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THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY

CURRENT DEVELOPMENTS IN DELEGATIONS AND OTHER INTERNATIONAL ORGANISATIONS ON THE SAFETY OF MANUFACTURED NANOMATERIALS- TOUR DE TABLE

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Series on the Safety of Manufactured Nanomaterials

No. 17

CURRENT DEVELOPMENTS/ ACTIVITIES ON THE SAFETY OF MANUFACTURED NANOMATERIALS

Tour de Table at the 5th Meeting of the Working Party on Manufactured Nanomaterials
Paris, France 4-6 March 2009

Environment Directorate
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT
Paris 2009

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)*

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or contact:

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

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

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

In each meeting of the WPMN, the delegations have an opportunity to provide their developments on the safety of manufactured nanomaterials, so called "Tour de Table". An earlier version of this document was originally provided to the 5th meeting held 4-6 March 2009 in Paris, France. This document compiles information provided by member countries and other delegations on current developments on the safety of manufactured nanomaterials (section I) in their countries or organizations. There are also written reports on current activities related to nanotechnologies/ nanomaterials in other International Organisations including the International Organisation for Standardisation (section II). In addition, Section III includes the report from the OECD Secretariat at the 5th meeting.

The Working Party endorsed this document at its 5th Meeting on March 2009. This document is published on the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology of the OECD.

This is intended to provide delegations and other stakeholders with a "snapshot" of information on activities related to manufactured nanomaterials, as well as other activities on nanotechnologies, at the national and international level. This "snapshot" was current at the time of the 5th meeting of the WPMN (March 2009).

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

Background

1. 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 nanomaterials. This will facilitate the implementation of the eight 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.

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

Headings for the Tour de Table

3. 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. It also expected that there would be considerable variation amongst delegations as to the issues they wish to address, so there should be some flexibility in the way the information is provided. Those delegations who made submissions for the 4th meeting of the WPMN (June 2008) may wish to simply review their previous submission and make modifications or additions to the information as needed.

4. In addition, it was kindly requested that delegations add a short bulleted list of highlights at the top of their submissions. The highlights are expected to give readers a general idea of key events since the last meeting of the Working Party.

Firstly, please provide a list of the latest developments in your country and organisation since the 4th meeting of the WPMN (June 2008) as highlights to appear at the top of your document (see recommended format below). Then identify work completed, underway or planned in your country or organisation, which relates to activities on health and environmental safety aspects of manufactured nanomaterials (focusing on the chemicals sector):

1. Any national regulatory developments on human health and environmental safety including recommendations or discussions related to adapting existing regulatory systems or the drafting of laws/ regulations/ guidance materials;
2. Developments related to voluntary or stewardship schemes;
3. Information on any risk assessment decisions;
4. Information on any developments related to good practice documents;
5. Research programmes or strategies designed to address human health and/ or environmental safety aspects of nanomaterials;
6. Information on any public/ stakeholder consultation.

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

RESPONSES FROM DELEGATIONS

AUSTRALIA

Highlight of developments since the 4th meeting of the WPMN

- The Australian Government released three documents under the National Nanotechnology Strategy (NNS): '*The Australian Government Approach to the Responsible Management of Nanotechnology*'; '*A Review of Possible Impacts of Nanotechnology on Australia's Regulatory Frameworks – the Monash Report*'(July 2008); and NNS Annual Report 2007-08 (January 2009).
- A technical review on the environmental fate of manufactured nanomaterials will be released in early 2009.
- NICNAS issued a voluntary Call for Information on industrial nanomaterials in October 2008 to gauge the extent of nanomaterial introduction into Australia.
- Development of an Australian consortium to participate in the OECD Sponsorship Program for the safety testing of cerium oxide, zinc oxide and silver nano-particles.
- Extensive public awareness and community engagement activities have been undertaken in 2008.

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

In July 2008, the Australian Government released two documents. The first, '*The Australian Government Approach to the Responsible Management of Nanotechnology*', sets out three objectives that will guide government agencies, including regulators and policy makers in their decision making process and policy development for nanotechnology. The first objective states that any decisions should use an evidence based decision process that 'Protect(s) the health and safety of humans and the environment'. The second document was the release of '*A Review of Possible Impacts of Nanotechnology on Australia's Regulatory Frameworks* – the Monash Report', an independent analysis of the regulatory frameworks with regard to their ability to adequately address the health, safety and environmental impacts from nanotechnology. A key conclusion of the report was that "All regulatory frameworks applying to conventional products also were found to apply to nanomaterials and nanotechnology-based products." The report also found that while Australia's regulatory regime is well placed to respond to the impact of nanotechnology, there are certain aspects of the regulatory system that may require amendment in the future, and involve a long-term effort across government agencies. Individual agencies referred to in the

report are now examining their regulatory frameworks and actions identified are summarised in Table 4 of the NNS Annual Report (see Attachment). Specifically, NICNAS is developing a regulatory strategy for managing industrial nanomaterials that will apply to new and existing chemicals.

As per the strategies described previously in the 4th WPMN tour de table submission, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), in consultation with its Nanotechnology Advisory Group (NAG) issued a 2nd voluntary Call for Information (closed 23 January 2009) to gauge the extent of nanomaterial introduction into Australia. This extends the 1st call in 2006 to include industrial nanomaterials at the research and development stage, and aims to ascertain what categories of physicochemical and toxicological data are held on each nanomaterial. NAG's view is being sought for options in addressing potential gaps identified in the Monash Report. The outcomes of the 2006 Call were provided to the 2nd WPMN of April 2007 in the Tour de Table document.

