre for Medical Research of Medical University of Graz, **nanotoxicology studies** regarding **SiO2** and **polystyrene** are performed (contact: Eleonore Fröhlich, EURO-NanoTOX).

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

Together with the Department of **Freshwater Ecology**, the Department for Environmental Geosciences University Vienna conducted a research project dealing with the behaviour, fate and effects of different TiO2 nanoparticles in the aquatic environment.

7. Information on any public/ stakeholder consultation

After a public consultation phase, in which the Austrian Nanotechnology Action Plan was published on several websites, the National Action Plan was revised by including comments of this consultation phase (see Highlights).

An Austrian **Nanotechnology Information Platform (NIP)** is currently built up to discuss and focus on how to deal with information & communication needs of the public.

The Austrian Umweltbundesamt in co-operation with the quality radio station Radio Österreich 1 launched the "Initiative **Risiko:dialog".** The aim is to open dialogues on risk topics – with potential effects on human health, environment and society – with stakeholders and the public in an early stage. One of the started dialogue processes concerns nanotechnology and potential risks. Several partners from ministries, agencies, and research institutions were included.

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

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

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. Thus, the focus is on investigating the very (individual and collective) processes through which stakeholders such as scientists, politicians but also members of a wider public construct and evaluate future possibilities as well as possible futures of nanotechnologies (see: http://sciencestudies.univie.ac.at/en/research/making-futures-present-nano-and-society/).

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

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.

In the project **NanoRate** risks and benefits of nanoproducts were assessed: Partners in this project are IFZ - Inter-University Research Centre for Technology, Work and Culture, Austrian Consumer Association, Österreichisches Ökologie Institute and Joanneum Research (contact: Manfred Klade, IFZ). It is funded by the Jubiläumsfonds of the Austrian Nationalbank and the Federal Ministry of Agriculture, Forestry, Environment and Water Management (BMLFUW). For download of final report see: http://www.umweltnet.at/article/articleview/83094/1/7033

A scientific study regarding "**Sustainability assessment of nano-products**" is conducted in cooperation of the Environment Agency Austria and the University of Applied Sciences, Technikum Wien (contact: Jana Bolldorf), see: http://www.umweltbundesamt.at/nachhaltigkeitsbewertung

CANADA

Highlight of Developments since the 6th Meeting of the WPMN

The following activities have taken place since the 6th meeting of the OECD Working Party on Manufactured Nanomaterials in October 2009:

- The release and adoption of the Interim Policy Statement on Canada's Working Definition for Nanomaterials. The Interim Policy is effective immediately and comments on this policy statement are being collected so that it may be updated as necessary. See Section 1 and 6 for more details.

- A Workshop on the Human and Environmental Risk Assessment of Nanomaterials was convened by Canada on March 24-26, 2010. The Workshop provided an open forum for detailed dialogue on nanomaterials among Canadian and international science evaluators, research scientists and regulators. See Section 1.

- The 4th Tri-National Workshop on Standards for Nanotechnology was held in Ottawa, Canada on February 3rd and 4th, 2010. Lectures included a variety of research and development topics focusing on measurement and characterisation methods supporting toxicological research, health, safety and the environment consistent with the ISO/TC 229 Task Group "Measurands for Toxicology Research and Development". See section 5.

Work completed, underway or planned

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

Federal government actions

A. Canada has announced the adoption of the Interim Policy Statement on Canada's Working Definition for Nanomaterials and it's public posting (http://www.hc-sc.gc.ca/sr-sr/consult/_2010/nanomater/draft-ebauche-eng.php). The Interim Policy is now in effect and comments on this policy statement are being accepted until August 31st, 2010.

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

In preparing the Interim Policy Statement on Canada's Working Definition for Nanomaterials, Canada sought the informal feedback of some international stakeholders, industry trade groups and standards associations.

B. A Workshop on the Human and Environmental Risk Assessment of Nanomaterials was convened by Canada from March 24-26, 2010. This workshop provided an open forum for detailed dialogue on nanomaterials among science evaluators, research scientists and regulators. The Workshop was attended by experts from Australia, Canada, Europe, Korea and the United States of America.

The Workshop was designed to be complementary to the work of the OECD Working Party on Manufactured Nanomaterials (WPMN) and followed on from the recent Workshop on Risk Assessment in a Regulatory Context that took place September 16-18, 2009 in Washington DC.

Workshop participants agreed that scientific knowledge on the properties, environmental fate, behaviour and toxicity of nanomaterials is advancing, however, currently is still inadequate to allow general trends/structure-activity relationships to be made. Nanomaterials should continue to be assessed on a case-by-case basis, efforts should be made to minimize exposures and releases to the extent possible, and jurisdictions should continue to cooperate on research projects aimed at the development of scientific data on nanomaterials. Workshop participants emphasised that exchanges of information and views on nanomaterials at this time are especially helpful for promoting best practices in risk assessment and risk management.

C. Canadian Standards Association (CSA) Standards has formed a Technical Committee on Nanotechnologies - Occupational Health and Safety. Initial activities include working to adopt the published international ISO Technical Report, ISO/TR 12885:2008 on *Health & Safety Practices in Occupational Settings relevant to Nanotechnologies,* as well as to produce a national standard to provide guidance for workers using nanomaterials in the workplace. The Committee's inaugural meeting was held on May 7th, 2009 and work is continuing in subsequent meetings through 2010.

D. Canada is the lead for the ISO TC/229 WG1 Task Group on Nomenclature. This Task Group includes active representation from the United States, Japan, Germany, France, Australia, and includes regulators, industry, and academia, as well as observers from the Chemical Abstracts Service and 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. In July 2009 the Task Group completed the report: "Considerations for Developing a Nomenclature Model for Nano-Objects". Canada has now welcomed United States in co-chairing this activity, and is continuing development of a framework for nomenclature models for nano-objects. Canada has pursued and secured a liaison between ISO/TC 229 and IUPAC to further this nomenclature work.

E. Canada has completed a report titled, *Nanotechnologies — Terminology – Initial framework model for core concepts*, under ISO TC/229 JWG1. Also, Canada has led a project (JWG1-PG5) to develop definitions for core terms resulting from the taxonomy system. ISO 80004-1 *Nanotechnologies — Vocabulary — Part 1: Core terms* has now been approved after ISO Draft Technical Specification balloting.

F. Under the International Cooperation on Cosmetic Regulation (ICCR), Canada is participating in the international ad hoc working group on nanomaterials in cosmetics (ICCR Nano WG) that was initiated in December 2009. This working group is composed of regulators and industry representatives to identify specific criteria for nanomaterials in cosmetics. Completion of recommended criteria for ICCR acceptance is expected in July 2010. The ICCR Nano WG will then commence work on endpoints for risk assessment relevant to cosmetics safety (starting late 2010).

2. Developments related to voluntary or stewardship schemes

No information provided.

3. Information on any Risk Assessment Decisions

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

- *Industrial or commercial chemicals:* To date, a total of 8 nanomaterials and a total of 17 substances which have the potential to be on the nanoscale have been notified and assessed under *Canadian Environmental Protection Act, 1999* (CEPA 1999). The Significant New Activity Provisions of CEPA 1999 have been used for 23 substances to require the submission of additional information and assessment prior to use of a substance at the nanoscale or in other nanoscale applications.

- *Pharmaceuticals:* A number of nanotechnology based products in the areas of medical devices and drugs are currently under review by Canada, under the current regulations and policies.

- *Pesticide applications:* Some inquiries have been made, but no notifications have been submitted.

- *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 Workplace Hazardous Materials Information System (WHMIS) is implemented through coordinated federal, provincial and territorial (FPT) legislation. Supplier labeling and Material Safety Data Sheet (MSDS) requirements are set out under the Hazardous Products Act (HPA) and associated Controlled Products Regulations. The compliance and enforcement programme for the WHMIS supplier labelling and MSDS requirements of the HPA is conducted by the 13 FPT Occupational Safety and Health (OH&S) agencies in Canada in conjunction with the WHMIS employer requirements established by these 13 OH&S agencies. To ensure Canadian workers are protected from possible hazards specific to manufactured nanomaterials, Canada's National Office of WHMIS is investigating the possible need to: (i) Implement changes to WHMIS hazard criteria to address manufactured nanomaterials, and (ii) Implement changes to WHMIS disclosure requirements on MSDSs;

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

C. CSA Standards is adapting the published international ISO Technical Report, ISO/TR 12885:2008 on Health & Safety Practices in Occupational Settings relevant to Nanotechnologies for use in Canada, through its accredited standards development process, to produce a guideline standard for workers using nanomaterials in the workplace. This work continues in 2010. Labour and government interests at the Sep. 2009 CSA Nano-Occupational Health and Safety Technical Committee meeting stressed the importance of, and agreed to pursue, within this same committee, the development of plain-language means for education on these guidelines to workers.

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

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

Scientific research

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

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

Funding and partnering opportunities are currently being considered by Canada to a) develop in-house analytical chemistry infrastructure for the measurement of nanoparticles in food; b) to assess the health effects of orally ingested nanomaterials for addressing exposure through food contamination from packaging materials, or through nanostructures in food additives; c) to evaluate the effects of nanomaterials in food on nutrient bioavailability, functionality and efficacy for addressing the regulation of nanotech products designed.

Canada is also currently engaged in both in-house and collaborative research projects involving a range of different nanomaterials (e.g., nanoparticulates of zero-valent iron, gold, silver, TiO2, also carbon black, single walled carbon nanotubes, and C_{60} fullerenes). Testing includes pulmonary and cardiovascular injury; reproductive, developmental and transgenerational effects; exposure and tissue penetration, interactive effects with microorganisms, immune 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.

Canada has hosted various workshops pertaining to challenges in nanotechnology, such as the 4th Tri-National Workshop on Standards for Nanotechnology (Feb, 2010), which addressed measurement and characterisation in support of toxicology R&D for Human Health and Environment., focusing on identification of measurands for toxicological research on nano-objects, and the measurement science supporting accurate measurement and characterisation. This workshop supported the Canadian contribution to the North American Platform Program (NAPP) in Metrology in Support of Nanotechnology, strengthening partnerships between Canada, the United States and Mexico. Information on the 4th Tri-National Workshop on Standards for Nanotechnology is available at: https://www.nrc-cnrc.gc.ca/eng/events/inms/2010/02/03/tri-national-workshop.html.

Moreover, Canada also chaired the International Bureau of Weights and Measures (BIPM) Workshop on International Needs for Metrology at the Nanoscale in February 2010. The Workshop brought together

representatives from national metrology institutes with other stakeholders involved in nanomaterials to address: "What activities are required to establish an effective international infrastructure for metrology at the nanoscale?". The Workshop successfully gathered 105 participants from 47 different institutes or companies. The agenda and complete report can be found at http://www.bipm.org/en/events/nanoscale/

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

In January of 2008, Canada co-sponsored the Canadian Workshop on Multidisciplinary Research on Nanotechnology: Gaps, Opportunities and Priorities, in collaboration with the other two federal research funding agencies. The summary report of this workshop can be found at (http://www.cihr.ca/e/38469.html).

Policy research

Canada, in collaboration with the OECD Secretariat, is leading the next phase of OECD WPN work on developing indicators and statistics for nanotechnology, one part of which is expected to include testing of a model company questionnaire.

6. Information on any public/ stakeholder consultation

Canada has announced the adoption of the Interim Policy Statement on Canada's Working Definition for Nanomaterials and its publication. The Interim Policy is effective immediately and comments on this policy statement are being collected so that it may be updated as necessary.

In preparing the Interim Policy Statement on Canada's Working Definition for Nanomaterials, Canada sought the informal feedback of some international stakeholders, industry trade groups and standards associations. A link to the publication is attached:

http://www.hc-sc.gc.ca/sr-sr/consult/_2010/nanomater/draft-ebauche-eng.php

CZECH REPUBLIC

Highlights of developments since the 6th meeting of the WPMN

- The activities addressing health, safety, and environmental aspects of manufactured nanomaterials were mainly individual presentations at conferences, seminars, and short courses. No systematic activities and programmes at a governmental, NGO, academic level or in private sector have been established or performed.
- The awareness of public health authorities towards growing use of nanomaterials and the associated public health risks has been enhanced through education in seminars, short courses and lectures.

- Large number of research projects on nanomaterials and nanotechnologies has been funded in the Czech Republic, however, only few individual projects (not listed here) address predominantly health, safety, and environmental aspects of nanomaterials.
- A conference NanoRisk as a activity of the 7FP´s project FramingNano was held on March 2, 2010 in Prague.

Work completed, underway or planned

1. National Regulatory developments

No developments

2. Developments related to voluntary or stewardship schemes

No developments

3. Information on any risk assessment decisions

No developments

4. Information on any developments related to good practice documents

No developments

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

No developments

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

There are individual research projects addressing or associated with the above topics, funded from public sources via national grant agencies, however, these are not projects on a governmental level.

7. Information on any public/stakeholder consultation

No information

FINLAND

Work completed, underway or planned

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

Finland is a member of the EU and accordingly follows the EU regulations. Finland is actively participating in REACH competent authority (CARACAL) subgroup on nanomaterials (CASG-nano) and

in the development of technical guidance how to apply the regulation on nanomaterials in RIP oNs 1, 2 and 3.

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

The various ministries have established an ad hoc discussion forum on nanotechnology in order to follow and participate in the national and international discussions.

2. Developments related to voluntary or stewardship schemes

No information provided.

3. Information on any risk assessment decisions

No information provided.

4. Information on any developments related to good practice documents

No information provided.

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

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

The University of Joensuu participates in the OECD Sponsorship Programme with aquatic ecotoxicology testing of nano-silver (and nano-iron) as 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.

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; and

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

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

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

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

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

- European Commission 6thFramework Programme project together with several institutes on " *Infalmmatory and genotoxic effects of engineered nanomaterials (NANOSH)"*
- 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 workplase air (NANODEVISE)"*. Here FIOH has the lead.
- European Commission 7thFramework project "Scale-up nanoparticles in modern papermaking
- Academy of Finland project *"Engineered nanoparticles: synthesis, characterisation, exposure and health hazards"*
- European Commission DG SANCO project " *Safety evaluation of manufactured nanomaterials by characterisation of their potential genotoxic hazard (NANOGENOTOX)*"
- European Network on the Health and Environmental Impact of Nanomaterials

7. Information on any public/ stakeholder consultationInformation 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.

No information provided.

FRANCE

Highlight of developments since the 6th meeting of the WPMN

Actions at the European level

- France has replied to the call for proposals issued by the European Commission regarding the joint action on “nanomaterials safety” referred to in the Commission Decision of 23 February 2009 on the

adoption of the Work Plan for 2009 for the implementation of the second programme of Community action in the field of health.

- This action, known as the "**Safety evaluation of manufactured nanomaterials by characterisation of their potential genotoxic hazard – NANOGENOTOX"** project**,** involves 17 bodies from 11 Member States (BE, BG, DE, DK, ES, FI, FR, IT, NL, PL, PT). A further two countries have registered as collaborating countries (to monitor actions): UK and IR. In France, 4 institutions have come forward as associated partners, namely: AFSSA, Institut Pasteur de Lille, INRS and CEA. The French Ministry of Health is a collaborating partner.

- This project, in association with the OECD programme of safety tests on a representative set of 14 commercially available nanomaterials, consists in a study of the genotoxicity of nanomaterials contained in consumer products:

  - titanium dioxide: 4 types of nanomaterial including one grade produced in France and 2 cosmetic grades used in cosmetic products;

  - silicon: 4 grades of which two are manufactured by Rhodia (one food grade and one grade used in the manufacture of tyres); and

  - carbon nanotubes: 7 grades representing all of the current market, consisting of one grade of single – walled nanotube and 6 grade of multi – walled nanotube (one of which is manufactured in France)

- The project has been divided into four successive segments:

  - Complete characterisation of the nanomaterials used;

  - In vitro tests of the 15 nanoparticles in two types of standard test recognised as being sensitive and specific tests using lines of human cells that are characteristic of the exposure route: 2 cell types for the pulmonary tract; 1 cell type for the gastro-intestinal tract, in which AFSSA is experienced (CaCo2); two reconstituted skin models. These tests will be monitored by means of a robustness test of the most promising tests by at least 12 of the 17 laboratories;

  - Toxicokinetic study in rats to identify the doses and sampling times that need to be respected in the in vivo genotoxicity test and to identify the target organs where nanoparticles are likely to accumulate; and

  - In vivo genotoxicity tests in rats to validate the sensitivity and specificity of the in vitro tests.

