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

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Series on the Safety of Manufactured Nanomaterials

No. 37

Current Developments in Delegations on the Safety of Manufactured Nanomaterials - Tour de Table at the 10th Meeting of the WPMN Paris, France, 27-29 June 2012

Environment Directorate
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT
Paris, 2013

Also published in the Series of Safety of Manufactured Nanomaterials:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

No. 34, *Current Development/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 9th Meeting of the Working Party on Manufactured Nanomaterials (2012)*

No. 35, *Inhalation Toxicity Testing: Expert Meeting on Potential Revisions to OECD Test Guidelines and Guidance Document (2012)*

No. 36, *Guidance on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials (2012)*

ABOUT THE OECD

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

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

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

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

OECD Environment Directorate,
Environment, Health and Safety Division
2 rue André-Pascal
75775 Paris Cedex 16
France

Fax: (33-1) 44 30 61 80

E-mail: ehscont@oecd.org

FOREWORD

The Working Party endorsed this document at its 10th Meeting in June 2012. It is intended to provide information on the outcomes and developments of the WPMN related to the safety of manufactured nanomaterials.

This document is being published under the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, which has agreed that it be declassified and made available to the public.

TABLE OF CONTENTS

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

Background

The purpose of the agenda item 4 (the Tour de Table) is to give each delegation the opportunity to describe recent or planned national initiatives and/or events related to the safety of manufactured nanomaterials. This will facilitate the implementation of the projects of the WPMN by allowing delegations to share their experiences and preoccupations with respect to safety, and will identify opportunities for future co-operation and co-ordination.

As with previous meetings of the WPMN, delegations provided written submissions in advance of the meeting and highlighted (in their interventions) points that were not already included in their written submissions. The WPMN agreed that these reports were informative and recommended that they are made available publicly. These reports have been declassified by the Chemicals Committee and are publicly available as publications in the series on *the Safety of Manufactured Nanomaterials* [ENV/JM/MONO(2012)13].

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 9th meeting of the WPMN (December 2011) might wish to simply review their previous submission and update it as needed. Information submitted could be supported by any supplementary information, or supporting documentation, especially if it was available in electronic form including links to website.

Format for the Tour de Table

Highlight of developments since the 9t meeting of the WPMN

- Request for information on nanomaterials issued on…..…… (Day/Month/2012)
-

Work completed, underway or planned

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

1. **Any national regulatory developments on human health and environmental safety including recommendations or discussions related to adapting existing regulatory systems or the drafting of laws/ regulations/ guidance materials;**
2. **Developments related to voluntary or stewardship schemes;**
3. **Information on any risk assessment decisions;**
4. **Information on any developments related to good practice documents;**
5. **Information on any developments related to Integrated Testing Strategies and/or Alternative test methods**
6. **Research programmes or strategies designed to address human health and/ or environmental safety aspects of nanomaterials;**
7. **Information on any public/ stakeholder consultation;**
8. **Information on research programmes or strategies which focus on life cycle aspects of nanomaterials, as well as positive and negative impacts on environment and health of certain nano-enabled applications. (You may wish to contact your colleagues participating in SG9.);**
9. **Information on any development related to exposure measurement and exposure mitigation**

Additional Information

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

RESPONSES FROM DELEGATIONS

AUSTRALIA

Highlight of developments since the 9th meeting of the WPMN

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

- Safe Work Australia is implementing a Nanotechnology Work Health and Safety Program. Nine research reports, a work health and safety assessment tool for handling engineered nanomaterials and one safe handling guidance document have been published.

- The Australian Consortium working on the OECD Sponsorship Program for the Safety Testing of Manufactured Nanomaterials has commenced upload of data to the NanoHub database.

Work completed, underway or planned

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

The Australian government regulator for industrial chemicals, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), is continuing its strategy for the regulation of industrial nanomaterials. Under this strategy, NICNAS uses a working definition for industrial nanomaterials (applicable to this sector only) that was developed in consultation with stakeholders and its Nanotechnology Advisory Group (NAG):

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

[Explanatory Notes to the working definition:

- intentionally produced, manufactured or engineered materials are distinct from accidentally produced materials

- 'unique properties' refers to chemical and/or physical properties that are different because of its nanoscale features as compared to the same material without nanoscale features, and result in unique phenomena (e.g. increased strength, chemical reactivity or conductivity) that enable novel applications.

- aggregates and agglomerates are considered to be nanostructured substances

- where a material includes 10% or more number of particles that meet the above definition (size, unique properties, intentionally produced) NICNAS will consider this to be a nanomaterial.]

Administrative arrangements for nanoforms of new chemicals (i.e. those that are not on the national inventory) were implemented by NICNAS in 2011. NICNAS is now progressing regulatory options for notification and assessment of nanoforms of existing chemicals in consultation with its stakeholder advisory group. Public consultation on these issues is scheduled for late 2012.

More information on NICNAS's regulatory activities is available from the NICNAS website at

http://www.nicnas.gov.au/Current_Issues/Nanotechnology.asp

Safe Work Australia has provided information relating to nanomaterials in the model Codes of Practice for;

i) Preparation of Safety Data Sheets for Hazardous Chemicals and

ii) Labelling of Workplace Hazardous Chemicals, which were published on the Safe Work Australia website in December September 2011.

http://www.safeworkaustralia.gov.au/Legislation/model-COP/Pages/Model-COP.aspx#3

2. Developments related to voluntary or stewardship schemes

The Australian Government has published an independent report investigating the feasibility of the Government implementing a nanotechnology product registry. The study is available at the Department of Industry, Innovation, Science, Research and Tertiary Education's website (http://www.innovation.gov.au/Industry/Nanotechnology/NationalEnablingTechnologiesStrategy/Documents/FeasibilityMandatoryNanotechProductRegistry.pdf). The project consulted a representative set of stakeholders representing Government, Research, Industry, Unions and Non Government Organisations. In conducting this exercise, the consultants sought to establish the costs relative to the benefits additional to those already delivered by current regulatory frameworks. The study concluded that there is little indication of a net benefit from the implementation of a nanotechnology product registry.

3. Information on any risk assessment decisions

Within the industrial chemicals sector, no notifications have been received for a nanomaterial under the NICNAS working definition, since the 9th WPMN.

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

4. Information on any developments related to good practice documents

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

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

- Nanotechnologies — Occupational risk management applied to engineered nanomaterials Part 1: Principles and approaches

- Nanotechnologies — Occupational risk management applied to engineered nanomaterials — Part 2: The use of the Control Banding approach in occupational risk management.

- Nanotechnologies — Safety Data Sheet (SDS) preparation for manufactured nanomaterials

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

None.

6. Information on any public/ stakeholder consultation

NICNAS continues to progress the technical component of its overall nanotechnology strategy that complements regulatory developments (described under Regulatory Developments section). Technical activities are aligned as appropriate with national and international developments in this area, and include:

- Developing risk assessment capabilities;

- building knowledge on health effects of six particular nanomaterials of relevance to Australian industry. These are titanium dioxide, zinc oxide, cerium oxide, fullerenes, carbon nanotubes and nano silver;

- leveraging linkages with national and international agencies to maximise efficiency of research;

- continuing participation in the activities of the OECD Working Party on Manufactured Nanomaterials; and

- continuing participation in ISO TC229, through the Standards Australia Nanotechnology Committee (NT-001) to facilitate reliable characterisation and testing of nanomaterials.

The Australian Consortium (CSIRO, Deakin University, Monash University, National Measurement Institute, Macquarie University, RMIT University, University of Adelaide, University of Queensland, University of South Australia) has moved into the reporting phase of the OECD Sponsorship Program for Safety Testing of Manufactured Nanomaterials. Upload of data to the NanoHub database for physico-chemical characterisation, environmental fate, environmental toxicology and mammalian toxicology endpoints for zinc oxide, cerium oxide and silver will be completed by June 2012.

Work conducted by the Australian Consortium for the OECD Sponsorship Program for Safety Testing of Manufactured Nanomaterials has generated significant outputs:

- 8 publications in peer reviewed journals to date, with many more manuscripts currently in preparation; and

- Australia contributed to the JRC Scientific and Technical Report JRC 64075 "NM-Series of Representative Manufactured Nanomaterials - Zinc Oxide NM-110, NM-111, NM-112, NM-113: Characterisation and Test Item Preparation"

  http://publications.jrc.ec.europa.eu/repository/handle/111111111/23031; and

- Australia has also contributed to the JRC Scientific and Technical Report on CeO2, similar to the report on ZnO (to be published); and

- A number of unpublished, internal reports describing methods used for testing the OECD nanomaterials, reporting data, and discussing results have been generated;

- Over 40 conference presentations; and

- Enhanced collaboration between Australia and a number of international research organisations including: University of Exeter, UK; Colorado School of Mines, USA; Göteborg University, Sweden; University College Dublin, Ireland; National Institute for Public Health and the Environment, The Netherlands.

Members of the Australian Consortium will be expert reviewers of OECD Dossiers prepared for zinc oxide and cerium oxide, containing all data on these nanomaterials that were contributed to the OECD Program by over 10 participating countries.

The Australian Consortium to the OECD program has been selected as a case-study highlight in the Australian Academy of Science (AAS) National Nanotechnology Research Strategy (NNRS) to be released during 2012.

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

- Ensure nanotechnology is covered appropriately within the work health and safety regulatory framework

- Improve understanding of the hazardous properties of engineered nanomaterials

- Assess the effectiveness of workplace controls in preventing exposure to engineered nanomaterials

- Develop procedures for detecting and measuring nanomaterials emissions and exposures in workplaces

- Provide information and guidance for Australian nanotechnology organizations

- Ensure consistency with international approaches and contributing to international work

Eighteen projects have been commissioned by Safe Work Australia to progress work in these key areas. Nine research reports have been published, with the following reports published since the 9th WPMN Tour de Table report:

  - Nanoparticles from Printer Emissions in Workplace Environments

- Brief Review on Health Effects of Laser Printer Emissions Measured as Particles

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

Further reports will shortly be published.

The work program is supported by two reference groups:

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

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

Safe Work Australia has also published a Work Health and Safety Assessment Tool for Handling Engineered Nanomaterials which can be used by organisations and regulators when assessing the use of nanomaterials. The assessment tool allows the user to record the types of nanomaterials manufactured or supplied, the processes and controls used to prevent exposure to nanoparticles and problems faced with managing nanotechnology work health and safety.

Focus is being placed on developing training and guidance materials. Since the 9th WPMN Tour de Table report a guidance document on Safe handling and use of carbon nanotubes has been published.

http://www.safeworkaustralia.gov.au/AboutSafeWorkAustralia/WhatWeDo/Publications/Pages/AT201008WorkHealthAndSafetyAssessmentTool.aspx

A Nanotechnology work health and safety training course is currently being developed.

Food Standards Australia New Zealand (FSANZ) has recently published a paper titled “Regulation of nanotechnologies in food in Australia and New Zealand” in the International Food Risk Analysis Journal available at the following link.

http://www.intechopen.com/source/pdfs/26273/InTech-Regulation_of_nanotechnologies_in_food_in_australia_and_new_zealand.pdf

7. Information on any public/ stakeholder consultation

The National Enabling Technologies Strategy’s Stakeholders Advisory Council has held a further three meetings since the last Tour de Table. Two projects are being developed in consultation with this council relating to regulatory governance of new technologies, and developing a framework to evaluate the social and economic impacts of new and emerging technologies.

The National Enabling Technologies Strategy Public Awareness and Community Engagement (NETS-PACE) section has developed a framework to provide guidance for best practice community engagement in Science and Technology. The framework is based on outcomes from its 2011 multi-stake holder engagement process. The framework, called STEP (Science and Technology Engagement Pathways) is

being developed and trialled over a year of activities entitled 2012 STEP into the Future. More information can be found at www.innovation.gov.au/step

At the International Conference on Nanoscience and Nanotechnology (ICONN) in February 2012 NETS-PACE hosted the public forum, Nanotechnology and the Environment – Have Your Say. The event started with a panel of speakers presenting on the issues of nanotechnology and the environment before addressing questions from the audience, which consisted of delegates from the conference, the general public, and a select group of scientifically unengaged members of the public. After the panel discussion the audience then broke into small groups to discuss the possibilities and challenges facing nanotechnology, and what information the broader public requires on the technology. Each table then presented a summary of its discussion. The audience response to this format of engagement was strong, with 79 per cent responding favourably to the event in audience surveys, while the general public's desire to know more on the issues was also prevalent with nearly 80 per cent of attending members of the public responding that they wanted to know more. For 2012 NETS-PACE also plans to continue its annual public awareness research, this time on both biotechnology and nanotechnology. Results are anticipated to be published in the second half of the year.

NICNAS has held several stakeholder education sessions which included updates on administrative arrangements for new nanomaterials. To date over 100 industry participants have attended these sessions with another 300 registered to attend future sessions up to 30 June this year.

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

None.

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

NICNAS has commissioned a project to investigate local exposure to nanoforms of titanium dioxide, zinc oxide, cerium oxide and silver and to subsequently develop exposure scenarios that can be applied to estimate exposure of workers, the public and the environment to these substances under reasonably anticipated conditions of use. NICNAS intends to combine this information with its own hazard reviews to estimate possible risks their use pose to workers, the public and the environment. This will assist future NICNAS risk and will help to determine the most appropriate framework for managing nanoforms of existing chemicals.