- The overall budget amounts to 6.2 million euros, of which the EU is being asked to contribute 46% (2.89 million euros).

- The French Ministry of Health has earmarked a budget of 250 000 euros a year for 3 years (2010-2013) to fund part of the expenditure by the French institutes involved in the programme.

Actions at the national level

- The Planning Act relating to implementation of the Grenelle Environment Round Table was adopted on 3 August 2009. Article 42 of this Act provides for the organisation of a national public debate, a

mandatory statement on nanomaterials marketed in France, information for the public and consumers, information for workers, and the design of a methodology for the assessment of risks and benefits.

- **National public debate on general options regarding nanotechnology development and regulation**

Organised by the Commission nationale du débat public (National Public Debate Commission), the debate was formally opened on 15 October in Strasbourg and was pursued in 16 other cities in France for a period of four months before closing on 23 February 2010. The following topics were discussed: European governance; life cycle of nanostructured products and protection of the environment; nanotechnologies and consumer protection; industrial processes/nanotechnologies and worker protection; nanoparticles and air pollution; nanotechnologies and textiles; nanotechnologies and competitiveness; IT and individual freedoms; nano-medicine; construction materials and multi-use applications; housing and energy; nanotechnology and food security; nanoparticles in the body; toxicity studies; domestic security and national defence; industrial R&D; convergence between nanotechnologies, biotechnologies, IT technologies and cognitive sciences (including neuroscience); protection of the environment; North-South sustainable development; new materials for capital goods and governance.

The documents produced as part of this debate (Owner's file (dossier du Maître d'Ouvrage) – six Ministries and one State Secretariat – Actors' contributions (Cahier d'acteur), etc.), as well as the summary record and conclusions of the debate can be consulted on the following web site: http://www.debatpublic-nano.org/.

The government is currently planning the actions it intends to pursue and the measures it plans to take in response to the conclusions of this debate.

- **Mandatory declaration of nanomaterials introduced on the market**

The Act setting out a national commitment to the environment, the so-called Grenelle II Act, was adopted on 29 June 2010. Article 185 of this Act relates to the prevention of risks to human health and the environment arising from exposure to nanoparticulate substances:

"Persons who manufacture, import or distribute nanoparticulate substances, in the form of nanoparticles or contained in unbounded mixtures, or materials designed to discharge such substances under normal or reasonably expected conditions of use, shall periodical declare to the administrative authority, for the purposes of traceability and public information, the identity, quantities and applications of these substances, as well as the identity of the professional users to whom they have been sold either for payment or free of charge."

"The information relating to the identity and applications of the substances thereby declared shall be made available to the public."

"Persons who manufacture, import or use the substances referred to in Article L. 523-1 shall provide, at the request of the administrative authority, all available information which relates to the hazards pertaining to such substances and the exposures they are likely to give rise to, or which is of use in assessing the risks to human health and the environment."

"Nanoparticulate substances that enter into the composition of health products (drugs for human and veterinary use), pesticide and biocide products, cosmetic products and food additives shall be subject to this mandatory declaration."

Work completed, underway or planned

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

2. Developments related to voluntary or stewardship schemes

3. Information on any risk assessment decisions

4. Information on any developments related to good practice documents

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

The National Institute for the Industrial Environment and Risks (**INERIS**) is pursuing activities in several areas of "nano" science and technology within the Institute's directorates: the directorate for chronic risks in experimental toxicology is working on ecotoxicology, metrology, soils, health risk and exposure assessment; the directorate for accidental risks is working on phenomenology and the assessment of accidental risks.

The overarching Nanoris project (assessment of risks relating to the manufacture and use of nanomaterials) has been divided into two parts: chronic risks (toxicological and ecotoxicological) and accidental risks.

Toxicology

The aim of the toxicological part of the Nanoris project (chronic risks) was to study the agglomeration state of a MWCNT (Elgrabli et al. 2007[4]) and the various aspects of its toxicity by identifying any possible inflammatory, fibrosing, respiratory or histopathological effects (Elgrabli et al. 2008a[5]) and at the same time by studying the biopersistence, pharmacokinetics and clearance of this MWCNT (Elgrabli et al. 2008b[6]).

As part of the Nanosafe II (co-financed by Nanoris) and RespiNTTox project, new non-invasive techniques have been developed to track the biodistribution of nanoparticles. The research findings were published in two papers (Al Faraj et al. 2009; Al Faraj et al. 2010)[7] and paved the way for the Nanofoetox

[4] Elgrabli, D., S. Abella-Gallart, O. Aguerre-Chariol, F. Robidel, F. Rogerieux, J. Boczkowski and G. Lacroix (2007). "Effect of BSA on carbon nanotube dispersion for in vivo and in vitro studies." Nanotoxicology 1(4): 266 - 278.

[5] Elgrabli, D., S. Abella-Gallart, F. Robidel, F. Rogerieux, J. Boczkowski and G. Lacroix (2008a). "Induction of apoptosis and absence of inflammation in rat lung after intratracheal instillation of multiwalled carbon nanotubes." Toxicology 253(1-3): 131-136

[6] Elgrabli, D., M. Floriani, S. Abella-Gallart, L. Meunier, C. Gamez, P. Delalain, F. Rogerieux, J. Boczkowski and G. Lacroix (2008b). "Biodistribution and clearance of instilled carbon nanotubes in rat lung." Part Fibre Toxicol. 5: 20

[7] Al Faraj, A., A. Bessaad, K. Cieslar, G. Lacroix, E. Canet-Soulas and Y. Cremillieux (2010). "Long-term follow-up of lung biodistribution and effect of instilled SWCNTs using multiscale imaging techniques." Nanotechnology. 21(17): 175103. Epub 2010 Apr 6.

Al Faraj, A., K. Cieslar, G. Lacroix, S. Gaillard, E. Canet-Soulas and Y. Creì millieux (2009). "In Vivo Imaging of Carbon Nanotube Biodistribution Using Magnetic Resonance Imaging." Nano Letters 9(3): 1023-1027.

project aimed at studying the movement of CNTs through the placental barrier and at determining any pulmonary, reprotoxicological and neurological effects on progeniture..

In collaboration with Certam, a second part of the RespiNTTox project consisted in a comparison of the induced effects of SWCNTs following exposure through intratracheal instillation and inhalation.

At the same time, a project aimed at evaluating the biodistribution and possible systemic toxic effects of TiO2 nanoparticles following treatment through intravenous injection was initiated. The data collected from experiments will provide a basis for a PBPK[8] model for the nanoparticles tested in order to predict their toxicodynamics.

The Expos project is investigating the impact of air-borne pollutants on asthmatic populations. This project is currently studying the induced effects of co-exposure to NO2 and/or nanoparticles in ovalbumen sensitized rats.

Lastly, in an effort to reduce animal experimentation, INERIS is developing, as part of the Nanotrans project, a model of the alveolar-capillary barrier (between the lung and the bloodstream) with the aim of carrying out in vitro studies of the capacity of nanoparticles to cross this biological barrier and to predict any possible inflammatory, oxidising, etc., effects in the lung.

Ecotoxicology

First series of tests over the period 2007/2009:

- aquatic and terrestrial ecotoxicity tests: inhibition of algae growth and inhibition of the mobility of daphnia; inhibition of the growth of plant life by TiO2 and Zn0 powders ; comparison with the toxic effects of macropowders;
- comparison of the solution preparation procedures (ultrasound and magnetic stirring) on the stability of nanoparticle suspensions;
- analyses using an electron microscope to assess the structure of particles after they have been dissolved in different test media.

Participation in the ANR (French National Research Agency) programme

- Nanosep: Bibliographic summary: Toxicity and ecotoxicity of titanium nanoparticles, carbon nanotubes, fullerenes, cerium and silicon nanoparticles.
- Nanofrezes: “Use of iron nanoparticles for the remediation of subsurface water”, determination of the ecotoxicity of coated Iron 0 nanoparticles use for the treatment of subsurface water.

Post Grenelle Environment Round Table project

- ImPECNano : “Environmental impact of nanomaterials: exposure through their life cycle and ecotoxicity.” Determination of the stability of cerium oxide nanoparticles in different media for aquatic ecotoxicity tests. Monitoring of stability and structural changes by microscopy. Determination of aquatic toxicity (single organisms and simplified food chain) of cerium oxide in nanoparticle form and comparison with cerium oxide macroparticles.

[8] PBPK = Physiologically-based pharmacokinetic modelling.

Metrology

Current detection and identification tools, based on analyses of mass or size, only provided a very partial response to this need and new, more discriminating approaches had to be developed.

1. In air and work environments

In this context, laser-induced plasma spectroscopy, which is independent of the matrix considered (solid, liquid, gas) and the type of products present (gas or particles), offered promising potential in that it allowed the presence of nanostructured materials to be detected through their chemical identification. Consequently, working in collaboration with many partners (CEA, CNRS, IVEA, etc.), we have developed, optimised and validated an operational instrument whose detection thresholds have been quantified for different mineral or metallic nanoparticles. These results, which were used as a basis for a patent application and several papers, have thus demonstrated the relevance of this technique as a means of monitoring air which particles or nanoparticles are present by providing specific results regarding the nature of each type of particle present in concentrations ranging from a few µg/m3 to several hundred mg/m3.Furthermore, we have assessed this technique for use in in-situ monitoring of a silicon carbide nanoparticle manufacturing process, the aim being to study the feasibility of using the technique to detect and quantify fluctuations in the stoichiometry of the nanopowders produced.

Building on these results, INERIS, which is now recognised both nationally and internationally, has started work on several projects with funding provided by ANR, FEDER as well as the through the A2I Genesis project. These projects are all aimed at finalising these results and, in the short term, devising a pre-commercial demonstrator dedicated to monitoring air which might contain particles or nanoparticles. Moreover, in view of principle of LIBS measurements based on independent multi-element analysis of a given matrix, INERIS is also co-ordinating the EMILIBS projects (ADEME agreement pending) designed to propose a new metrological approach which will permit continuous monitoring of the main heavy metals in gaseous and liquid waste flows covered by the provisions of the Order of 2 February 2998 specifying emission limit values (ELVs).

INERIS has also begun work on developing metrological instruments specifically addressing nanofibres. The Carmen project (AFSSET, Picardy regional authority) is designed to lead to a new means of detecting and characterising carbon nanotubes suspended in air. To do this, we have started work on optimising the LIBS technique, we have proposed new means of taking dedicated samples for very high resolution microscopic analysis and we are studying new approaches (specific surface area, electrical mobility) that will also permit real-time detection.

In addition, INERIS has started work on investigating emissions from consumer products ("Assessment of nanoparticles emission from manufactured product: feasibility study"). The CaPréMod project (characterisation, modelling and prediction/prevention of dust emissions from powders) should in particular add to our knowledge in this area and should also put in place suitable means for suspending nanopowders.

Lastly, we have proposed an ANR Nano-Inhale project aimed at specifying, designing, developing and validating an infrastructure for studying the effects induced by exposure to manufactured nanoparticles, notably NTCs, administered through repeated inhalation at chronic to acute levels of concentration. The objective of the “Nano-Inhale” project would therefore be to gain access to nationwide infrastructure for studying the effects induced by exposure through chronic or acute inhalation of nano-fibres and complexed nanoparticles. It will be incorporated into the ANTIOPES network and could, for example, serve as infrastructure for a project aimed at studying the respiratory carcinogenicity of small inhaled doses of carbon nanotubes (NCs) administered repeatedly, and also as a means of validating innovative alternative approaches to both carbon nanotubes and complexed nanoparticles. To do this, we have already started

work aimed at developing a system of exposure by inhalation comprising an exposure chamber and devices for generating and creating suspensions of nanopowders or nanofibres and tools for real-time characterisation of the air present.

2. In water

Launching of the AquaNano project designed to identify the processes involved in the transfer of a selection of nanoparticles under realistic conditions that are representative of aquifers in France. The experiments put in place will aim in particular to quantify the main factors controlling the mobility and degradation of nanoparticles in subsurface water. Before that, however, AquaNano will seek to develop methods for recognising and quantifying manufactured particles in natural aqueous solutions.

Accidental risks, The aim of the accidental risk component of the Nanoris project was to assess methods for characterising the inflammability and explosiveness of nanoparticles. Because of their very large specific surface area, these materials can be highly reactive or even explosive. The materials studied were carbon blacks, MWCNTs, and aluminium particles. The latter can, under certain conditions, exhibit detonating effects and therefore can be very hazardous. Furthermore, it has been shown that the conventional means of characterisation developed for micropowders cannot be used systematically for nanopowders. New instruments need to be invented. In the European SAPHIR project (Safe Nanomanufacturing), INERIS is evaluating the industrial risks relating to the manufacture of high-performance nanopowders, as well as the associated costs. In the ANR project, Nanofeu, INERIS is studying the performance of fire-resistant nanostructured products and also the potential dispersal of nanoparticles from such materials in the event of a fire.

It has been demonstrated that nano-objects burn in a specific manner which is chemically controlled, whereas the combustion of larger particles is governed by diffusion. INERIS has demonstrated the implications of this observation with regard to safety parameters, and in particular the minimum energy required for combustion.

These findings have been published in ten papers.

More generally, INERIS is considering setting up a nanosafety platform in collaboration with the CEA (French Atomic Energy Commission) which would assist this new industry with risk assessment, the establishment of safety barriers in product processes and design, through exchanges with the CEA, the IRSN (Radioprotection and Nuclear Safety Institute), CEREGE (European Research and Teaching Centre for Environmental Earth Sciences), the UTC (*Université de Technologie de Compiègne*) and other actors in the Picardy region, to co-ordinate initiatives with regard to toxicology, ecotoxicology and accidental risks.

To give French industry the means to take full advantage of the advances offered by nanotechnologies, a new national programme, NanoInnov, was launched in May 2009. This programme draws on the expertise of three centres studying nanotechnology applications (Grenoble, Toulouse and the CEA/CNRS Saclay Institute). INERIS is involved in aspects relating to safety and the certification of workstations and persons working on nano-objects. This programme provides a link between basic research and application-based research by addressing issues relating to the social acceptance of these technologies.

ANR 2010

• Environmental and Health Contaminants (EHC) – Findings published on 30 June 2010

TITANIUMS

Internalisation mechanisms and toxicity of titanium oxide nanoparticles in eukaryotic multicellular organisms.

Co-ordinator: Hervé Seznec

http://www.agence-nationale-recherche.fr/documents/aap/2010/selection/ces-selection-2010.pdf

• Construction and management of risks relating to nanoparticles in industry and in research laboratories (Joint programme between the INRS and Pacte laboratory, 2010-2011)

The aim of this programme is to learn more about the prevention of risks with regard to nanoparticles in French industry.

This project is part of work addressing both the perceptions and representations of health risks relating to the work environment and the organisation of prevention and health and safety measures in firms. It is designed to analyse the knowledge, constructs, interactions and mechanisms which underpin collective learning about and collective implementation of health and safety measures in the workplace with regard to nanoparticles.

• NanoNorma "From innovation to application: What regulatory framework for nano-objects?" PNano/ANR programme (2008 – 2011) (http://www.nanonorma.org/)

Are existing technical and legal standards sufficient to take adequate account of the distinctive characteristics of nano-products (nanoparticles, nanostructured materials, objects containing nanoparticles or nanomaterials)?

After the drafting of new specialised technical standards, are we going to see the development of special legal regulations? Will the linkage between technical standards and legal regulations in this area satisfactorily cover the risks that might arise from the mass development of nano-products?

These are all key issues for the actors – public decision-makers, economic agents, researchers – involved in nanotechnology development.

This research project is aimed at helping to provide an answer to these questions by reviewing the technical and legal standards which are in preparation or which already apply to the regulation of nanotechnologies, as well as the ways in which they interact. Their ability to constitute a coherent prescriptive framework for nano-products will be assessed.

Their relevance and the efficiency of their interactions will be addressed in an interdisciplinary approach pursued jointly by legal experts, researchers into social and human sciences and reference scientists working in the fields of chemistry, physics, biology and toxicology. The issue of legal and technical standards applicable to nano-products and the ways in which their scope is combined will be addressed at different stages in the life cycle of an object, its discovery or its invention until its end use (protection of innovation, health and safety of workers, standardisation and chemical hazards, consumer information and protection).

This is a basic research project in the social and human sciences in which an industrial partner will be involved. This association is needed in order to contrast theoretical assumptions with the practical realities experienced by a technical and economic actor in the sector concerned.

6. Information on any public/stakeholder consultation

See the information above on the national public debate on nanotechnologies.

CoExnano (Vivagora – Ministry of Ecology, Energy, Sustainable Development and the Sea (MEEDDM), in charge of green technologies and climate negotiations) (2010 – 2011)

- The CoExnano initiative is an experimental process which is part of the **call for proposals for the REPERE project sponsored by the MEEDDM**: "Research and expert appraisal for the joint conduct of research and expert appraisal". Following the example set by the Grenelle Environmental Round Table, the aim is to bring research and civil society closer together, to diversify points of view and to construct robust oversight systems.

- VivAgora has decided to try out a new pluralist method of expert appraisal by investigating the field of **surface coatings containing nanocompounds**. These coatings allow existing materials to be given new properties (waterproofing, biocidal properties, pollutant removal, anti-abrasives, etc.). There is a large potential market for such applications in many industrial sectors (textiles, building, paint, packing, white goods, etc.). In collaboration with the MEEDDM, the expert appraisal will focus more particularly on coatings containing silver nanoparticles (biocides) or titanium dioxide (photocatalyst), which are considered to have substantial potential in both economic terms and in terms of human health.

- The CoExnano project consists in working together with many actors from the academic, economic, associative, administrative and political spheres, to build up a corpus of knowledge and to take stock of questions regarding the challenges (in terms of health, the environment and social issues) posed by coatings developed by the nanotechnology industry. The aims pursued are as follows:

i. To identify the benefits and risks associated with products containing nanocoatings based on nano-silver or nano-titanium;

ii. To identify critical situations requiring further in-depth research and/or notification of the public authorities;

iii. To promote greater skill and understanding in civil society with regard to the issue of the challenges posed by nanotechnologies so that civil society can play a constructive part in the joint expert appraisal;

iv. Provide public decision-makers with indications that will allow them to identify the conditions that will prompt stakeholders to commit themselves, to ensure that expertise is built up together; and

v. Promote collaborative practices upstream of product launches, introduce governance into laboratories and firms as part of the social responsibility of firms (RSE).

- By paying attention to these points, the project will be able to shed light on practical procedures for implementing the precautionary principle. The CoExnano project is therefore design to be an innovative experimental system which could be transposed to other areas and serve as a procedure for multi-actor collaboration on emerging risks.

GERMANY

Highlight of developments since the 6th meeting of the WPMN

- Feasibility study Nano Products' Register accomplished
- Dialogforum of German NanoKommission's working groups
- Launching of diverse research projects

Work completed, underway or planned

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

A) Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit, BMU):

A feasibility study on the introduction of a Nano Products' Register in Germany with emphasis on legal and regulatory aspects has been accomplished. The final report (in German with English summery) will be available under (www.bmu.de/gesundheit_und_umwelt/downloads/doc/46240.php); the English version is expected to be online by October 2010 on the Ministry's website.

B) Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit, BMU):

The four expert working groups of Germany's NanoKommission (2009-2011) dealing with the implementation of the principles, benefit and risk potentials, regulatory aspects of nanomaterials and further development of criteria on concerns and reliefs presented their interim reports on the "Dialogforum" on February 17 in Berlin and discussed their results with a broad expert audience. The related documentation (only in German) is available under http://www.bmu.de/files/pdfs/allgemein/application/pdf/nanokommission_zwischenergebnisse_bf.pdf .

C) Federal Environment Agency (Umweltbundesamt, UBA):

UBA presents a background paper "Nanotechnology for Humans and the Environment-promote opportunities and reduce risks" indicating aspects of nanotech's potential to relieve the environment. The paper also identifies risks posed to mankind and the environment and defines recommendations for action. The English version of the background paper is available under: http://www.umweltbundesamt.de/uba-info-medien-e/mysql_medien.php?anfrage=Kennummer&Suchwort=3906

2. Developments related to voluntary of stewardship schemes

3. Information on any risk assessment decisions

4. Information on any developments related to good practice documents

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

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

The Federal Institute for Occupational Safety and Health (BAuA) will fund a literature research to gather information on the physical chemical characterisation of nanomaterials serving their assessment under Regulation (EC) No 1907/2006 (REACH). The study will evaluate which of the physicochemical methods listed in Regulation (EC) No 440/2008 can be applied to substances in nanoscale and which of the physicochemical data of substances in microscale can be transferred to substances in nanoscale. Moreover, systematic differences concerning substances in nanoscale and microscale will be identified as well as additional physicochemical methods that are necessary to characterize nanomaterials. These methods should meet international standards and should be applicable under the EU REACH Regulation. The project is expected to be completed in May 2011.

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

BfR will undertake a three years' project addressing the genotoxicity of manufactured nanomaterials measured in vitro using three different cell culture systems.

C) Federal Environment Agency (Umweltbundesamt, UBA):

(1) Two German studies on behalf of UBA identified positive effects on the environment when applying nanotechnology: (a) Environmental relief effects through nanotechnical processes and products (Entlastungseffekte für die Umwelt durch nanotechnische Verfahren und Produkte); and (b) Investigations into the application of nanomaterials in environmental protection (Untersuchung des Einsatzes von Nanomaterialien im Umweltschutz). Both final reports are written in German and include an English summary:
[a)http://www.umweltbundesamt.de/uba-info-medien-e/mysql_medien.php?anfrage=Kennummer&Suchwort=3777 and b) http://www.umweltbundesamt.de/uba-info-medien-e/mysql_medien.php?anfrage=Kennummer&Suchwort=3778].

(2) The scientific study "Quantitative biokinetic analysis of radioactively labelled, inhaled Titanium dioxide Nanoparticles in a rat model" determined the biokinetics of TiO_2 nanoparticles in the whole body of rats after inhalation. Small fractions of TiO_2 nanoparticles translocated across the air-blood-barrier and accumulated in secondary target organs, soft tissue and skeleton. The amount of translocated TiO_2 nanoparticles is approximately 2 % of TiO_2 nanoparticle deposited in the lung. The final report in English will be available under http://www.umweltbundesamt.de/uba-info-medien-e/index.htm.

(3) As a direct contribution to the OECD Sponsorship Programme UBA currently launches two new research projects. In these projects different test methods will be applied in order to explore the environmental behaviour and fate of TiO_2 nanomaterials as well as to investigate the ecotoxicological impact of TiO_2 nanomaterials under realistic exposure scenarios. The tests will be applied under the consideration that adaptations of the applied test methods might be necessary to appropriately address the specific aspects of nanomaterial testing. For this aim protocols will be developed giving recommendations for adaptation.

(4) Within the programme "NanoNature" of the Federal Ministry of Education and Research a project called "UMSICHT (Abschätzung der Umweltgefährdung durch Silber-Nanomaterialien: Vom chemischen Partikel bis zum technischen Produkt)" (translation: "Assessment of environmental risks of silver nanomaterials: From the chemical particle to the technical product") was initiated. Within this project a consortium of 17 partners from research institutes, as well as industry and authorities (e.g. BMU and UBA) will investigate the potential environmental hazards of silver nanomaterials as well as of selected products containing nanosilver (textiles). The contribution of UBA within this project focuses on the assessment of aquatic toxicology using standardised test methods, as well as on the measurement of the antibacterial effects of nanomaterial containing products and the aging of these products – and thus the potential release

of nanosilver. At the final stage of the project the Federal Environmental Agency will prepare a preliminarily risk assessment of the selected nano silver products based on the results gathered within the project.

6. Information on any public/stakeholder consultation

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

BfR recently published a report regarding an analysis of internet forums focussing on consumer products that contain nanomaterials. The German version of the report can be downloaded from http://www.bfr.bund.de/cm/238/wahrnehmung_der_nanotechnologie_in_internetgestuetzten_diskussionen.pdf ; the English version is available under http://www.bfr.bund.de/cm/238/perception_of_nanotechnology_in_internet_based_discussions.pdf .

ITALY

Highlight of developments since the 6th meeting of the WPMN

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

- Two governmental agencies: ISPESL (National Institute of Occupational Prevention and Safety) and INAIL (Italian Workers' Compensation Authority[9]) have activated two working groups for addressing the problem of risk assessment and mitigation in occupational environments where nanomaterials are used.

- AIRI/Nanotec IT (Italian Centre for Nanotechnologies), which acts as a focal point of organisations dealing with nanotechnologies in Italy, with most of industry, academia and research institutions active in nanotechnologies being among its members, coordinates the FP7 project FramingNano and is a partner (dealing also with nanoregulation) of the FP7 project ObservatoryNano [10].

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

- Among the initiative activated in the last years there can be also cited CIGA *(Centre for Environmental Law Decisions and Corporate Ethical Certification)* at University of Padova [11] to study ethical implications of nanotechnologies.

Work completed, underway or planned

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

While at public and private level in Italy there is a general consensus on the need of facing the challenge posed by nanotechnology, the actual situation in the research and regulatory area on health and

[9] Not just a compensation authority but a global protection system for all workers http://www.inail.it/

[10] http://www.observatorynano.eu

[11] http://www.ciga.unipd.it/about_us_en.htm

safety aspects of nanomaterials is characterised by a general scarcity of initiatives at both public and private levels. Policy oriented discussion on the necessary approach for the development of research strategies and programmes to address health and risk implications of manufactured nanomaterials results still very scarce.

In the context of the national standardisation body (UNI) it has been activated a commission entitled Nanotechnology, which is structured in four working groups: Terminology; Instrumental measurement and characterisation; Health and safety aspects; Nanotechnological products and processes. Up to now their activities have been limited to the acquisition of information from the mirror commissions of ISO and CEN. Their active work is still to be planned.

2. Developments related to voluntary or stewardship schemes

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

3. Information on any risk assessment decisions

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

4. Information on any developments related to good practice documents

There are no initiatives on this aspect.

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

Specific research studies concerning mainly toxicological experiments in vitro on some type of nanomaterials are actually underway in a limited number of small groups of people in some university, research centres, or institutes, but they are conducted with a limited ambition level and poor co-operation/co-ordination among them. Some of these groups participate to the following two research projects funded by the European Commission under the Sixth Framework Program for Research, Technological Development and Demonstration (FP6): "Development of an Integrated Platform for Nanoparticle Analysis" (DIPNA) to verify their possible toxicity and the eco-toxicity, coordinated by Italy (University of Modena and Reggio Emilia), and "Risk Assessment for Particle Exposure" (PARTICLE-RISK) to which cooperate two research centres in Venice, University of Ca' Foscari and Consortium Venezia Ricerche. In addition at level of initial proposal very recently the National Institute for Occupational, Safety and Prevention (ISPESL) has proposed a project (yet to be approved and financed) to the Ministry of Health on the aspects of occupational exposure to nanomaterials (focused on carbon nanotubes), but the environmental safety aspects are not taken into consideration in this project. Recently, at ISS (National institute of Health) an interdepartmental and multidisciplinary working group on Nanomaterials has been established to support the efforts of the public initiatives in this field. As a part of this initiative, specific research projects are under development in order to assess the potential toxic effect for human health and environment of different nanoparticles.

6. Information on any public/ stakeholder consultation

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

The only exception which may be considered is an initiative taken by the association AIRI (Italian Association for Industrial Research) and its division NanotecIT (Italian Centre for Nanotechnology) aimed

to provide a census of the public and private organisations involved in nanotechnology in Italy (www.nanotec.it).

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

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

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

The role of public research is still fundamental. All major public research organisations (CNR/INFM, INSTM, INFN, ENEA)12 and universities are involved. Relevant resources are dedicated to this field and various initiatives have been put in place to improve the effectiveness of the efforts.

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

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

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

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

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

Additional Information/Comments

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

12

CNR: Consiglio Nazionale delle Ricerche (National Research Council);
INFM: Istituto Nazionale di Fisica della Materia (National Institute of the Structure of Matter);
INSTM: Consorzio Interuniversitario per la Scienza e Tecnologia dei Materiali (Inter-University Consortium for Materials Science and Technology).
INFN: Istituto Nazionale di Fisica Nucleare (National Institute of Nuclear Physics);
ENEA: Ente per le Nuove Tecnologie, l'Energia e Ambiente (National Body for New Technologies, Energy and Environment**).**

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

• Interaction human health / environment;

• Public perception and social/ethical policies; and

• Education for a responsible use.

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

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

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

JAPAN

Highlight of developments since the 6th meeting of the WPMN (October 2009)

• The National Institute of Advanced Industrial Science and Technology (AIST) published the English version of four interim risk assessment reports (one for general and three for each targeted materials: fullerenes, carbon nanotubes (CNTs) and titanium dioxides) on December 22, 2009[13].

• Ministry of Economy, Trade and Industry (METI) has publicised the results of voluntary information gathering on industries activities in March 2010 (only in Japanese)[14].

• Ministry of Health, Labour and Welfare (MHLW) published the commissioned survey report of FY2009, which includes the results of utilisation survey on typical nanomaterials and literature research on the toxicity of those nanomaterials, etc. (Most of them is in Japanese but the summary is translated in English)[15]. In addition, MHLW translated the report of the committee on safety measures for nanomaterials in English and put it on the website[16].

• Ministry of Health, Labour, and Welfare (MHLW) launched a six-year programme (FY 2009 - 2014) on the "Research project on the potential hazards, etc. of nanomaterials", which focuses on carcinogenicity of nanomaterials.

• Ministry of the Environment (MOE) has started 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.

[13] http://www.aist-riss.jp/main/modules/product/nano_rad.html?ml_lang=en

[14] http://www.meti.go.jp/policy/chemical_management/other/nano.html

[15] http://www.nihs.go.jp/mhlw/chemical/nano/nanopdf/H21houkoku/honbun/abstract.pdf

[16] http://www.nihs.go.jp/mhlw/chemical/nano/nanopdf/houkokueng.pdf

- 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" on June 10.

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 WPMN6

2. Developments related to voluntary or stewardship schemes;

METI calls on the industries to voluntarily report their safety data of and management activities on the manufactured nanomaterials to METI. METI has publicised each report on its website (see 4. in detail).

3. Information on any risk assessment decisions;

No significant change after WPMN6

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

In November 2008, METI organised a study group (The Expert Meeting on Safety Measures for Nanomaterial Manufactures etc.) focusing its discussion on the safety measures introduced by nanomaterials manufactures in voluntarily basis. Experts from industries made presentations on their voluntary activities for safety production of nanomaterials in three meetings which were open to the public. A study report was published in March 200917. Following the conclusion of the report, METI requested the manufacturers to further implement the voluntary safety measures, to enhance the communication with users and to provide voluntarily the information on test data and management methods to the public and METI. METI has publicised the gathered information through this survey on METI's website in March 2010 (only in Japanese).

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

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 "Guidelines for preventing the environmental impact of manufactured nanomaterials" was published to provide manufacturers with currently available information for the environmental sound management of

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

manufactured nanomaterials including immediate countermeasures to be taken as a guideline in March 2009[18]. Based on "Future Challenges" which were identified in the Guideline, MOE has started 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.