AUSTRIA

Highlight of developments since the 9th meeting of the WPMN

- Implementation of Austrian Nanotechnology Action plan recommendations: A national EHS programme focusing on nanosafety has released the second call for nanosafety focusing on environmental issues research in spring 2012. This EHS programme (http://www.ffg.at/nano-ehs) aims to bundle resources in the field of nanosafety in Austria. It is owned by the Federal Ministry of Agriculture, Forestry, Environment and Water Management and is funded by the Federal Ministry of Agriculture, Forestry, Environment and Water Management, the Federal Ministry of Federal Ministry for Transport, Innovation and Technology the Federal Ministry of Health, the Ministry of Labour, Social Affairs and Consumer Protection, the Federal Ministry for Science and Research, the Workers' Compensation Board and the Chamber of Commerce. In a first call

regarding health issues two projects are going to be funded: "Nano-Metals in FCM" and NanoProdEx (see bullet 9).

The second national EHS programme call was released in spring 2012 and is funded with 260.000 EUR (see http://www.ffg.at/2-ausschreibung-nano-ehs). Another 300.000 EUR will be provided to participate in the ERA-Net SIINN regarding studies on impacts of manufactured Nanomaterials on environment.

- The work on compiling an implementation report on the Austrian Nanotechnology Action plan has started. A public consultation is planned for autumn 2012, the finalisation is planned for end of 2012/ beginning of 2013.

- An Austrian Nano-Information-Website will be published end of 2012

Work completed, underway or planned

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

No national Austrian laws/regulations are planned at the time being. **The Austrian Nanotechnology Action plan** (adopted on 2nd March 2010 by the Austrian government, an English and German version can be downloaded on http://www.lebensministerium.at/umwelt/chemikalien/nanotechnologie/nano-aktionsplan.html). It includes about 50 measures which will be implemented by Austrian stakeholders on national, EU and international level till 2012. The action plan was lead-managed by the Federal Ministry of Agriculture, Forestry, Environment and Water Management (BMLFUW, contact: Renate.Paumann@lebensministerium.at, Austrian Federal Ministry of Agriculture, Forestry, Environment and Water Management) and elaborated on basis of a broad stakeholder involvement (see also chapter 7).

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

2. – 3. (None.)

4. Information on any developments related to good practice documents

The central labour inspectorate (part of the Federal Ministry of Labour, Social Affairs and Consumer Protection) mandated a project investigating Austrian nano-workplaces to get a preliminary overview on different uses and risk management applied. Building up on this report guidance in German language to ensure safe and healthy workplaces regarding nanomaterials was developed: "Leitfaden für das Risikomanagement beim Umgang mit Nanomaterialien am Arbeitsplatz". The guidance is targeting small and medium enterprises and shall support the central labour inspectorate in advising enterprises dealing with nanomaterials. (http://www.arbeitsinspektion.gv.at/AI/Arbeitsstoffe/nano/default.htm.)

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

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

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

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

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

NanoTOES (Nanotechnology: Training Of Experts in Safety), a Network of Initial Training (ITN) in the framework of FP7 coordinated by Prof. Dr. Albert Duschl from the University of Salzburg aims at development and validation of methods for examination of possible nanorisks for health and environment coupled with research for a better understanding of the involved mechanisms.

Furthermore it will focus on the education of young academics in the field of nanosafety and will be a European best practice" example in this respect. University of Salzburg´s main specialist work will be research on the effects of nanomaterials on the immune system.

In the FP7 project **NanoValid** Albert Duschl (University of Salzburg) is partner and work package leader for case studies (www.nanovalid.eu). The efforts led by University of Salzburg aim to apply methods and techniques developed in research laboratories for samples collected on-site in real or modelled working place environments.

In the FP7 project **MARINA** Austrian partners from University of Salzburg (contact: Prof. Dr. Christian Huber) and from Department for Environmental Geosciences, University Vienna (contact: Frank von der Kammer) are involved in several workpackages. UNIVIE is involved in material characterization and developing analytical methods for the **quantification of ENPs in environmental samples**. University of Salzburg plans to investigate nanoparticle **effects on the proteome level**. In the FP7 project **NanoLyse** the Department for Environmental Geosciences, University Vienna (UNIVIE, contact: Frank von der Kammer) is leading the workpackage for the **sample preparation and quantification of inorganic nanoparticles in food** and is responsible member of the project management board and also involved in the development of organic nanoparticle analysis. In a CEFIC-funded co-operation between four European Universities University Vienna is researching the Detection, Fate and Uptake of Engineered Nanoparticles in Aquatic Systems. **EURO-NanoTOX** is an open virtual national platform which is co-ordinated by the BioNanoNet Forschungsgesellschaft mbH. It elaborates strategies to conduct standardised toxicological on nanostructered material. See: http://www.euro-nanotox.at/

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

7. Information on any public/ stakeholder consultation

As a measure of implementation of the Austrian Nanotechnology Action plan an Austrian

Nanotechnology Information Platform (NIP) lead-managed by the Federal Ministry of Health and including stakeholders from several ministries, agencies, NGOs, research institutions and industry has been built up. Currently the setup of a national website for the public including chances and risks of nanomaterials is in progress.

A platform ("Österreichische Nanotechnologie-Plattform") of relevant ministries, agencies, NGOs, occupational health organisations, the Austrian Chamber of Commerce (WKO) and research institutions lead-managed by the Federal Ministry of Agriculture, Forestry, Environment and Water Management (BMLFUW) was established in autumn 2007 to exchange information and discuss specific nanomaterial related topics.

A media event was organised in January 2012 by the **city of Vienna** voicing a critical view on nanosilver and its use in consumer products. See http://wua-wien.at/home/umwelt-und-gesundheit/chemikalien-und-schadstoffe/hintergrundgespraech-nanosilber.

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

The project **SEBEROC** (Simulation and Evaluation of Better Regulation of Converging Technologies, carried out on behalf of the SKEP Network) aims at applying the "Better regulation" approach to the regulation of nanotechnology and genetic engineering. Austrian partner is IFZ-Inter-University Research Centre for Technology, Work and Culture Graz (contact: Manfred Klade; http://www.seberoc.info/home0.0.html)

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

See Highlights.

Austria is partner of the **ERA-net SIINN** ("Safe implementation of innovative Nanoscience and Nanotechnolgies") and workpakage leader of WP3 ("Risk assessment and life cycle validation"). BioNanoNet Forschungsgesellschaft mbH is partner in the project **NANOFORCE** "Nanotechnology for Chemical Enterprises – how to link scientific knowledge to the business in the Central Europe"; and responsible for the workpackage **"How to foster the responsible use of nanotech and manage associated risks".**

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

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

The project "**Nano-Metals in FCM**" (lead: Austrian Agency for Health and Food Safety (AGES), partner University Vienna) aims at developing methods for detection and quantification of nanomaterials by using food simulants. Market-ready samples of active and intelligent food packaging materials are chosen;

possible migration is enforced and tested via sophisticated analytical tools. Based on the findings, conclusions for product design as well as guidelines for the safety of intelligent packaging materials are given.

The project **NanoProdEx** (lead: BioNanoNet Forschungsgesellschaft partners: Umweltbundesamt, Umweltbundesamt, Montanuniversität Leoben, Mondi Uncoated Kraft & Fine Paper GmbH) investigates and identifies nanomaterials in consumer goods which are produced or used in Austria, with a subsequent prioritization of identified nano-products based on their relevance for worker and consumer protection will be performed. A questionnaire and face-to-face-interviews will be conducted to get access to relevant data for later on preparation of exposure scenarios based on this information and in due consideration of the REACH regulations.

Additional Information

Consideration of ethical implications;

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

CANADA

Highlight of developments since the 9th meeting of the WPMN

- The following activities have taken place since the 9th meeting of the Organization for Economic Cooperation and Development (OECD) Working Party on Manufactured Nanomaterials (WPMN) in December 2011:

  - Canada and the United States announced the creation of the Canada-United States Regulatory Cooperation Council (RCC) to better align the two countries' regulatory approaches, where possible. A RCC Joint Action Plan was published (http://actionplan.gc.ca/eng/feature.asp?pageId=381) which proposes, among other initiatives, to share information and develop joint Canada-U.S. approaches on regulatory aspects of nanomaterials. A Nanotechnology Work Plan (http://www.eap.gc.ca/eng/feature.asp?mode=preview&pageId=470) has now been published which outlines details such as developing consistent approaches to the risk assessment and management of nanomaterials, as well as sharing scientific and regulatory expertise.

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

Work completed, underway or planned

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

A. Following the creation of the Canada-United States Regulatory Cooperation Council

(RCC) to better align the two countries' regulatory approaches, the heads of the two countries on December 7, 2011 released a Join Action Plan on Regulatory Cooperation that included regulatory approaches to nanomaterials (http://actionplan.gc.ca/eng/feature.asp?pageId=381).

The RCC Nanotechnology Work Plan proposes to share information and develop joint Canada-U.S. approaches on regulatory aspects of nanomaterials. This will include developing consistent approaches to the risk assessment and management of nanomaterials, as well as sharing scientific and regulatory expertise.

A draft work plan was shared with stakeholders at a January RCC stakeholder technical review and advisory session held in Washington, United States. The workplan was well received and was revised based on stakeholder comments. The Nanotechnology Work Plan can be accessed at: http://www.eap.gc.ca/eng/feature.asp?mode=preview&pageId=470.

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

C. Discussions at the 4th annual meeting of International Cooperation on Cosmetic Regulation (ICCR-4) in Canada on cosmetics and cosmetic-like drug/quasi-drug products led to the formation of a new Joint Industry/Regulator Working Group. Canada is participating in the Joint WG which is a follow up from the previous ICCR Ad Hoc Nano Working Group that developed criteria for identification of nanomaterials within the context of cosmetic regulation. The criteria statement was as follows:

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

The purpose of the Joint WG is to examine the existing safety approaches for applicability to nanomaterials in use by (or relevant to) activities within the cosmetic industry. The main task of the Joint WG is to carry out a review of the existing safety approaches, and to identify any specific aspects relevant to consumer safety that should be taken into consideration in relation to the use of nanomaterials in cosmetics.

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

2. Developments related to voluntary or stewardship schemes

None.

3. Information on any Risk Assessment Decisions

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

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

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

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

- *Food related application*: Six notifications have been received. Two letters of no objection have been issued; the other four are still under review.

- *Others*: No notifications with respect to fertilizers, veterinary biologics, or animal feed have been received to date.

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

A. The Canadian Standards Association (CSA) Technical Committee (TC) on Nanotechnologies – Occupational Health and Safety has now completed the ballot process for national draft standard (CSA Z12885, Nanotechnologies – **Exposure control program for engineered nanomaterials in occupational settings**). It is expected to be published by Aug/Sep 2012.

The next standard to be reviewed by CSA TC for Canadian adoption is ISO/TR 13121:2011 **Nanotechnologies – Nanomaterial Risk Evaluation**.

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

C. Canada is the co-lead (together with the US) for the ISO TC 229 Working Group 1 Task Group on Nomenclature. This Task Group includes active representation from the United States, Japan, Germany, France, Australia, and includes regulators, industry, and academia, as well as observers from the Chemical Abstracts Service and the International Union of Pure and Applied Chemistry (IUPAC). The Group is tasked with developing a nomenclature system which meets the needs of regulators, industry, and academia. A liaison between ISO TC 229 and IUPAC has been secured and a subcommittee has been formed to pursue work on developing nomenclature.

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

Scientific research

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

Canada has supported multiple research projects under the Strategic Grants Program of the Natural Sciences and Engineering Research Council (NSERC). The nanomaterials used in these projects have included OECD priority nanomaterials such as TiO2, ZnO and Ag. The projects examined fate both in the aqueous and the subsurface compartments and include establishing methodologies for suspension and physical-chemical characterization of the nanomaterials prior to any exposure testing.

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

Canada is also currently engaged in research projects involving a range of different nanomaterials (e.g., nanoparticulates of zero-valent iron, gold, silver, TiO2, single walled carbon nanotubes, and C60 fullerenes). Testing includes pulmonary and cardiovascular injury; reproductive, developmental and transgenerational effects; exposure and tissue penetration, interactive effects with microorganisms, immune defenses, and genotoxicity. Alternative tests such as molecular (genomic/proteomic) and cellular in vitro techniques play an important part of the repertoire for such investigations. Other on-going projects include developing bioassays and biomarkers for nanomaterials, transformations and removal efficiencies of nanoparticles in wastewater treatment facilities, harmonizing and standardizing chemical and toxicological assays, toxicogenomics, evaluating fate in aquatic environments understanding the interaction of nanoparticles with microbial cells, soil effects research, and bioaccumulation and toxicity in benthic invertebrates, and ecosystem level effects studies of silver nanoparticles.

Policy research

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

The information generated by the surveys will be used to populate inventories, and draft a report on areas of shared interest and highlight opportunities for enhancing communication related to regulation and applications of nanotechnology in food and medical products. The report is expected to be completed in 2012/2013.

6. Information on any public/ stakeholder consultations

Refer to Section 1.A above.

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

None.