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

METI launched a five-year programme on the "Evaluation of the Potential Risks of Manufactured Nanomaterials based on Toxicity Tests with Precise Characterisation" in 2006, which focuses on toxicity test protocols and a risk assessment methodology of manufactured nanomaterials. The programme aimed at: 1) establishing preparation methods of test samples; 2) developing methods for measuring shapes and sizes of tested nanomaterials, for testing toxicity, and for analysing exposure; 3) publishing such results in the form of manuals; 4) carrying out risk assessment on typical of nanomaterials; and 5) proposing a risk management policy with formulating risk assessment documents. Fullerenes, carbon nanotubes (CNTs) and titanium dioxides are given priority as targeted nanomaterials. The programme is coordinated by the National Institute of Advanced Industrial Science and Technology (AIST), which also conducts much of this research in cooperation with the University of Occupational and Environmental Health and other universities. The New Energy and Industrial Technology Development Organisation (NEDO, an R&D management organisation) evaluates the progress of the programme. On October 16, 2009, AIST released interim reports on the risk assessment of the aforementioned three nanomaterials, in addition to a concept paper "The Principles and Basic Approach to Risk Assessment of Manufactured Nanomaterials." The English version is available for download from the AIST-RISS website[19]. The final Risk assessment reports on three nanomaterials are envisaged at the end of the project in mid 2011.

MHLW has promoted research on the human health aspect of several nanomaterials since 2003 through the Health and Labour Sciences Research Grants, etc. In 2010, six research projects, such as a basic research on development of methods for evaluating hazard and disposition of nanomaterials on human health, are progressing. In addition, MHLW launched a six-year programme (FY 2009 - 2014) on the "Research project on the potential hazards, etc. of nanomaterials", which focuses on carcinogenicity of nanomaterials. This project started to develop two-year inhalation study of multi-walled carbon nanotube.

The National Institute of Occupational Safety and Health Japan (JNIOSH) has been conducting a three-year project study on possible health issues due to exposure to manufactured nanomaterials in the workplace since April 2007. This project includes 1) a questionnaire survey on occupational health practices for handling and use of nanomaterials in the workplace, 2) studies on sampling and analytical methods, and 3) toxicological studies in vitro with human cultured cell lines and in vivo by intratracheal administration.

In 2006, the National Institute for Environmental Studies (NIES) launched a nanotoxicology programme where both *in vitro* and *in vivo* toxicities of nano-structured particulate materials are to be revealed. The programme includes 1) interaction of nano-fibres including CNT with cell membranes, 2) transepithelial and transpulmonary migration of nanoparticles, 3) *in vitro* and *in vivo* toxicity assay of nanomaterials using heat-treated asbestos as reference samples. A high-throughput method to quantitatively measure *in vitro* uptake of CNT has been developed. The exposure chamber for inhalable nano-fibres has been installed and NIES has been conducting an acute inhalation study on carbon nanotubes using small rodents.

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

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

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

6. Information on any public/ stakeholder consultation

Three Ministries (METI, MOE and MHLW) together presented their latest activities at the UNITAR executive workshop in Tokyo on 8th March 2010, which was widely open to the public[20].

7. Others (major budget plans on safety of manufactured nanomaterials in FY 2010)

project name	**governing ministry**	**FY2010 (million yen)**
Research project on risk of chemicals Six projects, including a basic research on development of methods for evaluating hazard and disposition of nanomaterials on human health	MHLW	320
Research project on the potential hazards, etc. of nanomaterials	MHLW	160
Food Nanotechnology Project	MAFF	128
Evaluation of the Potential Risks of Manufactured Nanomaterials based on Toxicity Tests with Precise Characterisation	METI	401
Study on the methodology to prevent environmental impacts posed by Nanomaterials	MOE	19
Assessing the health risks associated with the disposition of environmental nanoparticles	NIES	50 (incl. other businesses)
Developing knowledge-based platform to support nanomaterial R&D for public acceptance	Cabinet office /MEXT	80

KOREA

Highlight of developments since the 6th meeting of the WPMN

- The Korean Ministry of Knowledge and Economy (MKE) is preparing a Guideline of safety nanotechnology. This guideline will give a responsibility and good practice on safety in developing nanotechnology or nanotechnology in commerce.

- MOE has developed the five-year plan for The Risk management of nanomaterials (2010~2014).

- MOE organised the "Nanomaterial Risk Expert Committee" in order to share the expertise and experiences and establish the collaborative system for the potential risk of nanomaterials.

- MOE organised the workshop to promote the collaboration among the governmental ministries in the nano safety research area.

[20] http://www.unitar.org/hiroshima/sites/default/files/Executive_Workshop_II-Nanotechnology-Infonote.pdf

Work completed, underway or planned

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

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

The Korean Ministry of Knowledge and Economy (MKE) is preparing a Guideline of safety nanotechnology. This guideline will give a responsibility and good practice on safety in developing nanotechnology or nanotechnology in commerce.

2. Developments related to voluntary or stewardship schemes

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

3. Information on any risk assessment decisions

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

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

4. Information on any developments related to good practice documents

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

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

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

Ministry of Environment (MOE)

MOE has conducted the Eco-technopia 21 project to promote the development of environmental technologies since 2001. Under this umbrella, MOE started a project on human health and environmental safety of nanomaterials, such as fullerene (C60), MWCNT, silver nanoparticles, TiO2, and SiO2, as target materials in the framework of Eco-technomia21 from April 2007, which will be continued until 2010. The ultimate goal of the research is to support the establishment of infrastructure in order to minimize potential risks possibly occurred from the manufacture, distribution and disposal of nanomaterials and nanomaterials-containing products. MOE implemented the projects such as ‘Research on the most relevant dosing metric for the ecotoxicity management system of manufactured nanomaterials (2009~2012)’ in order to find the correlation between the dosing metric and the risk assessment and ‘Genomic studies of

nano-particles to bacteria, yeast and fish' to develop alternative methods for nano-toxicity tests. Furthermore, 'Guideline for the life cycle assessment (LCA) of nanomaterials' and 'Safety guideline for nano-safety management' were developed.

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

NIER has been conducting 4 projects on the development of test methods and a database for risk assessment of manufactured nanomaterials (2007~2010). The prototype of the database and the researches on the physicochemical properties, the environmental and mammalian toxicity and environmental fate of silver nanoparticles are on progress. NIER organised the Nanomaterial Risk Expert Committee and held the second meeting in May, 2010. This committee handles the nanomaterial safety issues, which include the areas on developing test methods, evaluating the validation of the data and national planning on the nanomaterial risk assessment.

Ministry of Knowledge and Economy (MKE)

The Ministry of Knowledge Economy (MKE) in collaboration with the Ministry of Education, Science and Technology (MEST) has initiated the programme "Strategy on Nano Fusion Industry Development" to strengthen research on the safety and social impact of nanomaterials. The MKE/KATS implemented "Risk Management Platform Technology for Nano Products (2009-2013)" which will provide an infrastructure for the certification of nano products based on a risk management system including characterisation, efficacy, quality and safety assessment along with standard development. Also MKE will set up the Risk Management Centre for Nano Products on 2010.

The Korean Agency for Technology and Standards (KATS), an organisation under MKE, has been developing national standards to ensure safety and support marketing of consumer products containing silver nanomaterials and CNTs. This work is initiated the Korea's role as an exporting country and to prepare for TBT (technical barrier to trade). KATS has published "Nanoparticle diameter measurement using TEM" (KSD 2716, 2008), and published KSA 6202(Guideline to safe handling of manufactured nanomaterials in workplace/laboratories as a national standard in 2009. KATS further proposed an international standard on "Preparation of MSDS (material safety data sheet) for nanomaterials", and is simultaneously developing a Korean standard for the preparation of MSDS in 2009. Guidelines for exposure monitoring, characterisation, and safety assessment of nanomaterials such as CNTs and silver nanoparticles are in development. Accordingly, a guideline for exposure monitoring of nanomaterials has already been launched. KATS has published "Nanotechnologies-Terminology and definitions for nano-objects-Nanoparticle, nanofibre and nanoplate" (KSAISOTS27687) as a national standard. KATS has launched to develop standard on antimicrobial efficacy testing of silver nanomaterial containing product in 2009. The final report and relevant standards will be available 2011. Guidelines for exposure monitoring, characterisation, and safety assessment of nanomaterials such as CNTs and silver nanoparticles are in development. The final report will be submitted by the end of June. Accordingly, a guideline for exposure monitoring of nanomaterials will be finalised by the end of 2010.

Korea Food & Drug Administration (KFDA)

KFDA has been operating the Nanotoxicology Project since 2007. The Nanotoxicology Project focuses mainly on providing toxicity data for preparing guidelines to evaluate safety and nano risk management

associated with foods, drugs, medical devices and cosmetics using nanoscale materials. Research areas in the Nanotoxicology Project encompass a wide range of safety issues related to manufactured nanomaterials including toxicological evaluation, risk assessment, risk communication, development of new toxicological evaluation methods, toxico/pharmaco-kinetics (TK/PK) and physico-chemical characterisation behaviour.

Silica, silver, gold, iron oxide, zinc oxide, titanium dioxide, carbon nanotube and chitosan nanoparticles have been used as test materials for preparation of guidelines to evaluate safety and effectiveness. Effects of size, shape and surface character of nanomaterials on general toxicity, genotoxicity, immune response, developmental and reproductive toxicity, PK profile, brain uptake mechanism, interaction with biomaterials were mainly investigated. From 2010 to 2012, we plan to conduct in-depth studies on the selected nanomaterials, such as silica and zinc oxide to understand the mechanism of toxicity and to identify physico-chemical characterisations in biological systems.

KRISS (Korea Research Institute of Standard Science)

KRISS has been developing the National Measurement Standards of (nano) materials. In connection with this topic, the research project on "Development of Characterisation Techniques for Nano-materials Safety" was launched (2009 – 2015). This project is composed of four parts; i) physic-chemical property characterisation of nanoparticles such as silver, gold, titanium dioxide, polystyrene, silicon dioxide, CNTs and quantum dot is ongoing, and finally develops their CRMs, ii) Surface structures and its compositions are studied using XPS, MALDI-ToF, ToF-SIMS etc.. iii) The size measurement of nano particles is also executed out with SMPS, DLS, PBMS, TEM, BET and AFM as a part of OECD-WPMN and VAMAS (TWA34) projects. Nanoparticle trace technology using ToF-SIMS and Raman spectroscopy is under developing. iv) The studies on the transport and potential transformation of nanomaterials(ADME) is under investigation.

6. Information on any public/ stakeholder consultation

MoE organised the workshop to develop the strategic plan for nano-safety promote on 9th. Dec. 2009. MoE, MEST, MKE, KFDA, academia, research institute and industries participated to the workshop and shared the information and experiences.

MoE organised the workshop to promote co-operation among ministries on 18th June 2010. MoE, MEST, MKE, KFDA, National Assembly Research Service (NARS), academia, research institute and industries participated to the workshop and shared the information and experiences. During the workshop, the future plans on the nano safety research and outlook was discussed.

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

NORWAY

Highlight of developments since the 6th meeting of the WPMN

- The Climate and Pollution Agency (the former SFT) has introduced a voluntary scheme to get a better overview of nanomaterials in chemical products. The Product register in the Climate and Pollution Agency has included a question in their declaration form about the content of nanomaterials in their chemical products.

- The Norwegian Institute of Occupational Health has established a working group (*Nanogruppen*) together with The Norwegian Labour Inspection Authority and the Climate and Pollution Agency related to primarily occupational health aspects of nanotechnology.
- The Norwegian Labour Inspection Authority is leading a project "*A descriptive study on use, production, and import of nanotechnological products in the Norwegian work life"* in collaboration with the Federation of Norwegian Industries, The Norwegian Confederation of Trade Unions (LO), The National Institute of Occupational Health (STAMI) and the Climate and Pollution Agency. Results will be published the summer 2010.

Work completed, underway or planned

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

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

2. Developments related to voluntary or stewardship schemes

See first bullet point under "Highlight of developments…"

3. Information on any risk assessment decisions

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

4. Information on any developments related to good practice documents

A document related to good practice will be developed by Nanogruppen, See second bullet point under "Highlight of developments…"

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 Research Council of Norway has a strategic research programme on nanoscience, nanotechnology and new materials, called NANOMAT. The programme period is 2002-2011. NANOMAT also supports research on ethical, legal, social and environmental aspects, including human health and risks (ELSA). The Council published in 2005 a report where these aspects are discussed. From 2005 funding of relevant projects started. 3 % of NANOMAT's funding so far is related to ELSA. A national strategy for nanoscience and nanotechnology was adopted by the Council in autumn 2006 and forward to the Minister of Education and Research. NANOMAT hosted a major conference in Lillehammer June 15th-19th 2009, where presentations from several acclaimed researchers, also in the field of safety for human health and environment were hold. More info on this website: http://www.forskningsradet.no/servlet/Satellite?c=Page&cid=1226993562769&p=1226993562769&pagename=nanomat%2FHovedsidemal

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

7. Information on any public/ stakeholder consultation

The Norwegian Board of Technology published a report in 2008 regarding Nanomaterials, risk and regulation (only in Norwegian). Download the report via this link: http://nano.teknologiradet.no/Nanotox_rapport_for_web_nR1yA.pdf.file

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

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.

None

Additional Information

None

SWEDEN

Highlight of developments since the 6th meeting of the WPMN

In Sweden, two reports on nanomaterial and nanotechnology were published early this year:

- *KemI Report No 1/10* on the need for regulations and other measures in order to make a satisfactory assessment of the risks posed by nanomaterials (in Swedish with an English summary - available at www.kemi.se)
- *Vinnova Policy VP 2010:01* on the development of a strategy addressing both the opportunities and risks associated with the use of nanotechnology (in Swedish with an English summary - available at www.vinnova.se).

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;

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

2. Developments related to voluntary or stewardship schemes;

No information provided.

3. Information on any risk assessment decisions;

No information provided.

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

No information provided.

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

No information provided.

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

a. The Swedish Chemicals Agency (KemI) was last year commissioned by the Government to analyse the need for regulations and other measures in the EU and in Sweden in order to make a satisfactory assessment of the risks posed by nanomaterials to human health and the environment. The commission was reported in February 2010 and among activities proposed to the Government by the Swedish Chemicals Agency were:

- To introduce a mandatory reporting system for occurrence of NM on the market;
- To formulate a definition that distinguish NM from bulk materials;
- To review the Reach and CLP legislation for applicability on NM in 2012;
- To prioritize resources for work within EU expert groups (e.g. CASG nano) to develop guidance on NM;
- To regulate the use of NM as additives in biocide products;
- To support (financial and/or personnel resources) the development of testing methods of NM for health and environmental hazards within the OECD/WPMN;
- To promote targeted research grant programs for the area of health and environmental risks of NM and to increase financial support for research on risks; and
- To contribute to SAICMs goal to disseminate information on NM from industrial to developmental countries by taking part in OECD work on NM.

b. The Swedish Governmental Agency for Innovation Systems (Vinnova) was last year commissioned by the Government to, in consultation with the Research Council (Vetenskapsrådet) and after consultation with the Swedish Research Council for Environment, Agricultural Sciences and Spatial Planning (Formas) and the Swedish Chemicals Agency (KemI) in accordance with their respective competence to develop a strategy for addressing how the opportunities and risks, which may be associated with the use of nanotechnology, can be exploited and taken into account in light of the fast developments in the field of nanotechnology. The commission was reported to the Government in January 2010. Proposals related to health and environmental safety by Vinnova were in brief:

- To form a nanotechnology delegation with representatives of the government, industry, academia and relevant authorities. The group may facilitate national dialogue and may also guide foreign actors in the Swedish system;
- To support and coordinate the international work carried out by different departments and authorities within nanotechnology;
- A policy should create the conditions to interweave the innovation and risk processes. Since risks and opportunities go hand-in-hand, it is important for risks to be managed continuously throughout the entire process;

- To create growth by linking nanotechnology to existing efforts within Swedish areas of strength, such as environment and health;
- In order to increase utilisation of nanotechnology in Sweden, public actors should work actively to link nanotechnology to broad public goals, such as environment and health goals;
- To create growth by linking nanotechnology to existing efforts within Swedish areas of strength, such as environment and health; and
- To initiate dialogue with the public.

7. Information on any public/ stakeholder consultation

No information provided.

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

No information provided.

THAILAND

Since the 6th meeting of WPMN, a number of nano-safety development and activities have taken place in Thailand.

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

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

1. The National Nanotechnology Center (NANOTEC) has established:

2. Establishment of Nanosafety Information and Knowledge Management Center (NIKM)

3. Developing of "Nano Q" as a standard nanomark for selected Thai nano-products to identify types, sizes, and properties of nano-particles

4. Developing of National Nano-safety Guideline compliance with laboratory and industrial protocol

5. Initiating the training programme for South-east Asian countries in nanotechnology and nano-safety.

6. Organizing 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.

7. Strengthening nanotoxicity and ecotoxicity research of nanosilver, TiO2, fly ash particles .

8. Developing of the National Nanosafety Strategic Plan focusing on human health, environment, and national security

9. Collaborative research programs with the Swiss Federal Institute for Materials Testing and Research (EMPA)

10. Participation as part of the Thai Delegation in the ISO/TC229 Nanotechnologies standard development activities

11. Collaboration with the steering group of the Intergovernmental Forum on Chemical Safety (IFCS) forum VI with the lead of the Ministry of Health and the Ministry of Science and Technology.

12. Collaboration with SAICM/UNEP in chemical and nanosafety management issues

Strategic goals of NANOTEC:

1. Conduct research on measuring nanomaterials in the workplace, including developing new measurement methods and validating measurement methods. Also, the nanotoxicity in human health, and environment is being investigated.

2. Strengthen the capability of nanosafety and risk assessment program.

3. 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 Nanosafety Information and Knowledge Management Center (NIKM) in collaboration with Chulalongkorn University. NIKM will serve as the focal point in monitoring movements in issues related to nanomaterials and nanotechnology. It will also serve as a focal point in disseminating such knowledge to the Thai public. Over time, NIKM is expected to become an independent agency in order to boost its credibility as an impartial organisation.

Thai Industrial Standard Institute (TISI)

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

Chulalongkorn University

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

Nano-safety in Thailand Q&A:

3. 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 2010, three initiatives related to nano-safety have been driven by NANOTEC. They were the establishment of National Nano-safety Guideline, the development of National Nano-safety Strategic Plan, and the founding of Nanosafety Information and Knowledge Management Center (NIKM), in collaboration with Chulalongkorn University. Also, the concept of Nano-Q, as a certified nano-product label or a nanomark, have been initiated and planned to implement within this year by Nanotechnology Association of Thailand.

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

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

- NANOTEC consequently commissioned Chulalongkorn University to prepare a nano-safety status report in 2007. The main objective of this exercise was to gather international information on all aspects of nanosafety and nanoethics. Data sources include university centers that receive US government grants related to nanosafety/ nanoethics, independent policy research institutes, independent academics, e.g. in South America, and international organisations such as OECD, ISO, and APO (Asian Productivity Organisation). In addition, this exercise attempted to 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.

4. 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.

5. 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.

6. 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.

7. 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 programme specifically designed to address the human health and environmental safety aspects should be available through NANOTEC after such research works are completed.

8. Information on any public/ stakeholder consultation.

NANOTEC has regularly organised nanosafety public seminars e.g. NanoThailand 2008 and the Nanosafety and Ethics Forum, Nanosafety in Thailand: Status report of Thai Nano-products and is planning to organize NanoThailand 2010, an international conference and exhibition of nanotechnology and its application, during Nov. 18-20th 2010. Nanosafety session is included.

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

UNITED KINGDOM

1. Information on any developments related to good practice documents

Work is currently underway to develop a "Guide to Assessing Airborne Exposure in Occupational Settings Relevant to Nanomaterials", which will complement the guide to safe handling and disposal of manufactured nanomaterials. Also under development is a "Guide for SMEs on Legislation and Standards for Nanomaterials and Nanotechnology-based Products", which has been designed to support both new and existing SMEs to introduce nanotechnology based products and processes in a safe and responsible manner. Finally, a revision of the first UK nanotechnology terminology document, PAS 71 – vocabulary – nanoparticles, published in June 2005, is underway following the publication of relevant documents by ISO. All three documents will be published in autumn 2010 following international review and comment.

The Responsible Nano Code is a framework of best practice for organisations working on the development, manufacture, retail or disposal of products using nanotechnologies. It has been developed by a non government multi stakeholder group in the UK. An interim update is available, which outlines the

seven Principles of the Responsible Nano Code to be adopted by organisations; this will be developed into a more detailed benchmark for organisations to be assessed against. Further details on this more detailed framework and information on the benchmark are available at: http://www.nanoandme.org/social-and-ethical/corporate-responsibility/responsible-nano-code/

2. Recently concluded projects

A Lifecycle Assessment study of the route and extent of human exposure via inhalation for commercially available products and applications Containing Carbon Nanotubes (CNTs)

This study, undertaken by the UK's Food and Environment Research Agency (FERA) has looked at the likelihood and possible pathways of inhalation exposure arising throughout the life cycle of a representative selection of commercially available CNT-containing products (lithium-ion batteries, epoxy adhesive resin, and textiles). For each of the products, the study analysed the possibility of inhalation exposure to CNTs during different stages of the life cycles (raw material manufacturing, product formulation, packaging, transportation, use and final disposal stages). The study also assessed the current protocols for lifecycle assessment (LCA), established by the International Organization for Standardisation (ISO), for their relevance and adequacy in relation to assessment of inhalation exposure to CNT and other nano-products.

Link to report: http://randd.defra.gov.uk/Document.aspx?Document=CB0423_9128_FRP.pdf

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

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

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

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

UK Health Protection Agency National Nanotoxicology Research Centre

The HPA Centre for Radiation, Chemical and Environmental Hazards (CRCE), with its expertise in toxicology, biokinetics, aerosol physics, air pollution and inhalation research, has responded to the challenge of the health concerns and knowledge gaps associated with nanomaterials by establishing the National Nanotoxicology Research Centre (NNRC) at CRCE, Chilton. When fully commissioned the NNRC will be able to generate and characterise aerosols of a range of nanomaterials. Progress with the development of the facilities is going well. A large UK-US project in which HPA play a role has recently been awarded funding.

Recently commissioned projects

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

The Natural Environment Research Council, in cooperation with the Engineering & Physical Sciences Research Council, the Department for Environment, Food & Rural Affairs (Defra), the Environment Agency and the United States Environmental Protection Agency, is in the process of considering research proposals against a major joint research effort to develop and validate predictive tools and similar conceptual models that predict exposure, bioavailability and effects of manufactured nanomaterials in the environment. In addition, researchers will be asked to develop novel techniques for detection and characterisation of nanomaterials in complex environmental and biological systems. Total funding is expected to be in the region of $8M. It is expected that successful grants will be announced in 2010.

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

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

The UK Department for Environment, Food & Rural Affairs (Defra) has commissioned Oakdene Hollins Ltd to develop a methodology for estimating, in monetary terms, the benefits of nanotechnology. Whilst there have been several studies considering the potential benefits, or market value, of nanotechnology a widely accepted methodology does not currently exist. The project will involve testing the methodology on nanotechnology applications falling within Defra's remit (e.g. land remediation, water treatment, agriculture) to assess their potential benefits to the UK. However, the resulting methodology will be capable of being applied to any current or emerging nanotechnology applications or products and will therefore be of use to governments, industry and academia throughout the world. Stakeholders from government, industry and academia discussed a draft of the methodology at a workshop in June and we expect the project to conclude in the autumn.

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

The Natural Environment Research Council, in cooperation with the Engineering & Physical Sciences Research Council, the Department for Environment, Food & Rural Affairs, the Environment Agency and the United States Environmental Protection Agency, has funded three research consortia through a major joint UK-US initiative to develop and validate predictive tools and similar conceptual models that predict exposure, bioavailability and effects of manufactured nanomaterials in the environment. A total of $12M will be invested across these projects which will investigate both terrestrial and aquatic ecosystems and

cover a wide range of disciplines including material science, detection and characterisation, biological interactions (ecotoxicology), modelling, risk analysis, and novel technology development. Full details are yet to be formally announced. Contact: Dominique Balharry DOLH@nerc.ac.uk

3. Information on any public/ stakeholder consultation

Launch of the "UK Nanotechnologies Strategy: Small Technologies, Great Opportunities"

The UK Government's Nanotechnologies Strategy was published on 18 March 2010.

The Strategy was informed by an evidence gathering consultation exercise, which ran from July-October 2009. The data collected was analysed and considered during the development of the UK Nanotechnologies Strategy.

The Strategy will ensure that the various governance issues are effectively coordinated and demonstrate the work that is being done across UK different departments, agencies and organisations. The aim of the Strategy is that The UK's economy and consumers will benefit from the development of nanotechnologies through Government's support of innovation and promoting their safe, responsible and sustainable development in a way which reflects the needs of the public, industry and academia.

The UK Government Strategy makes a number of commitments including:

- The establishment of a new Nanotechnologies Collaboration Group to facilitate ongoing communication and collaboration between Government, academia, industry and other interested parties;
- A new website to keep the public informed about work on nanotechnologies;
- An ongoing portfolio of Government and publically-funded research into a wide range of crucial EHS issues; and
- The UK continuing to contribute to international work programmes including those of the OECD.

The Strategy can be accessed via the following link: http://interactive.bis.gov.uk/nano/

UNITED STATES

Highlight of developments since the 6th meeting of the WPMN

EPA issued several Consent Orders regulating new chemical submissions of carbon nanotubes under TSCA. (Winter 2009/Spring 2010)

EPA will issue final Significant New Use Rule (SNUR) for three specific carbon nanotubes that were subject to new chemical notification under TSCA. (Summer 2010)

EPA is developing a SNUR under section 5(a)(2) of TSCA to require notification of new nanoscale materials based on existing chemical substances.

EPA has announced its plans to issue a new policy under which pesticide companies would be required to report the presence in their products of nanoscale materials and to provide to EPA any additional information relevant to assessing the safety of the nanoscale material.

NIOSH is sponsoring an upcoming conference on "Nanomaterials and Worker Health: Occupational Health Surveillance, Exposure Registries, and Epidemiological Research", which will be held in Colorado

on July 21-23 2010. More information is available at http://www.cdc.gov/niosh/topics/nanotech/keystone2010/

NIOSH updated its "Strategic Plan for NIOSH Nanotechnology Research and Guidance" (http://www.cdc.gov/niosh/docs/2010-105/) and "Progress Towards Safe Nanotechnology in the Workplace: A Report from the NIOSH Nanotechnology Research Center" (http://www.cdc.gov/niosh/docs/2010-104/).

Work completed, underway or planned

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

Since January 2005 EPA has received and reviewed more than 100 new chemical notices for potential nanoscale materials under TSCA including fullerenes and carbon nanotubes. EPA has permitted manufacture of these nanoscale materials under limited conditions.

On January 24, 2009 EPA issued direct final Significant New Use Rules (SNURs) for two new chemical substances identified as carbon nanotubes. EPA received a notice of intent to submit adverse comments. Under its regulations EPA withdrew the direct final SNURs and published a proposed rule on November 6, 2009. EPA has extended the comment period and received several public comments. EPA will shortly issue a final SNUR which will take into account those comments.

On February 3, 2010, EPA issued a proposed SNUR for a different chemical substance also identified as a carbon nanotube. EPA considers this carbon nanotube a different chemical substance than the carbon nanotube described in the previous paragraph. EPA has received several public comments and will also issue a final SNUR which will take into account those comments.

EPA issued additional Consent Orders regulating new chemical submissions of carbon nanotubes. A sanitised version of such a consent order is available. To date EPA has issued SNURs for less than 40 new chemical nanoscale materials. Because of confidential business information claims by submitters, EPA is unable to identify the chemical substance as a nanoscale material in every new chemical SNUR it issues for nanoscale materials. EPA will continue to issue SNURs for new chemical nanoscale materials in the coming year.

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

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

EPA 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.

NIOSH is developing communication documents which will convey the potential health risks and recommend measures for the safe handling of Carbon Nanotubes as announced in the April 8, 2009, Federal Register Notice on "Request for Information on Carbon Nanotubes (CNTs) Including Singel-Walled Carbon Nanotubes (SWCNTs) and Multi-Walled Carbon Nanotubes (MWCNTs)."

EPA conducted a FIFRA (Federal Insecticide, Fungicide and Rodenticide Act) Scientific Advisory Panel on November 3-6, 2009 in Arlington, Virginia to consider and review a set of scientific issues associated with nanosilver and other nanometal pesticide products. EPA sought advice and guidance regarding hazards and exposures related to such products. For more information including minutes from the meeting please consult http://www.epa.gov/scipoly/sap/meetings/2009/110309ameeting.html.

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

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

2. Developments related to voluntary or stewardship schemes

NIST representatives, in their roles as chair of two of the mirror committees of the US Technical Advisory Group to ISO TC229 (Nanotechnologies) have facilitated cooperation and coordination between OECD-WPMN and ISO TC229. The WPMN has a formal liaison with the ISO TC229 and the two organisations share work results prior to public release. ISO TC229 is assisting the WPMN Sponsorship Programme for the Testing of Manufactured Nanomaterials by compiling information that will be used by the Programme participants to prepare Dossier Development Plans for testing of the 14 priority nanomaterials in the Programme. Specifically, the TC229 is developing a list of physical-chemical parameters such as particle size that should be determined prior to toxicity testing, and the relevant measurands and measurement methods for each parameter. It is anticipated that this ISO document will be released in late 2010.

In addition, the TC229 is developing two new documents, one that will include a listing of existing toxicity testing protocols relevant to nanomaterials, and a sister document that describes relevant sample preparation and dosimetry information. NIST representatives, as Chairs of the mirror committees, have directly solicited input from the WPMN SG4 and SG7 for the development of these two new work items as they are complementary to documents under development in those two steering groups.

3. Information on any risk assessment decisions

EPA has assessed more than 100 new chemical notices for potential nanoscale materials under TSCA since January 2005.

4. Information on any developments related to good practice documents

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

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

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

"Carbon nanotubes degraded by neutrophil myeloperoxidase induce less pulmonary inflammation," Kagan V.E., Konduru N.V., Feng W., Allen B.L., Conroy J., Volkov Y., Vlasova I.I., Belikova N.A., Yanamala N., Kapralov A., Tyurina Y.Y., Shi J., Kisin E.R., Murray A.R., Franks J., Stolz D., Gou P., Klein-Seetharaman J., Fadeel B., Star A., Shvedova A.A., Nature Nanotechnology, 2010, 5, 354 – 359.

"Potential for Occupational Exposure to Engineered Carbon-Based Nanomaterials in Environmental Laboratory Studies," Johnson D.R., Methner M.M., Kennedy A.J., Steevens J.A. Env. Health Pers., 2010, 118(1), 49-54.

"Nanoparticle Emission Assessment Technique (NEAT) for the Identification and Measurement of Potential Inhalation Exposure to Engineered Nanomaterials – Part A," Methner M., Hodson L., Geraci C. J. Occ. Env. Hygiene, 2010, 7(3), 127-132.

"Nanoparticle Emission Assessment Technique (NEAT) for the Identification and Measurement of Potential Inhalation Exposure to Engineered Nanomaterials – Part B: Results from 12 Field Studies," Methner M., Hodson L., Dames A., Geraci C. J. Occ. Env. Hygiene, 2010, 7(3), 163-176.

6. Information on any public/ stakeholder consultation

On March 30-31 2010, the US National Nanotechnology Initiative (NNI) held a workshop titled, "Risk Management Methods & Ethical, Legal, and Societal Implications of Nanotechnology: Living with Nanomaterials -- Maximizing the Benefits, Minimizing the Risks." The workshop probed the state of the science for risk management methods and the ethical, legal, and societal implications of nanotechnology, and identified gaps and emerging trends in nanotechnology-related environmental, health, and safety research. The NNI will issue workshop proceedings later this year, and the proceedings will serve as input for the next version of the NNI's EHS research strategy.