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

Canada is engaged in a project led by the International Life Sciences Institute (ILSI) to look at releases of nanomaterials from industrial consumer matrices (e.g., coatings). The objectives of this project are to develop information on different test methodologies and nanomaterials used to study releases from matrices, and to develop standard methodologies (validated through interlaboratory testing) to quantify releases of nanomaterials from a matrix. At present, Technical Groups are drafting White Papers to inform on the present state pertaining to multi-walled carbon nanotubes (MWCNTs) in polymer matrices. The White Papers will be used for discussion at an Expert Workshop in June, 2012 after which a state of the science report will be drafted to provide recommendations and direction for the laboratory testing stage. Government agencies in the United States, Non-Governmental Organizations and Industry are also engaged in the project. Additional information can be found at http://www.ilsi.org/ResearchFoundation/Pages/NanoRelease1.aspx.

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

None.

DENMARK

Highlights of developments since the 9th meeting of the WPMN

- Funding for establishing a Danish Center for Nano Safety in 2012 (see below under section 9)
- Funding for establishing a register for registration of products containing nanomaterials (section 1 below).

Work completed, underway or planned

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

Recently the Danish Government has allocated funding (approx 3,2 mio € from 2012-15) for establishing activities aimed at gaining clarity about the consequences for consumers and the environment due to the use of nanomaterials. The activities include the establishment of database on products with nanomaterials. At present the Danish EPA is in a planning phase in order to investigate the various possibilities for establishing such a database.

2. Developments related to voluntary or stewardship schemes

None.

3. Information on any Risk Assessment Decisions

The Danish Environmental Protection Agency (EPA) has in spring 2010 ordered withdrawal of a specific spray sealing product marketed as a nanoproduct from the market. The spray product in itself did not contain nanomaterials but generated a nanolayer on the treated surfaces and produced reactive nanosized aerosols during spraying.

The product has been notified to the European RAPEX system:

http://ec.europa.eu/consumers/dyna/rapex/create_rapex.cfm?rx_id=298

(see 42-1057/10)

The withdrawal was due to very high toxicity by inhalational exposure to mice, see publication:

http://toxsci.oxfordjournals.org/content/116/1/216.full.pdf+html

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

4. Information on any Developments Related to Good Practice Documents

The Danish industrial trade organisation has issued guidance on how to handle nanomaterials in the occupational environment. Most of the material is in Danish language, however an English version of "Nanoparticles in the working environment" in laboratories is available at

http://www.ibar.dk/Vejledninger%20mm/Liste/~/media/Industrien/PDF/NANO%20NY%202011/LAB/Lab_pjece_english_2version.ashx

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

None.

6. Information on any public/ stakeholder consultations

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

In one of the projects work was initiated for developing a screening tool (called "NanoRiskCat") for exposure and hazard assessment of products containing nanomaterials. However, further work and development has to be done in order to improve the screening procedure and develop a more practical and user friendly screening tool:

http://www.mst.dk/Publikationer/Publications/2011/12/978-87-92779-11-3.htm

In another project seven widely used nanomaterials were evaluated in relation to uses and environmental and human health hazard and risk in order to create a common basis and understanding of the current knowledge concerning these nanomaterials:

http://www.mst.dk/Publikationer/Publications/2011/08/978-87-92779-09-0.htm

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

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

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

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

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

Under the Ministry of employment, that Danish Government has funded a 4 mio € grant for Center for Nano Safety for a period of 3 years. The center is established at the National research Center for the Working Environment and includes several national collaboration partners (http://www.arbejdsmiljoforskning.dk/da/projekter/dansk-center-for-nanosikkerhed). Work will focus on projects on various issues such as: measurements and exposure assessment of nanoparticles in the occupational environment; mitigation and risk reduction measures, and risk assessment of specific uses of nanomaterials.

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

The National Research Centre for Working Environment has recently published their work regarding comparison of dust released from sanding conventional and nanoparticle-doped wall and wood coatings. The addition of engineered nanoparticles to the products only vaguely affected the geometric mean diameters of the particle modes in the sanding dust when compared to their reference products, see:

http://www.nature.com/jes/journal/v21/n4/full/jes201032a.html

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 and Finnish Safety and Chemicals Agency (Tukes) as Competent authority for chemicals, plant production products and biocides is actively participating in REACH competent authority (CARACAL) subgroup on nanomaterials (CASG-nano) and had been involved 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 Ministry of Health and Social Affairs has established an official discussion forum on nanotechnology in order to follow and participate in the national and international discussions.

2.– 3. (None.)

4. Information on any Developments Related to Good Practice Documents

The Finnish Institute of Occupational Health has prepared practical guidance on the use of nanomaterials at working places. This will be published during 2012.

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

Tukes and Finnish Institute of Occupational Health are participating in the FP7 project proposal NANoREG.

The University of Eastern Finland participates in the OECD Sponsorship Programme with aquatic ecotoxicology testing of nano-silver and nano-iron as part of the Nordic Nano Steering group under the Nordic Chemicals Group. Nordic Chemicals group and Tukes also organized a workshop late 2011 on the regulating and assessing the safety of nanomaterials.

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

Forestcluster LTD (a public-partnership for science, technology and innovations) runs a EffNet (Efficient Networking towards Novel Products and Processes, 2010 – 2013) program that focuses, on one hand, on developing radically new energy and resource efficient web production technologies and, on the other hand, reengineering the product concept of fiber based products with nanocellulose[1]. The E15 million program develops and demonstrates new types of products, but carries out also safety assessment of nanocellulose applications and studies their life-cycle.

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

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

- European Commission 6thFramework Programme project together with several institutes on " Inflammatory and genotoxic effects of engineered nanomaterials (NANOSH)" The project end date was March 31, 2010, but reporting of the results of the project is going on.

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

- European Commission 7thFramework project "Novel concepts, methods and technologies for the production of portable easy-to-use devises for the measurement and analysis of airborne Engineered nanoparticles in workplace air (NANODEVISE)". Here FIOH has the lead.

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

- Academy of Finland project "Engineered nanoparticles: synthesis, characterization, exposure and health hazards"

- European Commission DG SANCO project " Safety evaluation of manufactured nanomaterials by characterization of their potential genotoxic hazard (NANOGENOTOX)"

- European Network on the Health and Environmental Impact of Nanomaterials

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

- European Commission 6thFramework Programme SKEP ERA-NET project (Scientific Knowledge for Environmental Protection) on "Nanomaterials in REACH –evaluation of applicability of existing procedures for chemical safety assessment to nanomaterials (nanoREACH)", in the Workpackage on Precautionary procedures for nanomaterial safety assessment.

- European Commission 7thFramework Large Scale Integrating Collaborative Project on "Nanopatterning, Production and Applications Based on Nanoimprinting Lithography (NaPANIL)", in the workpackage on dissemination and exploitation: social-ecological analysis of nanopatterning and related applications with a consortium of 20 European partners coordinated by VTT Finland.

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

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

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

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

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

7. - 9. (None.**)**

FRANCE

Highlight of developments since the 9th meeting of the WPMN

- Further to enactment of the Act establishing the principle of a declaration of manufactured nanomaterials and issuance of the Decree setting out the general lines of the latter, the details of its contents are currently being discussed by the interested parties. At the same time, consideration is also being given to the basic aspect of the computerised data that will allow the automatic collection and checking of declarations. France is working in close collaboration with both EU Member States and EU Commission departments.

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;

See above.

2. - 3. (None.**)**

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

The French National Institute for Occupational Safety and Health (INRS) has published a guidance document for safety and health management in laboratories dealing with nanomaterials (ED 6615, available on http://inrs.fr, only in French for the moment). A practical factsheet on air filtration and best practices during handling of engineered nanomaterials has also been recently published (ED 138, available on http://inrs.fr, in French).

INRS has written a guidance document for the prevention of risks associated with nanomaterials in the building sector, which was published by the specialist magazine Le Moniteur, March 2012, n°5651.

The French National Health Insurance Fund has set up an expert group on occupational risks of nanomaterials, chaired by INRS. This group will deliver appropriate response to help inspectors and support safety practitioners.

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 French National Institute for Occupational Safety and Health (INRS) is conducting a multidisciplinary Nano project to address occupational risks of nanomaterials and will continue in the framework of its next strategic plan (2013-3017). This Nano Project is focused on the following objectives: assessing the effects of nanomaterials on health, through toxicological and epidemiological studies; assessing occupational exposure, in particular through studies of measurement instrument performance, field testing and developments of protocols to characterize nanoparticles; managing risks related to nanomaterials, in particular control technology and personal protective equipment research. In 2012, INRS expanded its

research capacities with a new building completely dedicated to the Nano project, including a laboratory for generating nanoaerosols suitable for inhalation toxicological studies.

7. Information on any public/ stakeholder consultation;

At the last General Assembly of members of the NanoGenotox project on 3 May 2012 in Brussels, all interested parties were invited to a presentation on the progress made with work and discussions relating to this project. A summary record of this afternoon meeting will shortly be posted on the project's web site (www.nanogenotox.eu).

This project will end in March 2013 and a final conference open to all parties is planned for the end of February 2013 to present all the results obtained.

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

None.

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

The French National Institute for Occupational Safety and Health (INRS) has published Recommendations for characterizing potential emissions and exposure to aerosols released from nanomaterials in workplace operations (ND 2355-226-12, available on www.hst.fr/nano/index.html, in French). This guidance was developed in partnership between INRS, INERIS and CEA.

GERMANY

Highlight of developments since the 9th meeting of the WPMN

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

  The third phase of the NanoDialog started in December 2012. By now, three expert dialogues on risk management in the nano world, on traceability of nanomaterials and on green nano are completed. Results and reports on the dialogues can be downloaded at the BMU homepage: http://www.bmu.de/english/nanotechnology/nanodialog/doc/47803.php

  The preparation of the last expert dialogues in phase three is under way. It will tackle the potential of research as a local factor and will take place in October 2012.

Work completed, underway or planned

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

  The German Competent Authorities will soon publish an accompanying document on integrating nanomaterials into REACH. The draft paper will be distributed also among the OECD WPMN participants as soon as it is finished.

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

The German Hazardous Substances Committee is working on a recommendation for safe handling of nanomaterials based on the German Hazardous Substances Ordinance.

2. - 3. (None.)

4. Information on any developments related to good practice documents

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

In co-operation with the Association of the German Chemical Industry BAuA has updated their common guidance for safe handling of nanomaterials at the workplace from 2007 (will be published on BAuA website soon)

There´s also an 2012 update of BAuA´s overview on good practice for safe handling of nanomaterials (http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/Nanotechnologie/Links-Beispiele.html)

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

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

Members from the Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR) and the JRC (EC) organized the 3rd expert Consultation Meeting on the role of Alternative methods in Nanotoxicology at OECD Paris.

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

BAuA has published the results from a literature survey on the Relevance of in vitro methods for the evaluation of chronic toxicity and carcinogenicity of nanomaterials, fine dust and fibers (http://www.baua.de/en/Publications/Expert-Papers/F2043.html)

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

A) Federal Environment Agency (Umweltbundesamt, UBA):

Environmental risks of nanomaterials: Fate and behaviour of TiO2 nanomaterials in the environment, influenced by their shape, size and surface area:

On behalf of Federal Ministry of Environment and Federal Environment Agency, the Institute of Energy and Environmental Technology e.V. (IUTA e.V.) investigates the behaviour and mobility of nanomaterials in the environment. Standardized test methods are applied; furthermore these test methods are adapted for nanomaterials testing. Guidelines related to soil and sewage plant tests were investigated in this study. The results obtained for the three TiO2 nanomaterials are

also important for closing the gap of information about environmental behaviour. The specific nanomaterials studied were UV Titan M262, which is coated, and the uncoated P25 and PC105.

The fate and behaviour of P25 was studied in a laboratory sewage treatment plant – based on the OECD Guideline 303A. The experiments in the laboratory sewage plant were performed over a period of three weeks. The mobility of the three TiO2 nanomaterials was tested in columns with three different soil types – based on the OECD Guideline 312. The adsorption behaviour of P25 and UV Titan M262 in different soil types was tested based on the OECD Guideline 106.

It can be concluded, that the OECD Guidelines 303A and 312 are applicable to nanomaterials, here specifically TiO2. Still specific recommendations should be taken into account as given in the corresponding section of the report. OECD Guideline 106 was found to be not useful for nanomaterial testing due to lack of possibilities for differentiating adsorbed from non adsorbed (agglomerated) TiO2 nanomaterial. The report will be published soon at http://www.umweltbundesamt.de/chemikalien/publikationen.htm#Nanomaterialien

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

The BfR initiated a project to the collection and evaluation of health assessment data for nano-sized titanium dioxide. The study aims at generating a comprehensive database that is used for hazard profiling, identification of endpoint data gaps and nanospecific test guideline development based primarily on existing data.

The BfR initiated an in-house research project entitled "Nanoparticles in composite materials: Release from consumer products under practical conditions" to elucidate real exposure to nanomaterials in various consumer products. Additionally migration studies of nanoclay encapsulated in plastics will be studied in a project funded by the Ministry of Environment, Agriculture, Nutrition, and Forestry of Rhineland-Palatinate. A second project "Classification of nanomaterials based on the potential oxidative stress detected by modifications on the protein level" is also carried out within the research programme of this State Department. Within the European FP7 programme the BfR will be partner in a new project called Nanoopinion (Monitoring public opinion on Nanotechnology in Europe) investigating the socio-economic impact of nanotechnology.