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

EUROPEAN COMMISSION

Highlight of developments since the 6th meeting of the WPMN

- **November 2009:**

3rd Nano Safety for Success Dialogue: Building Trust in Nanotechnologies Brussels, 3-4 November 2009 (already described in previous report see: http://ec.europa.eu/health/ph_risk/ev_20091103_en.htm for details)

Nanotechnologies for sustainable development. On completion of the term of the European Commission's 'Nanosciences and nanotechnologies: An action plan for Europe 2005-2009', nearly 100 delegates met in Brussels, under the auspices of the Swedish Presidency, to consider the way ahead, with particular regard to the issues of nanotechnologies in relation to sustainable development.
Report available: http://ec.europa.eu/nanotechnology/pdf/swedish-presidency-event-summary_en.pdf

Public consultation- RTD Commission's Recommendation on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research: The Commission launched a public consultation from 20/10/09 until 03/01/10, for the first revision of the Commission's Recommendation on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research.
http://europa.eu/sinapse/directaccess/science-and-society/e-debates/nano-recommendation-2010/

- **December**

4th Meeting of the Competent Authorities subgroup on Nanomaterials (CASG Nano) **for the REACH Regulation** 9 December, Bruxelles. Issues such as the REACH Implementation Project on Nanomaterials (RIPoNs) substance identification, overview of approaches to nanomaterial definitions, communication in the supply chain, nanomaterial information in IUCLID (International Uniform ChemicaL Information Database), alternative testing methods for nanomaterials, ERANET cooperation on nanosafety were addressed.
IUCLID website at ECHA: http://iuclid.echa.europa.eu/index.php?fuseaction=home.project

Public Consultation- The Commission launched a public consultation launched from 17-12-2009 to 19-02-2010 as part of the preparation a new Action Plan for Nanotechnology.
http://ec.europa.eu/research/consultations/snap/consultation_en.htm

- **January 2010**

The **NANOCODE project** has been launched on 1st January 2010 **in support to the Commission's Recommendation on a Code of Conduct for Responsible Nanosciences** and Nanotechnologies Research. The objective of NanoCode is to define and develop a framework aimed at supporting the successful integration and implementation, at European level and beyond, of the Code of Conduct (CoC) for nanosciences and nanotechnologies (N&N) research as developed by the European Commission. See: www.nanocode.eu

- **February**

Outcomes of Public Consultation for the first revision of the Commission's Recommendation on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research**.** The consultation has

been opened to all stakeholders directly or indirectly involved or interested in Nanosciences and Nanotechnologies Research.

The most striking figures by categories are the following:

- 70 % of respondents from industry knew the CoC before the consultation;
- 100% of respondents from policy making think that the CoC should be revised and that it should not be limited to research; and
- 100 % of respondents from civil society organisations think that research should be more appropriately regulated.

Consultation results: http://ec.europa.eu/research/consultations/nano-code/results_en.pdf

Outcomes of Public Consultation on Nanomaterials and Nanotechnology. Launched in December to support the preparation of a new action plan for nanotechnologies in Europe for 2010 to 2015. The main conclusion is that both experts and the general public see many benefits in nanotechnologies (more than 80% of respondents have either high or reasonable expectations of nanotechnologies) but also potential risks. The major concerns regarding policy centre on the safety of **nanomaterials** and their **regulation**. There is a perceived need to **strengthen** action in all areas of nanotechnology strategy pursued until now, from research and innovation to safety and outreach. Consultation results: http://ec.europa.eu/research/consultations/snap/report_en.pdf

- **March:**

-Fifth Ministerial Conference on Environment and Health "Protecting children's health in a changing environment" Parma, Italy, 10–12 March 2010

EC supported the Parma Declaration on Environment and Health. The declaration calls for "concerns raised by persistent, endocrine-disrupting and bio-accumulating harmful chemicals and (nano) particles; and by novel and emerging issues" and "for an increase of research into the use of nanoparticles in products and nanomaterials"

http://www.euro.who.int/parma2010

http://ec.europa.eu/health/healthy_environments/docs/parma_declaration_en.pdf

-The Commission publishes the **tender for project** entitled**: "industrial emissions of nano- and ultrafine particles"**. The overall objective of the project is to improve the understanding of emissions of nanomaterials and ultrafine particles in order to contribute to the setting of priorities for policies directed towards the regulation of those. Ref. ENV.C.3/SER/2010/0006

-Vice President Tajani and Commissioner Potočnik visit the European Chemical Agency in Helsinki (ECHA). See link for further details:

http://ec.europa.eu/enterprise/newsroom/cf/itemshortdetail.cfm?lang=fr&item_id=4143

-Kick-off of the **NanoGenoTox project** co-ordinated by AFSSET, which aims at providing a Safety evaluation of manufactured nanomaterials by characterisation of their potential genotoxic hazard. Several of the nanomaterials in the sponsorship programme are included in this project.

AFSSER press release: http://www.afsset.fr/index.php?pageid=452&newsid=545&MDLCODE=news

- **April:**

Joint CASG Nano and ENPRA Workshop on Early Harvest of Research Results on Nanosafety, 14-15 April, Ispra Joint Research Centre, Italy.

The workshop was organised by the Institute for Health and Consumer Protection (IHCP) of JRC together with Directorate Enterprise and Industry and the ENPRA project of FP7 on Risk Assessment of

Engineered Nanoparticles. The aim was to facilitate the discussion between researchers, regulators and stakeholders on research results that are relevant to the recently started REACH Implementation Projects on Nanomaterials (RIPoNs see next paragraph). For further information and to download the presentations:
http://ihcp.jrc.ec.europa.eu/docs/nbs_enpra/presentations_nano_workshop.pdf

➢ **May:**

5th Meeting of the Competent Authorities subgroup on Nanomaterials (CASG Nano) **for the REACH Regulation** 3-4 May Bruxelles.

The CASG Nano was informed about the Commission mandate to the SCENIHR on the scientific elements of the definition of nanomaterials and agreed to ask for the CARACAL endorsement for the documents on the Nanomaterials' information in IUCLID 5.2 and Overview of definitions of nanomaterials. RIPoN 1, 2 and 3 state of play were addressed (see next paragraph for details).

Work completed, underway or planned

➢ **The Nano Action Plan 2010-2015: Impact assessment**

The Impact Assessment for the new Nanotechnology Action Plan 2010-2015 is based on three pillars:
- Strengthen the societal dimension of Nanotechnologies
- Ensure high levels of consumer, worker and environmental protection
- Stimulate innovation and sustainable growth in the EU with Nanotechnologies

For each of these pillars, the problems and the objectives are identified. After that, three policy options are proposed, of which the societal, environmental and economic impacts, as well as the impacts on the three pillars are assessed. The preferred option will eventually lead to the new Action Plan.

Specific actions, covering the three pillars, will be defined in the Action Plan itself. The new Nanotechnology Action Plan 2010-2015 is expected to be adopted by the European Commission on November 2010.

➢ **Key Enabling Technologies:** Nanotechnology has been identified as one of the Key Enabling Technologies (KETs) in the Commission Communication 512(2009) from September 2009. As foreseen in the Communication a recently selected High Level Group will assess the competitive situation of the relevant KETs and develop a detailed strategy and recommend appropriate policy measures with an associated roadmap for a more effective deployment of KETs in Europe. As such, the KETs forms part of the new EU2020 strategy and are highlighted under two EU flagship initiatives, namely the "Innovation Union" and "An industrial policy for the globalisation area". The HLG is expected to hold a first meeting on the first half of July 2010.
http://ec.europa.eu/enterprise/sectors/ict/key_technologies/index_en.htm

➢ **REACH Implementation Projects on Nanomaterials (RIPoN)**

Three projects are in progress. The projects deal with Substance Identification (RIP-oN1), Information Requirements (RIP-oN2) and Chemical Safety Assessment (RIP-oN3). The projects' steering group consists of the JRC, the Commission's Directorates General for Environment and for Enterprise & Industry as well as the European Chemicals Agency (ECHA). The final output of the projects will be considered by ECHA, responsible for potential REACH guidance updates.

➢ **Nanomaterials definition**

The European Commission is currently developing a broadly applicable and enforceable working definition for nanomaterials. In support of this effort, a specific opinion of Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) is in preparation, and the Joint Research Centre of the European Commission is currently preparing a report on "Practical Considerations on Definitions for Nanomaterials for Regulatory Purposes". It will soon be published on the JRC website as a Reference Report.

See:

SCENIHR Request for a Scientific Opinion via Accelerated Procedure: Scientific basis for the definition of the term "nanomaterial"

http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_q_024.pdf

And

http://ec.europa.eu/dgs/jrc/index.cfm?id=2510

- **Safety for Success Nano Dialogue(s)**

After the annual initiatives, SANCO will promote further four nano-dialogues with two years, to be targeted on specific issues and to bring together the four main groups of stakeholders: Industry, Civil Society, Academia and Regulators. Next one will be the 15 June and its theme will be the application of nanotechnologies in textiles

- **TEC (Transatlantic Economic Council) Innovation Workprogramme - Nanotechnologies workstream**

As part of the forthcoming TEC Innovation Workprogramme which the European Commission and the US Department of Commerce are currently discussing, both parties will be agreeing to exchange information on how to create socio-economic value around nanotechnologies and how to promote a culture of openness to speed up market development. Work will also include the identification of barriers to the development of nanotechnologies and associated trade flows, such as inadequate (insufficient or too strict protection of) IPRs and also education/skills related barriers. Furthermore, this work could serve to make progress in the adoption of common US-EU business practices so as to influence emerging markets for nanotechnology products. Work should build on the work being done by international organisations such as the OECD and the ISO. First deliverables are expected in 2011.

- **Nanomaterials repository** for research projects has been set up at JRC-IHCP and available also to the OECD WPMN sponsorship programme, as standard samples to be shipped to the users. The repository currently contains titanium dioxide, silicon dioxide, carbon nanotubes, zinc oxide, nano-silver and ceria in a number of different qualities.

- **Code of Conduct:** Further to the public consultation for the first revision of the Commission's Recommendation on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research and further to a series of seminars with Member States, it is planned to adopt the revised Recommendation in 2010 (date to be communicated later on).

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

New website for the DG RTD NMP initiative EU Nanosafety cluster, to maximise the synergies between the existing FP6 and FP7 projects addressing all aspects of nanosafety including toxicology, ecotoxicology, exposure assessment, mechanisms of interaction, risk assessment and standardisation

www.nanosafetycluster.eu

- A **"Compendium of Projects in the European NanoSafety Cluster"** was published in March 2010. This is meant to be a dynamic document, with frequent updates consisting of project summaries, research work posters, and research actors.

ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/compendium-nanosafety-cluster2010_en.pdf

7th EU Research Framework Programme (FP7).

New funded projects under the following themes of the third call for proposals:

"Use, recycling and final treatment of nanotechnology based products as well as coordination on exposure scenarios to nanoparticles" (NMP Joint call with Theme 6: Environment - Climate Change):

- **NANOPOLYTOX**: Toxicological impact of nanomaterials derived from processing, weathering and recycling of polymer nanocomposites used in various industrial applications
- **NANOFATE**: Nanoparticle Fate Assessment and Toxicity in the Environment
- **NANOHOUSE**: Life Cycle of Nanoparticle-based Products used in House Coating
- **NANOSUSTAIN**: Development of sustainable solutions for nanotechnology-based products based on hazard characterisation and LCA

"Exposure scenarios to nanoparticles:

- **NANEX**: Development of Exposure Scenarios for Manufactured Nanomaterials

Analytical tools for characterisation of nano-particles in the food matrix (KBBE-2009-2-4-1):

- **NANOLYSE**: Nanoparticles in Food: Analytical methods for detection and characterisation

Under the fourth call, projects are in evaluation or in negotiation phase:

"Methods for managing the risk of Engineered Nanoparticles (ENs): in evaluation phase

"*Modelling toxicity behaviour of ENs" (joint call with USA)*: Five proposals shortlisted, in awaiting of the US evaluations.

"Research Infrastructures for processing, analysis and characterisation (physico-chemical properties, health and environmental impact) of engineered nanomaterials, nanoparticles and nanostructures": one proposal in negotiation

"Coordination of national programmes on nanotechnologies including nanotoxicology": one proposal in negotiation

From COOPERATION Theme 6 – Environment (Including Climate Change)

Activity: 6.3 Environmental Technologies Sub-Activity: 6.3.3. Technology Assessment, Verification and Testing

- **PROSUITE:** Development and application of standardised methodology for the PROspective SUstaInability assessment of TEchnologies

BUSINESS AND INDUSTRY ADVISORY COMMITTEE (BIAC)

PART I: ACC

The American Chemistry Council Nanotechnology Panel (Panel) participates in national and international forums to promote the use of nano-enabled products and technologies. The Panel continues its support of the research coordinated by the U.S. National Nanotechnology Initiative, and the activities of

the OECD WPMN and ISO TC 229. The Panel and the California Nano Industry Network in conjunction with the California Department of Toxic Substances Control (DTSC) conducted a workshop in Sacramento, California on November 16, 2009 to discuss California's data call-in for carbon nanotubes and exchange related information. The Panel continues to work with the Network, DTSC, and the Office of Environmental Health Hazard Assessment on data call-ins and other policies/programs addressing manufactured nanomaterials.

A long-time supporter of U.S. Environmental Protection Agency's (EPA) Nanoscale Materials Stewardship Program (NMSP), the Panel continues to discuss with EPA the further implementation of the Toxic Substances Control Act (TSCA) authorities to collect data under Section 8a, implement test rules (Section 4) for specific types of manufactured nanomaterials, and issue a generic significant new use rule (Section 5) addressing nanomaterials currently in commerce. The proposed rules are scheduled to be released for comment late in 2010. In addition, the Panel continues to explore non-occupational exposure and environmental fate and effects research opportunities with EPA's Office of Research and Development. Recognizing the importance of a regulatory-based definition for "nanomaterial", the Panel continues to work with CEFIC, JCIA, and VCI to provide increased clarity and consistency with respect to the term *nanomaterial* for use in regulations. This definition is based from the ISO approved definition of a "nano-object". Additional assessment of materials identified by this definition will vary on a material by material basis and will involve consideration of both hazard and exposure potential in the assessment of risk. This definition can then be used by stakeholders in upcoming reviews and discussions on approaches to regulate manufactured nanomaterials.

ACC and its Nanotechnology Panel support the modernisation of TSCA. ACC continues to evaluate the TSCA modernisation amendments introduced in the U.S Senate and outlined for introduction in the U.S. House of Representatives. These amendments currently do not mention nanotechnology in name, but several provisions of the amendments may have an impact on the introduction of new substances or new technologies, including nano. The amendments are not expected to be enacted this year.

Additional information is available at www.americanchemistry.com/nanotechnology.

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.

- Earlier this year, a Guidance was published governing 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 nanomaterials, nanotechnologies and nano-enabled products that help answer the social and environmental challenges and respond to the changing needs of society to improve quality of life of

this and future generations. We will ensure that our nanomaterials, products and technologies are researched, designed, manufactured and used safely and responsibly throughout their entire life cycle. We will initiate dialogue and engagement with stakeholders to ensure that the products we market answer the needs and priorities of our customers and stakeholders and make a strong contribution to boosting the European economy.

Work underway or planned

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

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

At the end of last year 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 the how to conclude on 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. All projects are foreseen to be finalised by the end of the year.

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 it 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 initiatives at the global level.

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

Through its Long-range Research Initiative (LRI), Cefic sponsors health and environment safety research on nanomaterials. 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.

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 nanoparticle specific effects in environmental toxicity testing”. The research is being led by the group of Dr Alistair Boxall, at the University of York. The outcomes of the project will help determine the environmental impact of nanomaterials in aquatic systems.

Both projects - started in December 2008 and will be finalised in December 2010- are contributions of Cefic (via BIAC) to the Sponsorship Programme of the OECD Working Party of Manufactured Nanomaterials

Finally, a third Cefic-LRI project has been launched is on testing and assessment of reproductive toxicity of Nanomaterials. The overall objective of this proposal is to analyze the suitability of current OECD guidelines to assess the reproductive toxicity of nanomaterials. Using two reference materials, present on the OECD list of 'representative manufactured nanomaterials for testing' (1), nano silicium dioxide and nano zinc oxide, the ability of current reproductive toxicity OECD guidelines to identify hazard associated with nanomaterials will be tested in this project. The 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?

Stakeholder Engagement

Cefic started its stakeholder engagement activities in June 2008: http://www.cefic.org/en/582.html. The aim was to facilitate an open and frank exchange of information so that industry, policy makers and other stakeholders could gain a better understanding of each other's point of view. During that first event, four Cefic companies shared information about functionality (how and why "nano" improves performance), safety and benefits – by using concrete examples from real-life situations. Our stakeholders were interested to understand the "what, how and why" of nano - as well as getting to grips with each step of the safety process: from research to production, marketing and end-of-life. Since then, we have kept to the "functionality - safety - benefits" approach to information-exchange, with the use of real-life examples, because we have found that this approach works well to increase understanding and helps focus the resulting debate on concrete issues.

Following the June 2008 event, Cefic built closer links to specific stakeholder groups such as academia, trade unions and regulators. Indeed, we now work with EMCEF (the European Chemical Workers Federation) on social dialogue around worker protection issues: http://www.emcef.org/Committees/cmt-show.asp?job=SD.

More recently, Cefic's Responsible Care programme looked at how it addresses novel technologies with a focus on nanotechnologies. The resulting report – designed to be continuously updated – is now publicly available: http://www.cefic.org/en/579.html. We also established a "Cross Industry Platform" for organisations sharing a common interest in nanomaterials, either as producers or downstream users. This platform enables the exchange of views and information about all aspects of nanomaterial issues at European and international level.

Finally, Cefic is now working directly with the European officials in order to increase common understanding of the issues and challenges around proportionate and efficient nano-regulatory frameworks that ensure safety whilst stimulating innovation and keeping Europe competitive.

PART III: JCIA

The Japan Chemical Industry Association (New Topics Working Group) is committed to the ongoing development of the nanotechnology industry, particularly with respect to safe and secure nanomaterial evaluation techniques for use in Japan and elsewhere based on the Action Plan set out in Nanomaterial Opinion Statement issued in July 2008.

Major initiatives are listed below.

(July 2009 –December 2009)

1. Ministry of Economy, Trade and Industry circular entitled "Nanomaterial Safety Measures" called for voluntary provision of safety information by the relevant industrial groupings in six nanomaterial categories: titanium dioxide, zinc oxide, silica, carbon black, CNT, and fullerene.

2. In December 2009 the Working Group submitted information on titanium dioxide and CNT including safety data, self-management procedures, and production volumes and applications.

(October 2009)

3. The Working Group analyzed the *Intermediate Report on Nanomaterial Risk Evaluation* released by the National Institute of Advanced Industrial Science and Technology (AIST) and forwarded an executive summary to member companies. The Working Group also briefed BIAC representatives on the report at the 6th OECD WPMN.

4. The Working Group has forwarded opinion statements to certain companies regarding nanomaterial hazard research papers published in Japan and elsewhere that are deemed to be of dubious scientific merit.

5. The Working Group has actively contributed to projects such as the Study Group on Information Usage and Dissemination to Promote Public Acceptance (since June 2008) and the Nanotechnology Standardisation Domestic Committee (since September 2008). These projects were set up by AIST, an OECD follow-up group. The Working Group has also taken part in international workshops run by the Japan National Institute of Occupational Safety and Health (JNIOSH) and was involved in preparation of the report of a Study Group of domestic experts entitled *International Trends in Worker Health and Safety in Nanoparticles Industries*.

(February 2010)

6. The Working Group delivered a presentation on studies of nanomaterial safety conditions in the OECD region to a member organisation, the Japan Titanium Dioxide Industry Association.

7. The Working Group delivered a presentation on nanomaterial standardisation procedures in OECD WPMN to the Workshop on International Nanotechnology Standardisation at Tokyo Big Sight through the Nanotechnology Standardisation Domestic Committee, and also served as a panelist at the event.

8. Representatives from the Working Group will serve on the TC 229 International Committee (June 2010, the Netherlands) to discuss standardisation of TiO2 specifications for inclusion in ISO TC 229. (The Working Group plans to raise issues with China's proposals for TiO2 material specifications.)

PART IV: NIA

The Nanotechnology Industries Association (NIA) provides the Lead Sponsor to the OECD WPMN Sponsorship of ZnO, as well as the Co-Lead Sponsor to the OECD WPMN Sponsorship of CeO_2, through coordination of ***PROSPEcT*** (*i.e. Ecotoxicology Test Protocols for Representative Nanomaterials in Support of the OECD Sponsorship Programme*), a Public-Private-Partnership between the UK Government and several industrial NIA members (PPP duration: 3 years; started: 1st January 2009; total value: GBP 3.7 Million).[21]

[21] 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

One year into the project, it has delivered all of its agreed deliverables and milestones which include protocols (please refer to the PROSPEcT website for more details, or to download the relevant protocols or watch a movie on the dispersion of nanoparticles: http://www.nanotechia-prospect.org/publications/basic) and continues to provide contributions and peer review to other protocols, as well as drivers to their discussion and harmonisation across and beyond the OECD WPMN Sponsorship Programme.

The NIA has further recently been successful in providing additional materials and representation of companies to the OECD WPMN (e.g. nano-silver).

(Other) NIA Projects:

Safety Assessment:

1. In late 2009, the NIA participated in the conduct ***Research into the likelihood and possible pathway of human exposure via inhalation arising throughout the lifecycle of a selection of commercially available articles containing carbon nanotubes***. This project was funded by the UK Department for Environment, Food and Rural Affairs (DEFRA) and the resulting report is currently in the process of being published by DEFRA.
2. Since December 2009, the NIA is conducting a research project *on* ***Development of Exposure Scenarios for Manufactured Nanomaterials (NANEX)***. The aim of the NANEX project is to develop a catalogue of generic and specific exposure scenarios for manufactured nanomaterials (MNMs) relevant for human exposure taking account of the entire lifecycle of these materials. NANEX will collect and review available exposure information and develop a set of generic exposure scenarios for three very relevant MNMs: (1) high aspect ratio nanomaterials - HARNs, (2) mass-produced nanomaterials, and (3) specialised nanomaterials that are currently only produced on a small scale. Data collected will include both quantitative (measurement results if available) and qualitative, contextual exposure information (risk management measures). In support of the project targets, the applicability of existing models for estimating occupational and consumer exposure as well as available model for estimating environmental release and human exposure through the environment will be reviewed and a small number of specific case illustrations, covering occupational, consumer and environmental release/exposure scenarios and carry out a gap analyses of the available knowledge and data and define research priorities will be conducted.[22]
3. Since January 2010, the NIA conducts ***REACH Implementation Plans on Nanomaterials (RIP-oNs):[23] Scientific and technical Support on Nanomaterials.***

RIP-oN2: 'Specific advice on fulfilling information requirements for nanomaterials under REACH[24]

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.

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

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

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

- 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[25]

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 project and shall cover:
- development of Exposure Scenarios,
- evaluation of operational conditions and risk management/mitigation measures and
- exposure estimation;
- Develop ideas for how to conduct hazard and risk characterisation for nanomaterials. The latter will involve threshold/non-threshold considerations.

Benefits of Nanotechnologies:

The NIA recently commenced a project entitled ***'Valuing Nanotechnologies - Methodology for estimating, in monetary terms, the benefits of nanotechnology'.***[26]

This project will address this issue by developing a methodology to quantify the value of a nanotechnology in comparison to conventional products. The methodology will be flexible; enabling specific geographic regions or industry sectors to be analysed in order to identify where the monetary benefit of the nanotechnology resides. It will also describe how the benefits are apportioned between users, manufacturers and the wider economy/environment. To simplify the methodology, various proxies and assumptions will be explored, in order to reduce the need to gather large amounts of information. On completion of the project the results and findings will be presented to the OECD to encourage developing a consistent methodology for valuing nanotechnology.

Communication:

In 2009, the NIA organised and offered a Advanced Workshop Course in Public Communication and Applied Ethics for Nanotechnologists. 27 The course was organised under the auspices of the Nanotechnology Industries Association and kindly funded by The Royal Academy of Engineering Ingenious Public Engagement Grants Programme to provide funding for projects that enable engineers to enhance their public engagement skills, consider the societal implications of their work and take part in debate with the public on engineering and its impact on society. 21 international representatives from academia and industry attended this year's 5-day intensive course and received training in a number of disciplines relevant to public communication and applied ethics.

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

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

[27] Follow these links to find out more about the Advanced Communications Project: http://www.nanotechia.org/content/activities2/current-projects/ingeniouscourse20090322/ or http://www.nanotechia.org/news/nia/praise-for-nia-workshop-on-public-communication-a

Commercialisation:

The NIA is currently conducting research into Best Practices for IPR and Technology Transfer in Nanotechnology Developments.[28] The Nano2Market project aims to develop and provide guidelines for technology transfer, rules for IPR and license agreements and license models in nanotechnology development projects. To achieve these objectives the project team is constructing value chains of the transfer of each technology, and aims to analyse specific representative applications of the different areas of the nanotechnology R&D European strategy: medical applications, information technologies, energy, materials, manufacturing, instrumentation, food, environment and security. The objective is to classify the technology application areas of nanotechnologies into different clusters according to: development cost, time-to-market, complexity of licensing, etc. In parallel, the actual and forthcoming market will be mapped and analysed according to competitiveness, geographical area, development potential, risks, etc. Specific data mining tools will help to conclude the key worldwide actors of development and commercialisation of the different technologies. Actual IPR cultures and technology transfer rules will be listed according to the features of their market and technology; matching thee IPR and technology transfer models with the concluded value chains and market and technology maps will result in the recommendation of best practice business models and efficient rules for technology transfer.

In agreement with the OECD WPN, the findings of the Nano2Market project final Nano2Market Dissemination event will be shared with the OECD WPN.

Market-Specific R&D:

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

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

Nanofluids (carrier liquids into which particles smaller than 100 nanometers have been dispersed) have shown significantly enhanced thermal properties in comparison to traditional cooling fluids. Two separate methods will be employed to produce the purpose designed nanofluids during the project. A single-stage process will employ wet chemical synthesis to form and disperse tailored nanoparticles within a carrier fluid and a two-stage batch process will add pre-produced nanoparticles to a carrier fluid.

Using both Risk- and 'Life Cycle'-Assessments, NanoHex will also evaluate the health and safety of nanofluid coolants and their potential impact on the environment. These results will then form an important component in assessing the final products overall economic viability.

Ultimately, the project will develop two different demonstrators for the cooling of Data Centres and Power Electronic Components, in order to illustrate the viability of using such nanofluids to reduce energy consumption and operating costs, cut carbon emissions, extend product reliability and enable the development of more sustainable processes and products.

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

Governance of Nanotechnologies:

Since 2006, the NIA is instrumental in the development and promotion of the Responsible Nano Code.[29]

Forecast of Emerging Technologies:

In 2007, the NIA conducted a survey amongst its members, in order to develop a Forecast of Emerging Technologies based purely on industrial opinion.30 The forecast makes exclusive use of data obtained from the industrial members of the NIA, thereby delivering a clear outline of the industrial development path for nanotechnology and its advancement over the next 15 years into more complex nanomaterials, structures and systems. The forecast examines the existing opinion of the economic potential for nanotechnologies and provides a 2020-view of the emerging technologies' impact.

A 2nd edition of the forecast is planned for 2010/2011.

Workshops & Reports:

In 2007, the NIA held an NIA Masterclass & Workshop: MICROMEGA – REACH for Nanomaterials, in order to shed light onto the past discussion around nanomaterials as part of the REACH Regulation, to clarify their current status within the legislation that was passed by the European Parliament and the Council of Ministers on the 18th December 2006, and to subsequently investigate necessary management strategies in the nanotechnology industries.31,32

Publications:

1. Consultation Responses & Evidence (interactive list):[33]

- ***May*** ***2010:***

NIA Comments on *DRAFT Report (compiled by the University of California at San Francisco's (UCSF) Program on Reproductive Health):* **'A Nanotechnology Policy Framework for California: Policy Recommendations for addressing potential Health Risks from Nanomaterials'**

- ***February*** ***2010:***

NIA consolidate comments to the European Commission Consultation **'Towards a Strategic Nanotechnology Action Plan (SNAP) 2010-2015'**.

- ***February*** ***2010:***

NIA comments on Australian Government (Department of Health and Ageing, National Industrial

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

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

[31] Follow this link to download the complete report: *NIA Masterclass & Workshop: Micromega - REACH for Nanomaterials*.

[32] Follow this link to find out more about the NIA Masterclass & Workshop MICROMEGA: http://www.nanotechia.org/content/publications/reports/

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

Chemicals Notification and Assessment Scheme (NICNAS) **'Proposal for Regulatory Reform of Industrial Nanomaterials'**.

- ***June*** ***2009:***

NIA Comments on Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) **'Opinion on Risk Assessment of Products of Nanotechnologies'**: **Submitted Version** (shortened and heavily abbreviated due to restrictions)

NIA-published Version (un-abbreviated and available from this website only)

- ***February*** ***2010:***

NIA Comment on the Australian Government, Department of Health and Ageing, National Industrial Chemicals Notification and Assessment Scheme **'Proposal for Regulatory Reform of Nanomaterials'**

- ***March*** ***2009:***

NIA Comment on the UK House of Lords Science and Technology Select Committee '**Call for Evidence: Nanotechnologies and Food'**

- ***March*** ***2009:***

NIA Comments to the US Environmental Protection Agency (EPA) on the **'Petition for Rulemaking Requesting EPA Regulate Nanoscale Silver Products as Pesticides' [EPA-HQ-OPP-2008-0650]**

- ***December*** ***2008:***

NIA Comment on EFSA '**Draft Opinion of the Scientific Committee on the Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety' (**Question No EFSA-Q-2007-124)

- ***September*** ***2007:***

NIA Comment on **'Preliminary Opinion on Safety of Nanomaterials in Cosmetic Products'** (Preliminary Opinion of the Scientific Committee on Consumer Products (SCCP) of the European Commission (EC))

- ***September*** ***2007:***

NIA Comment on US EPA **'Concept Paper for the Nanoscale Materials Stewardship Program under TSCA & TSCA Inventory Status of Nanoscale Substances – General Approach'** [EPA-HQ-OPPT-2004-0122]

- ***September*** ***2007:***

Response to European Commission's consultation paper **'Towards a code of conduct for responsible nanoscience and nanotechnologies research'** (in collaboration with the Responsible Nano Code Founding Partners: The Royal Society, Insight Investment, and the Nanotechnology KTN)

- ***July*** ***2007:***

NIA written evidence to the UK Royal Commission on Environmental Pollution '**Study on the Environmental Effects of Novel Materials and Applications'**

- ***May*** ***2007:***

NIA Comment on the Public Consultation on '**Appropriateness of the EU Technical Guidance Documents (TGD) of chemical legislation for nanomaterials'** (Opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) of the European Commission (EC), approved on 29th March 2007)

- ***May*** ***2007:***

NIA Response to the UK Government Council for Science and Technology report: **'Nanosciences and Nanotechnologies: A Review of Government's Progress on its Policy Commitments'**

- ***February*** ***2007:***

NIA Comments on the **Draft Nano Risk Framework** by the 'Environmental Defense – DuPont' Nano Partnership

- ***January*** ***2007:***

NIA Feedback on the US NNCO report **'Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials'**

- ***November*** ***2006:***

NIA Feedback on the German Government report: **'BAuA – Bundesanstalt fuer Arbeitsschutz und Arbeitsmedizin on the proposed research strategy'**

- ***October*** ***2006:***

NIA Feedback on the UK Government report: **'Characterising the potential risks posed by engineered nanoparticles - UK Government research – a progress report'**

- ***October*** ***2006:***

NIA Response to the UK Council for Science and Technology **'Call for evidence on Nanoscience and nanotechnologies: opportunities and uncertainties - Two-year review of progress on Government actions'**

- ***June*** ***2006:***

NIA Response to the (UK Government (DEFRA)) Consultation on a proposed **'Voluntary Reporting Scheme for engineered nanoscale materials'**

2. Statements & Opinions:[34]

- ***November*** ***2009:***

NIA joins **SEMI Europe Comments on the European Commission's Communication *"Preparing for our future: Developing a common strategy for key enabling technologies in the EU"* {COM(2009)512}**