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

BAuA has published the results from in vivo and in vitro studies on dispersion and retention of dusts consisting of ultrafine primary particles in lungs which show no significant deagglomeration of inhaled nanomaterials (http://www.baua.de/en/Publications/Expert-Papers/F2133.html)

BAuA has published the results from a study on local genotoxicity of fine and ultrafine particles in lung epithelial cells by evaluating the current literature and by using an immunohistochemical approach on existing lung tissue samples from (nano)particle-exposed animals. (http://www.baua.de/en/Publications/Expert-Papers/F2135.html)

6. Information on any public/ stakeholder consultation

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

On February 8 and 9, 2012, the Federal Institute for Risk Assessment (BfR) held a scientific conference on the health risk assessment of nanosilver. The aim of the conference was to provide an overview of the current scientific state regarding the production and application of nanosilver in consumer products and food. Therefore, all major aspects were taken into account like identity, analytical characterisation and exposure, toxicology, bacterial resistance and biocidal efficacy, risk assessment and data gaps.

(http://www.bfr.bund.de/de/veranstaltung/bfr_konferenz_nanosilber-128142.html)

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

A) Federal Environment Agency (Umweltbundesamt, UBA):

Analysis and strategic management of sustainability potentials of nanoproducts: On behalf of Federal Ministry of Environment and Federal Environment Agency, the Institute for Applied Ecology (Öko-Institut e.V.) has developed a general assessment system for evaluation of sustainability aspects of nanotechnology based products. It is intended that assessment tool will serve as a basis for strategic optimization of products. The project is finished. The results (German with an English summary) have been published in TEXTE 15/2012 (Link http://www.uba.de/uba-info-medien/4276.html).

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

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

In co-operation with other German stakeholders in OSH BAuA has published a tiered approach to an exposure measurement and assessment of nanoscale aerosols released from engineered nanomaterials in workplace operations (https://www.vci.de/Downloads/Tiered-Approach.pdf)

ITALY

Highlight of developments since the 9th meeting of the WPMN

- The English version of the "White Paper on engineered nanomaterials and occupational health effects" has been recently published online (http://www.ispesl.it/nanotecnologie/?pag=whitebook). The report is based on the activity of the Italian NanoOSH, a network of public and private OSH experts and stakeholders coordinated by the Italian Workers Compensation Authority (INAIL).

- The National Institute of Health (Instituto Superiore di Sanità, ISS) has organized the first National Congress on "Nanomateriali e salute" to present the activities of ISS Working Group on Nanomaterials (Rome, 10-11 May, 2012). The workshop was divided in six sessions, covering many of main aspects of nanotoxicity and nanomedicines activities in Italy. A round table on priorities of the Italian policy in the field of responsible development of nanotechnologies closed the event. About 200 delegates participated at the workshop.

Work completed, underway or planned

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

In Italy we are continuing the work on National registry on nanomaterials. The structure of the Italian nanodatabase is being set in collaboration with other EU Member States in order to harmonize the approach used to gather information on nanomaterials on the EU market.

2. – 5. (None.)

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

Reference activities on EHS are going on at ISS, INAIL, the Italian Standard body (UNI), U22 Technical Commission on Nanotechnologies and the National Institute of Metrological Research (INRIM).

In particular, the ISS is involved in an 18 month project funded by the Italian Ministry of Health on "Studio del potenziale tossicologico di particelle di argento, utilizzate nei dispositivi medici non impiantabili, in funzione della loro dimensione, distribuzione ed aggregazione".

Besides these initiatives, the 3rd Italian Nanotechnology Census of AIRI/Nanotec IT (2011) has pointed out that specific research activities on EHS and ELSI are going on at the University of Parma, Rome, Pisa, Pavia, Trieste, Milano, Modena and Reggio Emilia (mainly medicine, chemistry, physical departments). Amongst the research organizations with relevant activities in this field there can be cited, the European Centre for the Sustainable Impact of Nanotechnology (ECSIN) within Veneto Nanotech, the NEST Laboratory at the Scuola Normale Superiore di Pisa (IIT@NEST), several institutes within the National Research Council (CNR), the Italian National Agency for New Technologies, Energy and Sustainable Economic Development (ENEA).

Industrial association such as Federchimica (Chemical Industry Association) and AIRI/Nanotec IT (Italian Association for Industrial Research) are also active on EHS, ELSI and regulatory implications of nanotechnologies.

7. Information on any public/ stakeholder consultation

Stakeholders' consultations have been held on the European Code of Conduct on Nanotechnologies, within the NanoCode project (www.nanocode.eu) during a workshop held in June 2011, and in the framework of INAIL "White Paper on engineered nanomaterials and occupational health effects" during a workshop held in January 2012.

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

In 2010 started the European project LAMP (contract number 247928) dealing with nanomaterials for the OLED/Ts manufacturing. In the LAMP project was forecasted a task focused on Life Cycle Assessment of the materials, techniques and products manufactured within LAMP.

A preliminary work was already carried out by the team belonging to ENEA (www.enea.it) in the frame of LAMP on nanoparticles produced within the project (a publication at a National congress has been presented). During the next year will taken into account the impact on additional materials (polymers and nanocomposites), the laser processing and the device manufacturing produced within the project.

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

None.

JAPAN

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

None.

2. Developments related to voluntary or stewardship schemes

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

3. Information on any risk assessment decisions

None.

4. Information on any developments related to good practice documents

A study report of "the Expert Meeting on Safety Measures for Nanomaterial Manufactures etc.," based on the discussion on safety measures introduced by nanomaterial manufactures on voluntary basis was published by METI in March 2009[2]. Following the conclusion of the report, METI publicised information gathered which the manufacturers provided voluntarily information on test data and management methods, on METI's website in March 2010 (only in Japanese). The information gathered from the manufacturers is being revised and will be publicised within FY 2012.

Ministry of Health, Labour and Welfare (MHLW) established two committees on safety of manufactured nanomaterials in 2008. Those committees discussed safety of nanomaterials in occupational settings and in consumer products, respectively. The first committee issued the report in November 2008, and the second one in March 2009, which was translated into English. According to the report of the first committee, titled "Review Panel Meeting on Preventive Measures for Worker Exposure to Chemical Substances Posing Unknown Risks to Human Health (Nanomaterials)[3]", MHLW revised a notification for exposure prevention in the workplace in March 2009. Moreover, MHLW conducts commissioned surveys on the utilisation of typical nanomaterials and literature research on the toxicity of those nanomaterials, etc. every year since 2007, and published the report of FY 2009 and FY 2010. The report of FY 2009 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 the report of FY 2010, preliminary research on estimate of exposure to nanomaterial was conducted based on several scenarios.

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

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

From April 2012, Ministry of Health, Labour and Welfare Committee began consideration of risk assessment for the prevention of impairment of workers' health caused by exposure of the (Nanomaterials) titanium dioxide.

Japanese Industrial Standards Committee (JISC), established within METI, is the national member body participating as a P-member in ISO/TC229 (Nanotechnologies). JISC nominated the Convenor and Secretary of TC229/JWG2 (Measurement and characterization). During the period from December 2011 to April 2012, one TC229 document was published, which had been developed under JISC's lead:

- ISO TR 10929 "Nanotechnologies - Characterization of multiwall carbon nanotube samples" (published on 20 January 2012)

JISC currently leads the development of the following documents:

- TC229/WG2/PG13 - TS 16195 "Nanotechnologies -- Guidance for developing test materials consisting of nano-objects in dry powder form" (NWIP approved on 26 March 2010)

- TC229/WG4/PG6 - TS 17200 "Nanotechnologies -- Specification for nanoparticles in powder form: Characteristics and measurement methods" (NWIP approved on 10 May 2011)

In June of 2008, MOE established an expert committee on potential risk of manufactured nanomaterials to human health and the environment by the exposure in the ambient environment. The committee issued the "Guidelines for preventing the environmental impact of manufactured nanomaterials" to provide manufacturers with currently available information for the environmentally sound management of manufactured nanomaterials, in March 2009[4]. Based on "Future Challenges" which were identified in the Guideline, MOE has conducted and reported an experimental study on 1) effectiveness of countermeasures to reduce releases of nanomaterials to the environment, such as filters and coagulation sedimentation, and 2) applicability of existing measuring methods for nanomaterials in the ambient air and water in FY 2009. MOE has also started an experimental study on effectiveness of the incineration of nanomaterials as a countermeasure to prevent releases of nanomaterials to the environment in FY 2010.

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

None.

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

METI completed a five-year programme for "Evaluation of the Potential Risks of Manufactured Nanomaterials based on Toxicity Tests with Precise Characterisation" in FY 2010, which focused on toxicity test protocols and a risk assessment methodology of manufactured nanomaterials. The programme was coordinated by the New Energy and Industrial Technology Development Organisation (NEDO, R&D management organisation) and the National Institute of Advanced Industrial Science and Technology (AIST) which conducted much of this research in cooperation with the University of Occupational and Environmental Health and other universities. In the summer of 2011, AIST released reports on the risk assessment of the three nanomaterials (fullerene, carbon nanotubes and titanium dioxide) as well as a

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

concept paper "The Principles and Basic Approach to Risk Assessment of Manufactured Nanomaterials." The English translations of the executive summaries are available for download from the AIST-RISS website[5]. Some other documents such as "Methods of Preparation and Characterization of Manufactured Nanomaterials for Toxicity Testing" were also released. NEDO/AIST held a two-day international symposium in Tokyo on 29-30 September 2011 to explain the achievements of the programme, whose abstract book and lecture videos are available for download from the NEDO website[6].

METI launched a five-year programme for the "Development of Innovative methodology for Safety Assessment of Industrial Nanomaterials" in September 2011, which aims to develop fundamental hazard assessment methodology leading to a tiered risk assessment approach for industrial nanomaterials. The programme has two R&D themes: 1) establishment of equivalence criteria of nanomaterials and 2) establishment of an intratracheal instillation method as low-cost and convenient method for hazard assessment to acquire basic hazard information, both of which are for regulatory purposes.

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

The R&D results from these METI programmes will be contributed to OECD and ISO activities.

MHLW has promoted research on the human health aspect of several nanomaterials since 2003 through the Health and Labour Sciences Research Grants, etc. In FY 2012, eight research projects, including a basic research on development of methods for evaluating hazard and disposition of nanomaterials on human health, are progressing.

The Japan Bioassay Research Center launched a "Research project on the potential hazards, etc. of nanomaterials", commissioned by MHLW, which focuses on carcinogenicity of nanomaterials used/manufactured in the workplace (six-year programme, FY 2009-2014). Thirteen-week inhalation study has been performed (FY 2011) as the preliminary studies for two-year inhalation study of MWCNT. In addition, in order to elucidate of the carcinogenic mechanism, in vitro chromosome aberration and in vivo micronucleus tests will be carried out in FY 2012.

The National Institute of Occupational Safety and Health Japan (JNIOSH) launched a three-year project study, "Toxicological Study on Ultrafine Particles of Metal Oxides", in April 2012. This project includes investigation on 1) genotoxicity, 2) neurotoxicity, and 3) reproductive toxicity of nano-sized TiO2 particle.

In 2006, the National Institute for Environmental Studies (NIES) launched a nanotoxicology programme to investigate both in vitro and in vivo toxicities of nanostructured particulate materials. In the 1st nanotoxicology programme (FY 2006-2010), NIES completed several studies concerning interaction of nano fibres including CNTs with cell membranes and in vitro transepithelial and transpulmonary migration of polystyrene or gold nanoparticles. In FY 2011 NIES started the 2nd nanotoxicology programme which includes in vivo toxicological study of MWCNT, in vitro and in vivo toxicological study of silver nanoparticles, toxicokinetics of fluorescence-labelled dendrimers, and ecotoxicological study of titanium dioxide nanoparticles using embryo and sac-fry fish.

[5] http://www.aist-riss.jp/main/modules/product/nano_rad.html

[6] http://www.nedo.go.jp/english/event_20110929.html

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

7. – 9. (None.)

KOREA

Highlight of developments since the 9th meeting of the WPMN

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

- MKE has prepared a "Guidance on safe management of nanotechnology based product". The goals of this standard are to specify appropriate compliances for nanoproducts manufacturers 1) to enhance acceptance of nanoproducts to the public, 2) to ensure sustainable development of nanotechnology, and 3) to promote safety for consumer and nanotechnology user. This guideline will give a responsibility and good practice on safety in developing nanotechnology or nanotechnology in commerce. This guideline was published as Korean Standard on 12 May 2011.

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

Work completed, underway or planned

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

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

MKE is completed a "Guidance on safe management of nanotechnology based product". This guideline will give a responsibility and good practice on safety in developing nanotechnology or nanotechnology in commerce. This guidance was published as Korean Standard on 12 May 2011.

2. Developments related to voluntary or stewardship schemes

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

3. Information on any risk assessment decisions

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

KATS (The Korean Agency for Technology and Standards, an affiliated body of MKE) has developed a draft guideline for exposure monitoring of nanomaterials such as Carbon nano tubes (CNTs) and silver nanoparticles, and method for exposure assessment. The guideline will be published as Korean Standard after the standard committee's review. KATS is developing the reference doses of silver nanoparticles for workers and consumers. The draft provisional reference doses have been presented in OECD WPMN SG8 meeting in Aug, 2011.

4. Information on any developments related to good practice documents

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

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

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

Ministry of Environment (MOE)

MOE implemented the projects such as 'Research on the most relevant dosing metric for the ecotoxicity management system of manufactured nanomaterials (2009~2012)' in order to identify the correlation between the dose metric and the risk assessment and 'Genomic studies of nanoparticles to rats, bacteria, yeast and fish' to develop alternative methods for nanotoxicity tests.

MOE and NIER (National Institute of Environmental Research, an affiliated body of MOE) have conducted the nanomaterials hazard assessment projects to review and adopt the OECD TGs on nanomaterials and cumulate the data related to physico-chemical properties, eco-toxicity, environmental fate and human-health in order to contribute to decision making since 2007. MOE and NIER launched the project for a survey on the production, use, import and export volumes, use pattern and the information on manufactured nanomaterials in order to establish inventory for nanomaterials. As a result, in December 2011, MOE conducted an inventory survey on nanomaterials and is performing a follow-up survey on four nanomaterials (CNT, ZnO, Ag, SiO2) to investigate their states of lifecycle circulation and specific usages, etc. NIER organized the Nanomaterial Risk Expert Committee and held the fifth meeting in Oct, 2011. This committee handles the nanomaterial safety issues, such as reviewing of the project planning on the nanomaterial safety assessment. Also, we are preparing a guideline on definitions of nanomaterials at an inter-ministerial level by the end of 2012.

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

Ministry of Education, Science and Technology (MEST)

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

KRISS (Korea Research Institute of Standard Science, a subsidiary body of MEST) has been developing the National Measurement Standards of materials (including nanomaterials). In connection with this topic, the research project on "Development of Characterization Techniques for Nanomaterials Safety (2009 – 2015)" was launched. This project is composed of four parts; i) physic-chemical property characterization of nanoparticles such as silver, gold, titanium dioxide, polystyrene, silicon dioxide, CNTs and quantum dot has been conducted in order to develop their CRMs, ii) Surface structures and its compositions are studied using XPS, MALDI-ToF, ToF-SIMS etc. iii) The size measurement of nanoparticles is also executed with

SMPS, DLS, PBMS, TEM, BET and AFM as a part of OECD WPMN and VAMAS (TWA34) projects. Nanoparticles trace technology using ToF-SIMS and Raman spectroscopy is under development. iv) The studies on the transport and potential transformation of nanomaterials (ADME) are underway.

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

Ministry of Knowledge and Economy (MKE)

MKE in collaboration with MEST has initiated the programme "Strategy on Nano Convergence Industry Development" to strengthen research on the safety and social impact of nanomaterials. The MKE/KATS implemented "Risk Management Platform Technology for NanoProducts (2009-2013)" which will provide an infrastructure for the certification of nanoproducts based on a risk management system including characterization, efficacy quality and safety assessment along with standard development. MKE recently submitted a “Plan for safety management of nanotechnology based products” to National Science and Technology Council and the plan was approved by the council. KATS has been developing national standards to ensure safety and support marketing of consumer products containing silver nanomaterials and CNTs. Guidelines for exposure monitoring, characterization, and exposure assessment of nanomaterials such as CNTs and silver nanoparticles were completed. Accordingly, a guideline for exposure monitoring of nanomaterials will be published in 2011 after standard committee’s review. KATS will develop a new standard for safe handling and disposal of nanomaterials in 2011. KATS is developing the reference doses of silver nanoparticles for workers and consumers. The provisional reference doses have been presented at OECD WPMN SG8 meeting in Aug, 2011.

Korea Food & Drug Administration (KFDA)

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

Test materials such as SiO2, silver, gold and ZnO have been used to prepare guidelines for safety evaluation. Effects of size, shape and surface properties of nanomaterials on general toxicity, genotoxicity, immune response, developmental and reproductive toxicity, brain uptake mechanism, interaction with biomaterials were mainly investigated. From 2010 to 2012, KFDA plans to mainly conduct studies on the selected nanomaterials, such as SiO2 and ZnO to get the information on physico-chemical properties, kinetics, and toxicity.

Ministry of Employment and Labor (MOEL)

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

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

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

6. Information on any public/ stakeholder consultation

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

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

THE NETHERLANDS

Highlight of developments since the 9th meeting of the WPMN

- The Netherlands initiated the European NANoREG project, which aims to address priority questions of legislators on aspects of manufactured nanomaterials such as characterisation, dosimetry, exposure issues, in-vivo testing, in-vitro testing, life cycle and safe by design.

- RIVM recently published the report "Interpretation and implications of the European Commission Recommendation on the definition of nanomaterial" in which RIVM elaborates on interpretation of the (recommended) definition of the European Commission and its consequences for the various regulatory frameworks.

Work completed, underway or planned

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

- On 8-9 March 2012 the European Policy Conference "Choices for Safety" took place in The Hague, the Netherlands. In an open setting the fifty participants (including delegates from 14 EU Member States and various stakeholders from EU-Industry, European NGOs, the European Parliament and the European Commission) discussed the several options to regulate nanomaterials where needed and appropriate. Conclusions from the meeting where used to prepare a letter to the European Commission, supported by 9 member states and Croatia. In this letter the European Commission is urged to adapt European legislation to enable an adequate risk assessment system for nanomaterials and gain better knowledge on what is on the market (e.g. which nanomaterials, products and uses).

- The Netherlands initiated the European NANoREG project. This project involves 60 partners from 14 EU member states which brings together regulators, toxicologists, researchers and industry. The 42 month project, with a total budget around 50 million euro, is coordinated by the Ministry of Infrastructure and the Environment of the Netherlands. It aims to address priority questions of Member State national legislators, which are channelled through JRC to different work packages where aspects such as characterisation of manufactured nanomaterials, dosimetry, exposure issues (occupational, consumer and environmental), *in-vivo* testing, *in-vitro* testing, life cycle and safe by design will be dealt with. The project will not develop new test methods, but will rather test and optimise existing procedures. NANoREG will (i) provide answers and solutions from existing data, complemented with new knowledge, (ii) Provide a tool box of relevant instruments for risk assessment, characterisation, toxicity testing and exposure measurements of manufactured nanomaterials, (iii) develop, for the long term, new testing strategies adapted to innovation requirements. The interdisciplinary approach involving the three main stakeholders (Regulation, Industry and Science) will significantly contribute to reducing the risks from manufactured nanomaterials in industrial and consumer products. A great deal of interest has been shown in this project and its potential global impact by the USA, Japan, Australia, Canada, Russia and China, and links will be forged as the project progresses to ensure a maximum impact from NANoREG results.

2. Information on any risk assessment decisions;

Within the REACH process the Netherlands has proposed silica for substance evaluation. Currently, work is underway to evaluate the available data in the REACH registration to determine if additional data may be needed, specifically in relation to the nanosized properties of synthetic amorphous silica.

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

The Social and Economic Council of the Netherlands (SER) has recommended the use of provisional nano reference values as alternative for health based recommended occupational exposure limits or derived no-effect levels. The advice of the SER (only available in Dutch) includes a description on how these provisional reference values should be derived and used, according to the Dutch Trade Unions and the Confederation of Netherlands Industry and Employers.

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

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

RIVM is also funding research projects investigating the use of in vitro studies for hazard/ risk assessment of nanomaterials, possibilities to extrapolate safety data between different nanomaterials and identifying adequate dose metrics enabling the prediction of responses of different nanomaterials.

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

- NanoNextNL is a research and innovation program on nano- and microtechnology in the Netherlands. It has a budget of 250 M€, 125 M€ from government, the other half from universities, research institutes and the business community. In total over 110 partners participate, including more than 80 companies (about 70 small/medium enterprises). Research will be done

along the following lines: energy, nanomedicine, clean water, food, beyond Moore ('nano-electronics'), nanomaterials, bio-nano, nanofabrication and sensors & actuators. Beside these lines an integrated line covering Risk Analysis and Technology Assessment is formulated. The basic thought behind this integrated line is to turn information on risks into (pivotal) information that stimulates technological and economical development of nanotechnology. Therefore this line covers both links to the relevant technical lines, as well as risk research of a more generic nature. NanoNextNL has started in 2011 and runs until 2016.

- RIVM has become a member of QNano, the European Union-funded infrastructure for nanomaterial safety testing. This four year project which began in February 2011 comprises 27 top European analytical & experimental facilities in nanotechnology, medicine and natural sciences. It aims to create an integrated hub to support Europe's nanosafety research community.

- RIVM is actively involved in the working groups of the EU NanoSafety cluster. One of the activities in this cluster is the development of a NanoVision 2020.

Additional Information

- **Risks of Nanotechnology Knowledge and Information centre (KIR-nano).** KIR-nano aims at observing and monitoring the potential risks of nanotechnology, gathering relevant scientific literature, generating overviews of relevant legislation, and advising and informing governmental bodies and professionals. These activities are always performed from a risk assessment viewpoint. Its signalling function is put into practice by participating in national and international networks (e.g. OECD-WPMN, REACH CASG-Nano, ISO, SCENIHR, ILSI, EFSA, SETAC, WHO/FAO, ETP NanoMedicine) and bringing experts together into national expert panels on different topics (environment, food, consumer products, medical applications, and workers). In addition, KIR-nano is involved in the EU FP-7 projects EU-ObservatoryNano and NanoImpactNet. In this way, KIR-nano acts as an information exchange platform without performing research itself. KIR-nano regularly publishes newsletters in Dutch directed at professionals and regulators but publicly available (www.rivm.nl/nanotechnologie - in Dutch). It also recently published a report entitled "Interpretation and implications of the European Commission Recommendation on the definition of nanomaterial" in which RIVM elaborates on interpretation of the (recommended) definition of the European Commission and its consequences for the various regulatory frameworks, particularly regarding new nano-specific data requirements.

SOUTH AFRICA

Work completed, underway or planned

South Africa has produced 100 litres of 14 nm gold nanoparticles. This was achieved by employing the Mintek in-house developed Standard Operating Procedure (SOP). The product is to be distributed to various laboratories under the OECD's Sponsorship programme on the testing of manufactured nanomaterials PHASE I.

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

None

2. Developments related to voluntary or stewardship schemes

The South African Agency for Science and Technology Advancement (SAASTA) was mandated to implement and administer the Nanotechnology Public Engagement Programme (NPEP) on behalf of the Department of Science & Technology (DST). The NPEP launched in 2008, aims at promoting public understanding of and engagement with this emerging scientific field. This is achieved by profiling its achievements through different platforms such as media platforms, Science Festivals, Nano Tours, Conference Exhibition etc. The NPEP in collaboration with national facilities such as CSIR, Mintek etc. conduct National Nanotechnology facility tours. The objectives of both the tours and exhibitions include creation of awareness around nanotechnology, educating the public and enhance their understanding of nanotechnology; to get industries involved in the development of nanotechnology and taking the lead in nanotechnology innovation.

3. – 9. (None)

Additional Information

South Africa has successfully convened a workshop on gold nanoparticles 2-4 May 2012 held at Kloofzicht Lodge, Muldersdrift, in Johannesburg. The topics discussed pertaining to gold nanoparticles included In vitro Toxicity tests, Surface modification: fate and applications, Methods for physicochemical properties measurements, Synthesis and Characterisation, Biopersistence and exposure assessment of nanoparticles, Translocation and Genotoxicity, Ecotoxicity tests, Applications, Biodurability, as well as the Nanotechnology Public Engagement Programme (NPEP) in Promoting Public Understanding of and Engagement with Nanoscience and Nanotechnology in South Africa. Four discussion sessions were also held on "Pitfalls and recommendations as well as methodologies that need to be implemented to assess translocation, accumulation and biopersistency", "Pitfalls and recommendations on methodologies used to assess toxicity of nanoparticles in vitro", "Pitfalls and recommendations on methodologies used to assess toxicity of nanoparticles in vivo" and "Importance of biodurability of gold and other nanoparticles on their long term pathogenicity". Delegates from EC, JRC, South Korea, China, the Netherlands, and Denmark have joined the South African delegates working on the gold nanoparticles sponsorship programme. Representatives from the South African Science and Technology (DST) were also invited to attend the

SWITZERLAND

Highlight of developments since the 9t meeting of the WPMN

- Relying on the existing resources, the Swiss Federal Council continues the action plan for synthetic nanomaterials through the end of 2015, while at the same time setting priorities. In spring 2012, it has adopted a report to that effect, which also takes stock of the implementation progress of the 2008 action plan:

  http://www.bag.admin.ch/nanotechnologie/12167/index.html?lang=en
  (only available in German and French)

- In spring 2012, the new website www.infonano.ch was launched. The website brings together the formerly separate nano web pages of the different federal entities involved into the action plan, and it was designed to present a more comprehensive overview of the different issues and activities. The main contents of the website is tailored in a relatively plain language, thus providing basic information to a broad public. Navigating downwards the page, information becomes more in-depth and via further web links, scientific information can be obtained.

Work completed, underway or planned

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

Switzerland has settled a mutual agreement of recognition (MRA) with the European Union regarding the implementation of the new EU biocides regulation. The authorisation process will take into account manufactured nanomaterials. The work for details about the required endpoints and related studies is still under progress.

According to the Swiss chemicals regulations, as a first step before chemicals or chemical products may be brought to market, manufacturers are obliged to perform a self-control which includes furnishing information relevant to hazard and risk evaluation, as well as classifying and labelling their products and to decide whether there is an obligation to register or to undergo authorisation. A guidance document which deals on how to perform this self-control in the case of nanomaterials is in preparation, and a draft version will be published for review by the end of 2012.

2. Developments related to voluntary or stewardship schemes;

During 2011 and 2012, the precautionary matrix for synthetic nanomaterials and the related guidance documents have further been updated, and a useful, web-based version of the precautionary matrix has been established. The precautionary matrix is available under the following address:

http://www.bag.admin.ch/nanotechnologie/12171/12174/index.html?lang=en
(available in English, German, French and Italian)

3. Information on any risk assessment decisions;

None.