- ***March*** ***2009:***

NIA Statement on the publication of the '**Opinion of the Scientific Committee on the Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety**' (adopted by EFSA on 10 February 2009)

- ***November*** ***2008:***

NIA Comment on the **Twenty-seventh Report of the (UK) Royal Commission on Environmental Pollution, entitled *'Novel Materials in the Environment: The case of nanotechnology'***

- ***November*** ***2008:***

NIA Comment on the issuing of a new coverage exclusion form ***'CW 33 69 06 08 – Nanotubes and***

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

Nanotechnology Exclusion and associated Policyholder Notice PN 61 61 07 08' **(Continental Western Group)**

- ***September*** ***2008:***

NIA Letters to the **REACH Competent Authorities Subgroup on Nanomaterials (CASG Nano)** (in collaboration with CEFIC, EMA, and IMA Europe)

- ***September*** ***2008:***

NIA Comment on the paper entitled ***'In Vivo Skin Penetration of Quantum Dot Nanoparticles in the Murine Model: The Effect of UVR'*** (Mortensen et al., Nano Letters; 2008; ASAP Web Release Date: 08-Aug-2008; (Letter) DOI: 10.1021/nl801323y)

- ***May*** ***2008:***

NIA Statement on the publication of a paper entitled ***'Carbon nanotubes introduced into the abdominal cavity display asbestos-like pathogenic behaviour in a pilot study'*** (Poland et al., Nature Nanotech 3(6) (2008), online: 20th May 2008) [registered NIA Members can download the ***'NIA Suggested FAQs'***, and the ***'NIA Statement'***, prepared in response to the paper, from the *'Members only'-area* on the NIA website, by following the link to *'NIA Press Briefings, FAQs & Positions'*]

PART V: VCI

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

Principle documents:

- Implementing Responsible Care® for a Responsible Production and Use of Nanomaterials
- **Regulatory documents:**
- Requirements of the REACH Regulation on Substances which are Manufactured or Imported also as Nanomaterials
- Guidance for a Tiered Gathering of Hazard Information for the Risk Assessment of Nanomaterials
- Guidance for Handling and Use of Nanomaterials at the Workplace
- Guidance for the Passing on of Information along the Supply Chain in the Handling of Nanomaterials via Safety Data Sheets
- Guidance for Safe Recovery and Disposal of Waste containing nanomaterials
- Strategy Paper of the German Chemical Industry on the Standardisation of Nanomaterials

Documents on safety research:

- Roadmap for Safety Research on Nanomaterials
- Environmental Aspects of Nanoparticles
- Results of 10 years Research in Nanosafety (Working title, German version in preparation)

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

Together with its sector groups VCI will present the results of research on potential release of nano particles from end products probably by end 2010. The projects refer to different areas of nanomaterial application. Some safety research has already been published other projects are in preparation.

VCI is currently compiling information on nanoparticle exposition at the workplace and in the environment. The project aims at deriving best practices for exposition measurement. The results are intended to be published on scientific and political level.

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

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

Having discussed the issue within its membership, VCI plans to continue its engagement in stakeholder dialogue activities in the field of nanomaterials and environment. For 2011 a workshop with stakeholders and authorities is planned.

Furthermore VCI and its membership are supporting and sponsoring the international workshop on "Workplace aerosols" held in Karlsruhe, Germany from June 30 to July 2 2010.

More information is available at www.vci.de

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

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

The International Organisation for Standardization Technical Committee (ISO/TC) 229 - Nanotechnologies - was established in June 2005 with a UK secretariat and chair. It has held ten meetings to date, with the most recent in Maastricht, the Netherlands, in May 2010. The next meeting will be in December 2010 in Kuala Lumpur, Malaysia. The committee currently has 44 members - 35 "P" and 9 "O". The first two documents developed by the committee were published in 2008: ISO/TS 27687 – Nanotechnologies – Terminology and definitions for nano-objects – nanoparticle, nanofibre and nanoplate; and ISO/TR 12885 – Nanotechnologies - Health and safety practices in occupational settings relevant to nanotechnologies; and the third, ISO TS 80004-3: Vocabulary – carbon nano-objects – was published in May 2010. It is expected that the number of published documents will increase by 10 – 15 over the next 12 months.

The TC structure consists of 4 working groups (WG), the first two of which are Joint Working Groups (JWG) with IEC/TC 113 (Nanotechnology standardization for electrical and electronic products and systems): Terminology and Nomenclature (JWG1, convened by Canada); Measurement and Characterization (JWG2, convened by Japan); Health, Safety and Environment Aspects of Nanotechnologies (WG3, convened by USA), and Material Specifications (WG4, convened by China). The work programme at 1st July 2010 contained 37 work items under development – 7 in JWG1, 13 in JWG2, 11 in WG3, 5 in WG4 and 1 unallocated (Annex 1). Of the existing work items, the most relevant to the WPMN are those in WG3, though both the terminology work, in JWG1, which now includes an approved work item on nomenclature models for nano-objects, and the measurement and characterisation work in JWG2, have broad relevance.

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

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

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

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

- A new work item proposal within the scope of an existing technical committee or subcommittee may be made in the respective organisation by
  - a national body;
  - the secretariat of that technical committee or subcommittee;
  - another technical committee or subcommittee;
  - an organisation in liaison;
  - the technical management board or one of its advisory groups; and
  - the Chief Executive Officer.

- Acceptance requires

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

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

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

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

Annex: ISO/TC 229 Work Programme at 1st July 2010

JWG1

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

JWG2

- *ISO/TS: The Use of Transmission Electron Microscopy (TEM) in the Characterization of Single-walled Carbon Nanotubes*
- *ISO/TS: The Use of Scanning Electron Microscopy (SEM) and Energy Dispersive X-ray Analysis (EDXA) in the Characterization of Single-walled Carbon Nanotubes* – ***approved for publication***
- *ISO/TS: Characterization of single-wall carbon nanotubes (SWCNTs) using ultraviolet, visible and near infrared (UV-VIS-NIR) spectroscopy* – ***approved for publication***
- *ISO/TS: Characterization of single-wall carbon nanotubes using near infrared photoluminescence spectroscopy* – ***approved or publication***
- *ISO/TR: Use of Thermo Gravimetric Analysis (TGA) in the purity evaluation of Single Walled Carbon Nanotubes* – ***approved for publication***
- *ISO/TR: Use of Evolved Gas Analysis-Gas Chromatograph Mass Spectrometry (EGA-GCMS) in the Characterization of Single-Walled Carbon Nanotubes* – ***approved for publication***
- *ISO/TS: Use of Raman Spectroscopy in the Characterization of Single Wall Carbon Nanotubes.*
- *ISO/TR: Nanotechnologies - Characterization of multiwall carbon nanotubes(MWCNTs) - Collection of measurement methods*
- *ISO/TR: Guide to methods for nano-tribology measurements (Joint development with CEN TC 352 – CEN lead)*
- *ISO/TS: Determination of meso-scopic shape factors of multiwalled carbon nanotubes (MWCNTs)* – ***approved for publication***
- *ISO/IS: General framework for determining nanoparticle content in nanomaterials by generation of aerosols*
- *ISO/TS: Electrical resistance of carbon nanotubes using 4 probe measurement (Joint project with IEC TC 113, IEC lead)*
- *ISO/TS: Artificial gratings used in nanotechnology - description and measurement of dimensional quality parameters*
- *ISO/TS: Determination of metal impurities in carbon nanotubes (CNTs) using inductively coupled plasma-mass spectroscopy (ICP-MS)*
- *ISO/TS: Generic requirements for reference materials for development of methods for characteristic testing, performance testing and safety testing of nano-particle and nano-fibre powders*

WG3

- *ISO/IS: Endotoxin test on nanomaterial samples for in vitro systems -- Limulus amebocyte lysate (LAL) test* – ***FDIS stage***

- *ISO/IS: Standard for Generation of Metal Nanoparticles with the Evaporation/Condensation Method for inhalation toxicity testing –* ***FDIS stage***
- *ISO/IS: Standard for characterization of nanoparticles in inhalation exposure chambers for inhalation toxicity testing –* ***FDIS stage***
- *ISO/TR: Guidance on physico-chemical characterization of engineered nanoscale materials for toxicologic assessment (Harmonised with WPMN list – working closely to ensure that the two bodies complement each other's work and avoid duplication)*
- *ISO/TS: Guidance on safe handling and disposal of manufactured nanomaterials*
- *ISO/TR: Nanomaterial risk evaluation process*
- *ISO/TS: Guidelines for occupational risk management of nanomaterials based on a "control banding" approach*
- *ISO/TR: Preparation of Material Safety Data Sheet (MSDS) for nanomaterials*
- *ISO/TS: Surface characterization of gold nanoparticles for nanomaterial specific toxicity screening - FT-IR method*
- *ISO/TR: Guidance on sample preparation methods and dosimetry considerations for manufactured nanomaterials*
- *ISO/TR: Guidance on toxicological screening methods for manufactured nanomaterials*

WG4

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

Unallocated

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

IS = International Standard; TS = Technical Specification; TR = Technical Report.
FDIS – Final Draft International Standard
Dr Peter Hatto, Chairman, 1st July 2010

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

Highlight of developments since the 6th meeting of the WPMN

1. Publication of the Joint FAO/WHO Expert Meeting on the Application of Nanotechnologies in the Food and Agriculture Sectors: Potential Food Safety Implications, Rome, 1-5 June 2009 available in English

2. FAO/Brazil conference on nanotechnologies in the food and agriculture sectors held in San Pedro Brazil, 20 - 24 June 2010

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

4. Development of WHO Guidelines titled "Protecting Workers from Potential Risks of Manufactured Nanomaterials" (WHO/NANOH)

Activities on health and environmental safety aspects of manufactured nanomaterials

1. Publication of the Joint FAO/WHO Expert Meeting on the Application of Nanotechnologies in the Food and Agriculture Sectors: Potential Food Safety Implications, Rome, 1-5 June 2009 available in English

The hard copies of the report are available for all WPMN delegates. Summary of the meeting was provided at the 6th meeting of the WPMN.

2. FAO/Brazil conference on nanotechnologies in the food and agriculture sectors held in San Pedro Brazil, 20 - 24 June 2010

Based on the recommendation made by the experts during the above mentioned expert meeting FAO organized in collaboration with the Ministry of Agriculture of Brazil (EMBRAPA) an International Conference on Food and Agricultural Applications of Nanotechnologies, held from 20 to 24 June 2010 in São Carlos, SP, Brazil. 3 Technical Round Table (RT) sessions were organized: 1) Food applications of nanosciences and nanotechnologies; 2) Nanotechnologies in agriculture: new tools for sustainable development; and 3) Nanotechnology: the regulatory framework.

These 3 RT sessions were co-hosted with the European Food Safety Authority (EFSA), International Union of Food Science and Technology (IUFoST) and Organisation for Economic Co-operation and Development (OECD) respectively. Overall, the Round Table sessions with various stakeholders identified: 1) current available nanotechnology applications in food and agriculture sectors; 2) potential benefits and concerns of them; 3) key challenges; 4) strategies to overcome challenges identified; and 5) recommendations for international organisations. The detailed final report will be available in Fall 2010.

1) FAO/EFSA Round Table 1: Food applications of nanosciences and nanotechnologies

During preparation of this first session, an updated Table of known and projected applications was developed. RT panellists agreed that there are general potential benefits of such applications, including i) more efficient food production methods – less use of agrochemicals; ii) more hygienic food processing; iii) food products with improved tastes, flavours, mouth feels (healthy/nutritious/tasteful); iv) food products with less (or no) preservatives; v) longer shelf-life of food products – less food waste; vi) innovative lightweight, stronger, functional packaging; and vii) 'smart' labels to ensure food authenticity, safety, and traceability.

General challenges were identified in three areas: i) technological – e.g. detection, health effects, environmental impacts etc ii) societal – e.g. public perception/acceptance, inclusiveness and iii) issues specific to developing countries – e.g. technical know-how, costs, capacity, trade barriers etc. The RT concluded that in order to overcome these challenges, proactive collaborations and partnerships at all national, regional and international levels are essential. More specifically, the main innovation routes to nanotechnology applications are likely to arise from academia and small spin off companies, thus incentives/capital to drive this are needed. Small start-up companies are often taken over by larger ones through mergers etc, this may cause a barrier, but also opportunities to further developments. Industry sponsored research should be encouraged (Trainings via PhD projects etc). Venture capital companies are already seeking partnerships in developing countries. It is important to facilitate collaborations within a country between different R&D institutions, industry and government departments.

2) FAO/IUFoST Round Table 2: Nanotechnologies in Agriculture: new tools for sustainable development

The RT panellists recognized that nanotechnologies have potentials in the agriculture sectors, particularly in: i) producing sufficient quantity, quality, and variety of foods to feed the growing population sustainably and economically; ii) minimizing environmental footprints of agricultural production; iii) improving rural community well being; and iv) regaining as the foundation of manufacturing and commerce with new economical opportunities for farmers. 5 key areas in the agriculture sector were reviewed: i) plant production; ii) animal production; iii) value-added products; iv) environment; and v) education, communication and trainings. Below are the lists of priority issues identified, benefits identified and agreed, and challenges recognized in all 5 areas: 1) plant production; 2) animal production; 3) value-added products; 4) environment; and 5) education, communication and training.

Drawing conclusions from these discussions, RT panellists recommended that:

- international forum should be provided in order to agree on a shared vision and provide guidance on management of global issues;
- public domain of information and knowledge should be developed (database), to overcome proprietary barriers of knowledge and preserve a large field of public information;
- all stakeholders should seek for technological solutions that build on local and existing knowledge and capacities; ensuring additionality, complementing existing technologies;
- all need to ensure that nano-solutions do not simply put a band aid over problems, or introduce more serious problems than those they afford solutions to; and
- all need to consider impacts on biodiversity.

3) FAO/OECD Round Table 3: Nanotechnology: the regulatory framework

During this concluding Round Table session, challenges in various areas are identified. The areas include: definitions, risk assessment, food additives, vitamins and minerals, pre-market approval, food contact materials, enhanced uptake, food labelling, product safety (non-food), regulatory uncertainty, data requirements, consumer perspectives and challenges for developing countries.

The importance of having internationally agreed definitions was once again highlighted as it was during the FAO/WHO expert meeting in 2009. Experts suggested an appropriate international organisation to develop a dictionary of nanotechnologies, particularly in food and agriculture sectors. This is particularly important for labelling issues. As for the regulatory issues around risk assessment, it was recognized that exposure assessment is largely unanswered and there is a lack of detection methods for routine analysis in foods. It was suggested that an international exchange platform to be developed for sharing information and discuss on issues of global relevance.

The experts identified some strategies to overcome challenges above. They include: 1) identifying active facilitator in the international organisations in order for developing partnerships and collaborations between countries, 2) FAO and other partner organisations to continue identifying data gaps and collaborate with all stakeholders and collaborate with all stakeholders on generating data to plug the gaps and 3) FAO and other partner organisations to task the expert bodies (for example, JECFA – Joint FAO/WHO Expert Committee on Food Additives) to review Risk Assessment methods which can be applied to safety assessment of nanoparticles.

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

Based on the recommendation made by the experts during the FAO/WHO expert meeting in 2009, FAO and WHO agreed to establish an e-Discussion Group for the possible development of "Tiered Approach Diagram for Risk Assessment of Nanomaterials (NMs)". The overall objective of this activity is to seek further scientific advice from the experts on the use of a tiered risk assessment approach for application of nanotechnologies to food and feed.

4. Development of WHO Guidelines titled "Protecting Workers from Potential Risks of Manufactured Nanomaterials" (WHO/NANOH)

In May 2010, WHO initiated the development of WHO Guidelines titled "Protecting Workers from Potential Risks of Manufactured Nanomaterials" (WHO/NANOH). These Guidelines aim to facilitate improvements in occupational safety and health of nanotechnologies in a broad range of manufacturing and social environments by incorporating elements of risk assessment and risk management framework and contextual issues in the guidelines structure. They will provide recommendations to improve occupational safety and health of nanotechnology in all countries and especially in low and medium-income countries in line with the WHO's position as the United Nation's international health organisation charged to assist countries to attain "Health for All."