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

The safety data sheet guidance document for synthetic nanomaterials has been updated in April 2012:

http://www.bag.admin.ch/nanotechnologie/12171/12176/index.html?lang=en
(available in English, German, French and Italian)

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

The Competence Centre for Materials Science and Technology (CCMX) is one of several centres of excellence initiated at the national level by the board of the Swiss Federal Institute of Technology (ETH) in early 2006. It aims to serve the interests of Switzerland in the field of materials science in terms of research, education and technology transfer by reinforcing ties between academia, industry and the Swiss economy. Web address: www.ccmx.ch

From 2010 until 2014, the V.I.G.O. project of the CCMX MatLife programme is ongoing - a new evaluation tool for determination, description and comparison of the biological effects of nanoparticles and nanomaterials, a series of *in vitro* methods addressing four key aspects of cytotoxicity (viability, inflammation, genotoxicity and oxidative stress) will be developed and/or re-evaluated for their suitability to detect nanomaterial toxicity. The goal of the project is to create and validate a testing platform for these toxicological effects, which is based on existing OECD and ISO guidelines and will be comprised of at least two different assays for each of the four endpoints, taking into account the interference of several manufactured nanomaterials with some test systems.

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

Research associated with nanotechnology and nanomaterials is currently funded by the **Swiss National Science Foundation** with a National Research Focus (NRF) and a National Research Programme (NRP). The purpose of the **NRF "Nano Sciences"** is to generate impulses for "life sciences, sustainability and new information and communication technologies". Moreover, it was the basis for the foundation of the Swiss Nanoscience Institute (SNI) at the University of Basel.

The opportunities and risks of nanomaterials are analyzed in **NRP 64**, which was launched in December 2010. The funding of NRP 64 is CHF 12 million for the planned research period of five years. Several individual research projects within NRP 64 address specifically human health or environmental safety aspects of nanomaterials. Website: http://www.nfp64.ch/E/Pages/home.aspx

Furthermore, several Federal agencies are directly funding individual research projects that are addressing knowledge gaps relevant for regulatory purposes. Study results are continuously being published in the scientific literature.

7. Information on any public/ stakeholder consultation;

During May 8 -9, another yearly meeting of regulatory bodies from the four German speaking countries Germany, Austria, Switzerland and Liechtenstein was held in Zurich. The focus of this year's meeting was the role of press and media within the public discussion on nanotechnologies and nanomaterials. Web link to the press release:

http://www.innovationsgesellschaft.ch/media/archive2/Veranstaltungen/behoerdendialog_2012_zuerich/Pressrelease_BHD_2012_Zuerich.pdf

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

The Federal Office for the Environment has commissioned a new study in the field of prevention of major accidents. This study is assessing several different nanomaterials for their toxicological and ecotoxicological effects due to a release of substantial amounts on the occasion of a major accident. Through exposition and dispersion scenarios, the study identifies nanomaterials of concern and assesses the applicability of the existing regulation for the prevention of major accidents with regard to manufactured nanomaterials. The study report will be published by the end of 2012.

Concerning life-cycle aspects of nanomaterials, there are ongoing studies destined to model and predict the distribution of manufactured nanomaterials into the different environmental compartments. These studies

are mainly coordinated and performed by the Swiss Federal Laboratories for Materials Science and Technology (Empa). Study results are continuously published in the scientific literature.

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

None.

Additional Information

- The NRP 64 (see chapter 6) includes a number of projects that are explicitly assessing benefits and practical applications of nanomaterials and nanotechnologies.

  As the Commission for Technology and Innovation of the Federal Government, the CTI supports application-oriented research and development and promotes entrepreneurship. Between 2004 and 2010, the CTI has sponsored 74 microtechnology- and nanotechnology-related co-operation projects. Overall, nanotechnology-related co-operation projects carried out among universities and industry were sponsored with CHF 61 million; the federal government contributed close to half that, with CHF 28 million. The CTI-supported nanotechnology projects cover a wide range of innovation-oriented Swiss industry. Questions concerning the risks associated with the handling of nanomaterials are an important focus of these projects. At the same time, a number of projects are being sponsored that highlight the contribution of nanomaterials and nanotechnology towards more sustainable energy generation, efficient use of materials and manufacturing processes, protection of resources and reduction of harmful substances in the environment.

- The Swiss Centre for Technology Assessment (TA-Swiss) is currently performing a study about the opportunities and risks of nanomaterials for the environment and health, which will be published by the end of 2012. This study shall encompass all aspects of opportunity and risks related to nanomaterials, including resources, energy, social, ethical and economical considerations, as a basis for decision-making in Switzerland. Web address:

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

- Co-working with the UN Institute for Training and Research (UNITAR), Switzerland is actively promoting the incorporation of nanotechnology issues into the Global Plan of Action (GPA) of the Strategic Approach to International Chemicals Management (SAICM), and to formulate nano-specific issues within the different work areas of the GPA. In particular, these efforts aim towards awareness-raising and knowledge-building in developing and threshold countries. Until now, Switzerland has also sponsored two rounds of awareness-raising workshops on nano issues, thereby covering several countries and UN regions.

THAILAND

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

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

The National Nanotechnology Center (NANOTEC) has established:

- National Nanosafety Strategic Plan which had already been approved by the Executive Board Committee of NANOTEC, the Board of National Science and Technology Development Agency (NSTDA), the Board of National Science Technology and Innovation Policy Office, which then will be approved by the Cabinet

- Nanotechnology Information Center of Thailand (NICT) at Chulalongkorn University

- "Nano Q" as a nanomark for selected Thai nano-products to certify the presence of nanoparticles and nano-properties e.g. anti-bacterial and water repellent

- Three National Nano-safety Guidelines for the public, researchers, and industries

- Nanosafety training program with UNITAR which had already co-organized for the nanosafety roadmap workshop.

- Workshops and seminars of Nanosafety in Thailand: Status report of Thai Nano-products to disseminate knowledge in nanotechnology and its potential risk to the public.

- Nanotoxicity and ecotoxicity research program of nanosilver, TiO2, fly ash particles

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

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

- Collaboration with the Ministry of Public Health and the Ministry of Labor for nanoparticle screening in plants and manufactures.

Strategic goals of NANOTEC:

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

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

3. Standardize and validate nano-scale measurement and testing methods.

4. Integrate nanosafety roadmap into the National Chemical Safety Strategic Plan.

5. Evaluate the role of nanoparticle properties in exposure-dose-response relationships, develop and validate models for nanoparticle risk assessment, and determine risk estimates of occupational exposures.

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

Thai Industrial Standard Institute (TISI)

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

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 2012.

Nano-safety in Thailand Q&A:

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

At the beginning of 2012, three nanosafety guidelines have been developed for the public, researchers, and industries. The nano-label, so called Nano-Q, have been initiated and planned to approve some nanoproducts in the mid of 2012 by Nanotechnology Association of Thailand. Nanosafety roadmap was initiated as the direction and implementation of the National Nanosafety Strategic Plan. Nanosafety Roadmap Workshop was co-organized by NANOTEC and UNITAR.

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

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

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

2. Developments related to voluntary or stewardship schemes

Stewardship schemes are being studied in parallel with the nanosafety guideline development and the nano-mark initiative for textiles, color-paint, plastic and ceramics in order to certify nano properties e.g. anti-microbial and water-repellent.

3. Information on any risk assessment decisions

NANOTEC has regularly exchanged nanosafety information with the Thai FDA and Office of the Consumer Protection Board. Several misleading advertisements of nano-products were removed from the public media i.e. nano-water, nanosilver coated refrigerator, TiO2 coated air conditioner, nano-shirt etc.

4. Information on any developments related to good practice documents

The guideline mentioned in Item 1 will refer to all domestic and foreign good practice documents that are found during the literature review stage.

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

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

6. Information on any public/ stakeholder consultation

NANOTEC has regularly organized nanosafety public seminars, assembly forum, and international conferences including NanoThailand 2012, the largest international conference and exhibition of nanotechnology in Thailand, nanosafety session was included.

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

UNITED STATES

Highlight of developments since the 9th meeting of the WPMN

- EPA' Office of Research and Development will release its Strategic Research Action Plan for the Chemical Safety for Sustainability Program in June of 2012 (see http://www.epa.gov/ord/priorities/chemicalsafety.htm). The Research Plan includes most of EPA's nanotechnology environmental, health and safety research. Please see the Research Plan for specific research to be pursued. EPA will also release Requests for Applications under its STAR Grants Program in the Summer of 2012: these RFAs will likely include research on nanomaterials.

- EPA's Office of Research and Development has advanced research on a number of fronts in the 2011-2012 timeframe; a few examples of this work include the following:

  a. EPA researchers recently examined the manufacture and use of a range of nano-materials that are components of other products. These experts also studied the effect of nanocomponents on the four main components of the life cycle of resulting products: (1) material selection; (2) manufacture; (3) application; and (4) disposal/recycling. Because some health effects and risks associated with components used on this small scale may emerge only during discrete life-cycle phases, it is important for scientists to identify and interpret these risks. In September 2011, EPA published Guidance to Facilitate Decisions for Sustainable Nanotechnology, a document providing assistance for assessing the sustainability of nano-scale products.

  b. One nanotechnology that a team of EPA researchers are investigating is the fate and effect of nanometer-sized cerium particles used as fuel additives, particularly as they relate to air quality. The researchers are examining the difference between ordinary diesel emissions and those from diesel mixed with nano-cerium additives to better understand how adding nano cerium to fuel changes the composition of diesel exhaust. EPA scientists are also conducting atmospheric modeling research to estimate how cerium-induced emissions would change air quality if a portion, or all, U.S. diesel vehicles used nano-cerium fuel additives. Study results are expected in 2012.

  c. In the area of ecological effects, EPA researchers are also investigating whether nanomaterials might have harmful effects on ecological systems and non-human species. One outcome of the work is the finding that certain types of nano-scale titanium dioxide, a material currently used in many consumer products, were found to become very toxic to small aquatic organisms in the presence of sunlight (when tested in specific laboratory conditions). While non-toxic in laboratory settings, the addition of sunlight increases the toxicity of the material by a factor of 100 to 10,000, depending on the species tested. The phenomenon, called "phototoxicity," occurs at levels of natural sunlight that can be expected to occur under natural settings. EPA researchers have also developed rapid chemical assays that are highly predictive of these effects on whole organisms and are currently investigating these processes in terrestrial and marine systems. An additional area of focus in that realm is the toxicity and food chain transfer of single wall carbon nanotubes (a fibrous nanomaterial) in marine environments. The effort has demonstrated that these materials are relatively non-toxic to the tested marine species, and cannot be transferred along the marine food chain, from prey to predator. A key additional key outcome of this work has been the development of methods for extracting single wall carbon nanotubes from sediments and organisms and for their analysis using near-infrared technology.

- EPA is working in cooperation with NIOSH and CPSC to further research on workplace and consumer exposures to nanomaterials.

- EPA is working in cooperation with ILSI and other Federal partners on the release of carbon nanotubes from polymers.

- New Nanotechnology Signature Initiative

  On May 14th 2012, the agencies participating in the U.S. National Nanotechnology Initiative (NNI) announced their fourth Nanotechnology Signature Initiative. This signature initiative will stimulate the development of models, simulation tools, and databases that will enable the prediction of specific properties and characteristics of nanoscale materials.

  The signature initiative, Nanotechnology Knowledge Infrastructure: Enabling National Leadership in Sustainable Design (NKI) identifies four areas that will benefit from focused attention:

  1) A diverse collaborative community of scientists, engineers, and technical staff to support research, development, and applications of nanotechnology to meet national challenges

  2) An agile modeling network for multidisciplinary intellectual collaboration that effectively couples experimental basic research, modeling, and applications development

  3) A sustainable cyber-toolbox to enable effective application of models and knowledge to nanomaterials design

  4) A robust digital nanotechnology data and information infrastructure to support effective data sharing, collaboration, and innovation across disciplines and applications

Additional information may be found at http://www.nano.gov/sites/default/files/2012_05_14_nki_nsi_press_release.pdf

- U.S.-EU partnerships:

  The U.S. and EU have been working together to form 6 Communities of Research (CORs) based on conversations at the first U.S.-EU Bridging NanoEHS Research Efforts workshop, which was held in Washington DC on March 2011. These communities represent the ongoing commitment between the U.S. and EU to collaboratively address the open environment, health, and safety questions about nanomaterials. The CORs will provide a platform for scientists on both sides of the Atlantic to develop a shared repertoire of resources and strengthen their professional relationships.

  The first 3 CORs - Exposure through the Life Cycle, Ecotoxicity Testing and Predictive Models, and Predictive Models for Human Health - were launched at the March 2012 Society of Toxicology Annual Meeting in San Francisco. The remaining 3 CORS - Databases and Ontologies, Risk Assessment, and Risk Management and Control - will be launched at the NanoSafety Cluster meeting in Grenoble, France on May 31, 2012. The CORs will hold web meetings over the summer to build momentum leading into the second EU-U.S. Bridging NanoEHS Research Efforts joint workshop in Helsinki, Finland on October 25-26, 2012.

  Additional information may be found at http://us-eu.org/.

EUROPEAN COMMISSION (EC)

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

Worker protection

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

Following the announcement of a study to be elaborated during 2012 and the main objectives of which were described in the document Highlight of developments since the 8th meeting of the WPMN, work is progressing as anticipated. The call for tender described then was successfully launched and a contract signed with a consortium formed by Risk and Policy Analysts (RPA) and the University of Amsterdam (IVAM UvA). After a kick-off meeting held on the 9th of February 2012 clarity was shed on the work plan under the contract. The Nanos subgroup formed under the Chemicals Working Party (WPC) of the EU Advisory Committee on Safety and Health at Work will have met on the 6th of June 2012 to discuss and comment on the work plan proposed by the contractors at the kick off meeting. A workshop is foreseen as part of the deliverables, later in the year (29/30 November) and the final study report submitted shortly thereafter.

The discussion on the preparation of guidelines for nanomaterials will continue during the 2012 WPC meetings with the aim of preparing a draft opinion to be submitted to the ACSH plenary in tandem with the deliverables under the study.

As indicated in the Highlight document mentioned above the final objective of these activities is to allow for a set of conclusions that will inform an assessment and policy debate on the appropriateness of current Occupational Safety and Health legislation to protect workers from potential risks posed by nanomaterials and/or nanotechnology in EU workplaces.

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

7th EU Research Framework Programme (FP7)

a. 7 new projects selected under the fifth call for proposals have started, by topic:

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

- INSTANT: "Innovative Sensor for the fast Analysis of Nanoparticles in Selected Target Products
- SMART-NANO: "Sensitive Measurement, detection, and identification of engineered nanoparticles in complex matrices"
- NANODETECTOR: " Ultrasensitive plasmonic detection of single nanoparticles"

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

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

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

- ITS-NANO: "Intelligent Testing Strategy for Engineered Nanomaterials"

b. Work Programme 2012 and 2013:

iv) Under the 6th call for proposals, the following topics were addressed and proposals are currently under evaluations:

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

v) An orientation paper for the 7th and last call for proposals under FP7 lists the following topics:

- NMP.2013.1.3-1 Safety in nanoscale production and products.
- NMP.2013.1.3-2 Nanomaterials safety assessment: Ontology, database(s) for modelling and risk Assessment
- NMP.2013.1.3-3 Development of a systematic framework for naming and assessing safety of the next generations of nanomaterials being developed for industrial applications
- NMP.2013.1.4-3 Development of methods and standards supporting the implementation of the Commission recommendation for a definition of nanomaterial

More on: http://ec.europa.eu/research/participants/portal/page/fp7_documentation

c. Other:

- DG RTD NMP initiative EU Nanosafety cluster also continues their activities. More details at: www.nanosafetycluster.eu. The 2012 edition of the "Compendium of Projects in the European NanoSafety Cluster" is available: http://www.nanosafetycluster.eu/home/european-nanosafety-cluster-compendium.html

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

- The US-NNCO and European Commission DG RTD-Directorate G are fostering research cooperation on EHS issues of nanomaterials through joint workshops and the establishment of communities of Research. More on http://us-eu.org/

BUSINESS AND INDUSTRY ADVISORY COMMITTEE (BIAC)

PART I: ACC

The American Chemistry Council Nanotechnology Panel continues to advocate for the responsible development of nanotechnology among nanomaterial manufacturers and users. The Panel sponsors research and participates actively in national and international forums to advance scientifically sound approaches to the development of nanotechnology policy.

The Panel continues to engage on the U.S. Environmental Protection Agency's (EPA) use of existing regulatory authorities under the Toxic Substances Control Act (TSCA) to require reporting of certain information, implement test rules, and issue significant new use rules (SNUR) for nanomaterials[7]. The Panel continues to emphasize the needs for a consistent, practicable definition of nanomaterials and for considering the potential effects on small business. In addition, the Panel submitted to EPA formal comments on a proposed SNUR for two particulate substances. The Panel supported the proposed criteria for determining whether the substances would be used in a nano form.

The Food and Drug Administration (FDA) is also using its existing authorities to assess the use and safety of nanomaterials in pharmaceuticals, medical devices, cosmetics, and other products under its remit. FDA recently released two draft guidance documents on the safety of nanomaterials[8]. One deals with cosmetics, and the other deals with food and food packaging. The Nanotechnology Panel plans to submit comments on both draft guidance documents by the July 24 deadline.

The Panel is also engaged in numerous activities outside of regulatory venues. One new panel initiative is co-sponsoring with The George Washington University School of Public Health and Health Service an expert workshop titled "Strategies for Setting Occupational Exposure Limits for Engineered Nanomaterials." The purpose of the workshop is to bring together occupational health thought leaders from academia, government, industry, and non-governmental organizations to discuss new information and strategies for establishing and implementing occupational exposure limits (OELs) for engineered nanomaterials. Workshop sessions are expected to cover:

- Assessing the need for an OEL for an engineered nanomaterial when an OEL exists for the bulk material

- Comparing approaches currently used or proposed for setting OELs for engineered nanomaterials: advantages, limitations and data requirements

- Categorical OELs for engineered nanomaterials

- Practical issues related to establishing and using OELs for engineered nanomaterials: exposure assessment, dose metrics, sampling and analytical methods

[7] http://www.epa.gov/oppt/nano/#existingmaterials

[8] http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/default.htm

The workshop will take place September 10-11, 2012, in Washington, DC. A steering committee of experts from 3M, The George Washington University, New York University School of Medicine, the U.S. National Institute for Occupational Safety and Health, the U.S. Occupational Safety and Health Administration, Pacific Northwest National Laboratory, Toxicology Consultants, Inc., University of Massachusetts Lowell, and University of Rochester are designing the event. After the workshop, the steering committee plans to develop a workshop summary to be submitted for publication as a manuscript in a peer-reviewed nanotechnology journal.

In addition to the OEL workshop, the Panel continues to co-sponsor the NanoRelease Consumer Products research project managed by the International Life Sciences Institute's Research Foundation (ILSI-RF)[9]. The purpose of the project is to identify available methods for evaluating the release of nanomaterials from matrices, to identify new methods, and to test and evaluate selected methods. Multi-walled carbon nanotubes in polymer matrices will be the first experimental system. Expert teams are investigating various questions relative to the test materials and the methods that will inform the round-robin laboratory testing phase of the project. Other project co-sponsors include U.S. EPA, Environment Canada, Health Canada, Society of Chemical Manufacturers and Affiliates, U.S. National Institute of Standards and Technology, the Adhesive and Sealant Council, and the American Cleaning Institute. Labor unions, consumer advocates, and other U.S. government agencies participate either through the project steering committee or in an advisory capacity. In addition to our sponsorship, Panel members also invest considerable time serving on the project's steering committee.

One of the early outputs of the NanoRelease project was a literature review on what is known about the release of nanomaterials from solid matrices. The ACC Nanotechnology Panel is the sole sponsor of a project that would support ILSI-RF to update and publish the literature review in a peer-reviewed journal. Doing so will help to elucidate when and how release may occur and bring critical insights to future research on particle fate, transport, transformation, and effects.

Finally, the Panel is reviewing a potential ILSI-RF project called "NanoCharacter". The purpose of this project is to develop and publish a framework document in a peer-reviewed journal advocating for standard measurement and reporting practices for nanomaterial characteristics. Currently, the lack of consistent reporting on the physical and chemical characteristics of nanomaterials in the scientific literature complicates the ability to make weight-of-evidence statements across studies and identify important data for risk assessment. A critical part of the project will be to build consensus among the federal agencies that are the major sponsors of nanotoxicity research in the United States. This project is still in a formative stage, and the Panel hopes to share more detail in the future.

PART II: CEFIC

Highlights

- Active contribution of industry to national and international regulatory initiatives to effectively manage nanomaterials and nanotechnologies.
- Cefic was an active participant in the REACH Implementation Project aimed to evaluate the current guidance to the regulation with regards to nanomaterials.
- In January 2012, Cefic revised its Guidance describing how companies can apply the principles underpinning Responsible Care to their production and handling of nanomaterials.

[9] http://www.ilsi.org/ResearchFoundation/Pages/NanoRelease1.aspx

- 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 ensure availability of innovative and sustainable nanomaterials, nanotechnologies and nano-enabled products that help answer the social and environmental challenges and respond to the changing needs of society to improve quality of life of this and future generations. We strive for that our nanomaterials, products and technologies are researched, designed, manufactured and used safely and responsibly throughout their entire life cycle. We continuously initiate dialogues and engagement with stakeholders to ensure that the products we market answer the needs and priorities of our customers and stakeholders and make a strong contribution to boosting the European economy.

Work underway or planned

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

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

At the end of 2009 the first out of three REACH Implementation Projects started, aiming to evaluate the applicability of existing guidance with regards to nanomaterials. This first project addresses how to conclude on Substance ID and sameness with the purpose of forming SIEFs (substance information exchange forum) ahead of registration. The other two projects, which concern guidance on information requirement and how to conduct a chemical safety report, started in January 2010. All projects are now finalised and available on http://ec.europa.eu/environment/chemicals/nanotech/index.htm#ripon. Cefic welcomes the reports as the final outcome of an extensive evaluation of not only existing REACH guidance but also several hundred scientific reports to ensure nanomaterials are appropriately addressed. In the end, the reports confirm Cefic's views that in general the REACH guidance is applicable to nanomaterials with only few amendments needed. ECHA is incorporating the conclusions from the RIP-oN2 and 3 in the existing guidance to REACH.

In addition, Cefic and its members continue to actively contribute to the REACH Competent Authority subgroup on nanomaterials, initiated by the REACH Competent Authority Meeting. The aim of the subgroup is to consider how the overall provisions of REACH and its guidance documents could be applied to nanomaterials.

Cefic continues to contribute to the public debate regarding nanomaterials by providing scientific input to discussions on risk assessment methodologies and risk assessment measures to adequately control potential risks with nanomaterials. At the international level, Cefic works through the ICCA (International Council of Chemical Associations) to contribute to initiatives at the global level.

On October 18, 2011, the European Commission adopted its long-awaited recommendation for a definition of the term "nanomaterial". Cefic welcomes these efforts to develop a regulatory definition for nanomaterials to help provide legal certainty and consistency, but is concerned that the Commission's recommendation is too broad in scope and therefore difficult to integrate into existing legislation in a meaningful way.

Cefic fears implementing the proposed definition will add unnecessary burden for companies, leading to added costs and less efficient use of resources. In addition, its current form would define as nanomaterials some decades-old substances such as pigments used in paints and other everyday products. The chemical industry is also concerned by the lack of standardised measurement techniques, which are important for legal certainty.

Last year, Cefic together with ICCA, developed and agreed on a definition for nanomaterials (http://www.icca-chem.org/ICCADocs/Oct-2010_ICCA-Core-Elements-of-a-Regulatory-Definition-of-Manufactured-Nanomaterials.pdf). Cefic will now continue to offer the experience of the chemical industry to illustrate the practical consequences of the definition proposals under discussion based on real materials.

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

Through its Long-range Research Initiative (LRI), Cefic sponsors health and environment safety research on nanomaterials (www.cefic-lri.org). As a first example, one project (N1) led by Dr Otto Creuzenberg at the Fraunhofer Institute will test the suitability of OECD testing guidelines for nano zinc oxide and nano synthetic amorphous silica particles and define a tiered testing strategy for these nanoparticles. This project has started in 2010 – after a delay due to agreements needed on the reference material- and is now in the experimental phase. The ZnO part is already completed and the finalization of the SiO2 part is expected by summer 2012.

In order to address regulatory and public concerns, industry is evaluating, in a second Cefic-LRI research project (N2), the ecological risks that may be associated with nanoparticles. Currently accepted testing strategies will be evaluated, supplemented and improved, where needed, to address potential nano-specific effects focusing on ecologically relevant exposures. Through the LRI, the European chemical industry is sponsoring a project on the "assessment of nanoparticles specific effects in environmental toxicity testing". The research is being led by the group of Dr Alistair Boxall, at the University of York. The outcomes of the project will help determine the environmental impact of nanomaterials in aquatic systems. The project is now completed. Both projects are contributions of Cefic (via BIAC) to the Sponsorship Program of the OECD Working Party of Manufactured Nanomaterials.

Finally, a third Cefic-LRI project (N3) has been launched on testing and assessment of reproductive toxicity of Nanomaterials. The overall objective of this proposal is to analyze the suitability of current OECD guidelines to assess the reproductive toxicity of nanomaterials. Using two reference materials present on the OECD list of 'representative manufactured nanomaterials for testing' (1), nano silicium dioxide and nano zinc oxide, the ability of current reproductive toxicity OECD guidelines to identify hazard associated with nanomaterials will be tested in this project. The research is being led by Dr J. van de Sandt at TNO, in a consortium with BASF. The results of this project should address the following questions: do the existing OECD reproductive toxicity test guidelines adequately assess a potential hazard posed by nanoparticles, can the existing guidelines benefit from some revisions to better understand health risks posed by nanoparticles, and are there endpoints used to assess the potential hazard of industrial chemicals which may be inappropriate for testing nanoparticles? The project passed the suspension and aerosol characterization initial stage and 2nd-generation study is underway. Project completion is anticipated by end 2012.

Stakeholder Engagement

To draw on the strength of speaking on behalf of the entire industry, Cefic initiated last year an Industry Platform with participants from the supply chain. It has been proven a success and has achieved a better

coherency between different sectors but also allowed for a better alerting system on sector specific regulatory activities.

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

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

PART III: JCIA

Based on the action plan detailed in the Nanomaterial Opinion Statement formulated in July 2008, the Japan Chemical Industry Association (Working Group on New Issues) has been working to support the healthy development of nanotechnology, while at the same time paying attention to nanomaterial safety assessment initiatives in and outside Japan. This fiscal year, we have developed the following activities:

(1) In November 2011, we discussed the problems the chemical industry faces regarding the definition of nanomaterials proposed by the European Committee in order to present our opinions to the Ministry of Economy, Trade and Industry (METI). We pointed out that the definition, which is based on the number of particles rather than weight, creates problems due not only to difficulties related to materials management but also related to the lack of development of appropriate analysis equipment.

(2) In November 2011, METI organized a new examination committee on nanomaterial management and set up working groups on risk assessment and measurement technology as sub-organizations of the committee. These working groups are designed to examine problems regarding the risk assessment of various nanomaterials, as well as methods for measuring the distribution of particle diameters. We were requested to join the examination committee as technical members and started our activities as committee members in January 2012.

(3) In November 2011, we attended the 13th ISO TC229 WG4 Conference and presented opinions in support of the project proposed by Japan for the selection of measurement items toward the establishment of common standards on the basic properties of nanoparticle materials (using the following as criteria for materials standards: chemical composition, specific surface area, crystal structure, average crystallite diameter or average primary particle diameter).

(4) In February 2012, we attended a study session held by Osaka University in order to obtain the latest information as well as to provide the chemical industry's opinions on the university's research project. In view of the fact that this is the project's last year, we pointed out that the research has been overly focused on hazards, considering that the initial policy objective was to not only study hazards but also risk assessments. We also requested that research be conducted with a view to developing exposure assessment techniques, if possible.

(5) In March 2012, we presented a lecture on JCIA's global industrial initiatives regarding nanomaterial safety at the 132nd General Symposium held by the Pharmaceutical Society of Japan titled "The Frontline of the Nanomaterial Development and Safety Assessment: Industry, Government and University Initiatives." A consensus was reached at the conference that, as a unique industry-

government-academia joint project, a symposium like this could greatly contribute to the study of nanomaterial safety in the future.

(6) In September 2008, we joined the Japanese National Committee for ISO/TC229, an OECD follow-up group, in order to provide opinions as an active member thereof. As a high priority issue for FY 2012, we are currently focusing our efforts on the ISO/TC229 nano-labeling initiatives that are being advanced by CEN.

PART IV: NIA

Highlight of developments since the 9th meeting of the WPMN

- The NIA provided the BIAC co-lead representative to the WPN meeting 20-23 February 2012
- The NIA participated in the Expert Consultation Meeting of the WPMN Steering Group 7 on alternative test methods in nanotoxicology held on 27-29 March 2012.
- The NIA participated in the OECD Symposium on Assessing the Economic Value of Nanotechnology held on 27-28 March and the Workshop on Scoping the Needs of Governments and Collaborative Work to Meet those Needs held on 29 March 2012 in Washington DC.
- The NIA participated in the OECD Working Party on Resource Productivity and Waste workshop on "Safe Management of Nanowaste", 10 May 2012.
- The NIA collated and provided the first 'Raw Example Dossier' to the OECD WPMN (for review and commenting on by CoCAM (THFA)) as the first preliminary results collation of the OECD WPMN Sponsorship Programme; the example nanomaterial chose was nano-CeO2, due to the advanced measurement and testing status of this NM.
- The NIA attended the 9th WPN meeting in February 2012
- The NIA chaired & rapporteured sessions at the Joint OECD-NNI-AAAS Conference on Assessing the Economic Impact of Nanotechnology.

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

The NIA is continuing the coordination of the Global-NanoMaPPP, an international Public-Private-Partnership (PPP) for the Integrated Measurement and Testing of Representative NanoMaterials in Support of the OECD Sponsorship Programme.

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

- The NIA is continuing the coordination of the Global-NanoMaPPP, an international Public-Private-Partnership (PPP) for the Integrated Measurement and Testing of Representative NanoMaterials in Support of the OECD Sponsorship Programme. Global-NanoMaPPP provides continuing Sponsorship and Contribution of the following OECD WPMN nanomaterials: nano-ZnO, nano-CeO2, MWCNT, SWCNT, nano-Clay, nano-Silver, as well as nano-BaSO4.
- The NIA is continuing the coordination of the PROSPEcT project (Ecotoxicology Test Protocols for Representative Nanomaterials in Support of the OECD Sponsorship Programme).

- NIA is participating partner of the EU FP7 project MARINA (Managing Risks of Nanoparticles). (start date: 1st November 2011)

- The NIA participates in the FP7 project NanoMICEX (Mitigation of risk and control of exposure in nanotechnology based inks and pigments (start date: 1st April 2012)

7. Information on any public/ stakeholder consultation

On the 30th November 2011, the NIA held a workshop entitled 'Defining Nano!? - Compliance Requirements & Market Impact of the EU Definition of 'Nanomaterials'-'

In April 2012, the NIA submitted comments on the SAICM paper entitled Proposed Addition to the Strategic Approach Global Plan of Action - Activities on Nanotechnologies and Manufactured Nanomaterials.

PART V: VCI

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

Principle documents:

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

Regulatory documents:

- Requirements of the REACH Regulation on Substances which are Manufactured or Imported also as Nanomaterials

- Guidance for a Tiered Gathering of Hazard Information for the Risk Assessment of Nanomaterials

- Guidance for Handling and Use of Nanomaterials at the Workplace (updated in 2012)

- 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 (updated in 2012)

Documents on safety research:

- Roadmap for Safety Research on Nanomaterials

- Environmental Aspects of Nanoparticles

- 10 Years of Research: Risk Assessment, Human and Environmental Toxicology of Nanomaterials

These documents have been discussed with the public as well as with national and European authorities, and were also communicated to the OECD Working Party on Manufactured Nanomaterials (WPMN). The guidances for Handling and Use of Nanomaterials at the Workplace, and for Safe Recovery and Disposal of Waste have recently been updated.

Information on developments related to exposure measurement and exposure mitigation

In 2011, a special focus was given on workplace safety – also as VCI contribution to SG 8 of the WPMN. VCI, the German Federal Institute of Occupational safety and health (BAuA), the German Social Accident Insurance Institution for the Raw Materials and Chemical Industry (BG RCI), and the Federal Institute for Occupational Safety and Health (IFA) of the German Social Accident Insurance (DGUV) jointly evaluated actual experiences and took them as the basis for a joint strategy paper on a "Tiered Approach to an Exposure Measurement and Assessment of Nanoscale Aerosols Released from Engineered Nanomaterials in Workplace Operations". This information aimed at deriving best practices for exposition measurement and is currently communicated at scientific and political level.

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

In 2006, VCI and the German Federal Institute of Occupational safety and health (BAuA) had conducted a first survey on how industry is handling nanomaterials at the workplace. This survey is currently, with VCI's support and with an extended scope, repeated by BAuA. First results are planned to be communicated in summer 2012.

Further VCI activities

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

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

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

More information is available at www.vci.de

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

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

The International Organisation for Standardization Technical Committee (ISO/TC) 229 - Nanotechnologies - was established in June 2005 with a UK secretariat and chair. It has held twelve meetings to date, with the most recent being in Stresa, Italy, in June 2012. The next meeting will be in March 2013 in Querétero, Mexico. The committee currently has 44 members - 34 "P" and 10 "O". Twenty four documents have been published to date –see http://www.iso.org/iso/standards_development/technical_committees/list_of_iso_technical_committees/iso_technical_committee.htm?commid=381983 . The publication most relevant to the WPMN since its last meeting, in December 2011, is ISO/TR 13014:2012 - Nanotechnologies - Guidance on physicochemical characterization of engineered nanoscale materials for toxicologic assessment. The current list of documents under development has been shared with the members of the WPMN by the secretariat and comments are welcome.

ISO/TC 229 believes that close cooperation with the OECD WPMN will lead to valuable synergies and avoid duplication of effort by the two organisations. The relationship between TC/ 229 and the WPMN is governed by the terms of the 'ISO/TC 229 – OECD WPMN coordination paper – version 2, February 2009'. As an example of the benefits of collaboration, since the last WPMN meeting a series of TC 229 documents have been shared by the ISO secretariat with the TC 229 secretariat to facilitate the development of WPMN documents.

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

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

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

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

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

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

THE UNITED NATIONS INSTITUTE FOR TRAINING AND RESEARCH (UNITAR)

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

1. National Pilot projects

At the December meeting we informed the Working Party that UNITAR, with the support of Switzerland, had initiated national pilot projects related to nanotechnologies during 2011. The purpose of these pilot projects is to assist three non-OECD countries to assess and develop programmatic capacities to tackle nanotechnology issues at the national level. UNITAR has developed guidance and training materials to ensure that the participating countries are aware of the current state of the art in the nanotechnology field and of possible actions that can be taken at the national level – I have copies of the guidance here and it is available on the UNITAR website. The 3 countries involved are: Thailand, Nigeria, and Uruguay, and all three have held their project inception workshops earlier in 2012. Lessons learned from these projects will be presented in a side event of the International Conference on Chemicals Management at its third session, in September 2012. We plan for a dedicated side-event during which representatives of the 3 pilot countries will share experiences and lessons learned with interested SAICM stakeholders. We invite anyone here who will be at ICCM-3 to attend the event. Based on the experiences in these pilot projects, UNITAR plans to support further national projects using a similar concept, and UNITAR hopes that financing for such projects can be made available by donors.

2. SAICM-related activities

As most of you know, nano is considered as an ‘’emerging issue’’ in the SAICM process. We reported to you last time that at the first meeting of SAICM’s Open Ended Working Group, in Belgrade, Serbia, held 15-18 November 2011, UNITAR and the OECD presented a document regarding progress made

concerning the awareness raising with respect to the issues in the nanotechnology area, in particular focusing on information regarding the work to contribute to the implementation of ICCM-2 resolution II/4 E (largely dealing with the two rounds of regional workshops, progress in the country level activities, and progress related to the programme on the environmental, health and safety considerations of manufactured nanomaterials). In preparation for ICCM-3 in September this year, UNITAR and OECD have updated that report and it will be made available on the SAICM secretariat website.

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

NGOs and Consumer associations

1. Nano related claims on consumer products

ANEC (European consumer voice in standardization) and BEUC (European Consumer Organisation) are monitoring the use of nano-related claims on consumer products since 2009. In 2012, they have researched exclusively nano-silver claims, following a rising trend of claims related to the "antimicrobial" benefits of nano-silver. Overall, 117 products were found in different product categories, including cosmetics and babies products.

The extensive use of nano-silver by industry on one side is not match with consumer knowledge about the safety of nano-silver and its potential in contributing to the formation of antimicrobial resistance. Even though the safety of nano-silver is still being investigated as part of the Community Rolling Action Plan under REACH, as well as by the Commission's Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR), ANEC and BEUC inventory work shows that more and more products are appearing on the market that claim novel properties due to nano-silver.

Therefore an informative brochure "Nano – very small and everywhere – A technological magic silver bullet or a serious safety risk?" has been prepared and disseminated to public authorities and the NGO community.

The brochure includes key recommendations that we believe need to be reflected in the development of the EU policy on nanomaterials.

The full inventory and leaflet can be found on our websites:

www.anec.eu

www.beuc.eu

2. Legal review on EU chemical regulation on nanomaterials

CIEL (Center for International Environmental Law) has been recently published a research and study assessing the adequateness of REACH to regulate nanomaterials, and explore ways forward: "Just out of REACH: How REACH is failing to regulate nanomaterials and how it can be fixed" available at ***http://www.ciel.org/Chem/JustOutofREACH_Feb2012.html***

The study documents four key gaps for nanomaterials in the registration phase of REACH, an essential step that requires chemical manufacturers and importers to provide key health and safety information.

- REACH does not define nanomaterials, and contains no nano-specific provisions;

- Most nanomaterials will evade registration until 2018, yet they can still enter the EU market;
- REACH's schedule for registration hinges on the number of tonnes of a chemical, essentially missing all nanomaterials, which are generally produced in far smaller quantities; and
- REACH test guidelines fail to consider the special properties of nanomaterials.

"Just Out of REACH" also explores possible remedies to close these loopholes. Rather than re-opening REACH, the report proposes developing a stand-alone regulation, carefully aligned with the chemical rules, but specifically tailored to nanomaterials.

3. Standard development on nanotechnologies

ECOS (European Environmental Citizens' Organisation for Standardisation) is a non-profit umbrella organization working to ensure that environmental aspects are adequately addressed in technical standards for nanotechnology and nanomaterials. ECOS participates principally through its experts in CEN/TC 352 WG2 aiming at developing standards for methodologies for the characterisation of nanomaterials in the manufactured form and in ISO TC 229 (JWG1 and WG3) aiming at defining and developing unambiguous-uniform terminology and nomenclature (JWG1) as well as (WG3) Methods for (among others):

- Controlling Occupational Exposure to Nanomaterials,
- Determining Relative Toxicity/Hazard Potential of Nanomaterials,
- Environmentally Sound Use of Nanomaterials, for ensuring Product Safety of nanomaterials products
- Voluntary labelling of nanomaterials in products.

ECOS Objectives (http://www.ecostandard.org/?p=159):

- A sustainable deployment of nanotechnologies and nanomaterials.
- Clear definitions of nanomaterials and nanotechnologies as the lack of definitions leads to legal uncertainties and hampers the development of regulatory requirements;
- Adequate safety and risk assessment methodologies taking account of all significant characteristics of nanomaterials, incorporating the full application of the precautionary principle.