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

2. Developments related to voluntary or stewardship schemes

No developments since the 4th meeting of the WPMN.

3. Information on any risk assessment decisions

NICNAS has become aware of the presence of carbon fullerenes in cosmetics introduced into Australia and the concerns raised in various international reports (e.g. the British Royal Commission Report on Environmental Pollution). Fullerenes are new chemicals in Australia (i.e. not listed on the national inventory) and must be notified to and assessed by NICNAS prior to commercialisation unless an exemption applies (e.g. if they are introduced in low volumes and meet certain criteria). NICNAS has proactively engaged companies that are introducing these new chemicals for commercial purposes using the exemption provisions and has achieved a high level of voluntary cooperation. Companies were also asked to provide evidence in support of their self assessment that the chemical poses no unreasonable risk to human health and/or the environment, and the received information is currently being considered. NICNAS published advice to industry about this matter in its December 2008 NICNAS Matters, and subsequently advised industry *via* the February 2009 Chemical Gazette to approach NICNAS before utilising exemption provisions.

4. Information on any developments related to good practice documents

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

- NT-001 contributed to development of the ISO Technical Report on "Health and safety practices in occupational settings relevant to nanotechnologies", and was represented on the ISO Steering Group for this project. This Technical Report provides advice relating to health and safety issues when working specifically with nanomaterials.

- NT-001 is also represented on the ISO TC229 HSE Working Group, which coordinates the development of international HSE related nanotechnology standards.

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

NICNAS, via networking with the Commonwealth Scientific and Industrial Research Organisation (CSIRO), has facilitated the development of an Australian consortium to participate in the OECD WPMN Sponsorship Program for the safety testing of cerium oxide, zinc oxide and silver nano-particles. Australian companies are also contributing nanomaterials for testing to the international project sponsors.

CSIRO is also in the process of establishing a new research program into the health, safety and environmental effects of nanotechnology (Theme 5 - Nanosafety) as part of its Niche Future Manufacturing Flagship.

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

The Department of the Environment, Water, Heritage and the Arts (DEHWA) has completed a technical review on the environmental fate of manufactured nanomaterials to inform its risk assessment methodologies and provide scientific advice to regulatory agencies. Also, to address some of the research needs identified in the review, DEWHA has commissioned a research study into key fate properties of a representative group of nanomaterials in the environment.

The Department of Education, Employment and Workplace Relations (DEEWR) has developed a Nanotechnology Occupational Health and Safety (OHS) Program 2007-09 which is currently commissioning a review on the toxicology of engineered nanomaterials, with particular focus on examining research findings over the period 2006-2008. It is also running a survey of Australian businesses and research institutions and organisations to determine which engineered nanomaterials are being used, which controls are being used to prevent exposure, and to seek the views of participants on the issues they have in relation to nanotechnology OHS.

Information on any public/ stakeholder consultation

The Federal Minister for Innovation, Industry, Science and Research hosted a roundtable in July 2008 with representatives of the research, industry, union and civil society communities to hear views on the issues around nanotechnology development. Some topics covered included applying the precautionary principle to nanotechnology regulation, nanomaterial risk research, the need for transparency with the presence of manufactured nanoparticles, importance of R&D and collaboration, and consideration of the potential social and economic impacts of nanotechnology. It is planned that another event will be held in the middle of 2009.

The Australian Office of Nanotechnology (AON) Public Awareness program has undertaken a range of public awareness and community engagement activities in 2008. A series of free two-hour public forums on nanotechnology was held in all major Australian capital cities and completed in December 2008. The forums were taped and podcasts of most speaker presentations will be available on the AON website www.nanotechnology.gov.au and DVDs in early 2009.

Presentations on science communication and nanotechnology issues were provided by the AON to various university workshops, industry days and community events throughout 2008 as part of its community engagement activities. For example, from 5-7 August 2008, the AON participated in the 'Science in the City' event with the Australian Museum in Sydney to talk with high school students and teachers about nanotechnology. It is also planned that during the first half of 2009, more similar engagement activities will be organised in other Australian states and territories by AON and the Gene and NanoTechnology Information Service (GNTIS).

The report on the 'Australian Community Attitudes Held about Nanotechnology – Trends 2005-2008' was published in August 2008. This public awareness survey was commissioned to assess the Australian public's knowledge of, and views on, nanotechnology. This report compares changes of attitudes from 2005 and 2007 to 2008, and demonstrates that, among other key findings, since 2005 the number of respondents who see the benefits of nanotechnology as outweighing the risks has increased from 39 per cent to 53 per cent.

A one-day workshop with government, industry, researchers and community stakeholders to discuss various mechanisms for social inclusion and community engagement on nanotechnology issues was held in Canberra on 1 December 2008. The participants were asked to collaborate to develop principles and models for increased social inclusion and improved community engagement on nanotechnology issues. The workshop identified engagement gaps which it considers need addressing and identified follow-on events to involve key stakeholders in community development activities.

A national online nanotechnology school resource for secondary schools called AccessNano was developed by the science communications group Bridge8 in consultation with the Australian Science Teachers Association and completed in November 2008. During 2009, AccessNano will be promoted to secondary school teachers nationwide through online and printed science and education resources and feedbacks received will be used to improve AccessNano's website to cover more topics relevant to its stakeholders.

NICNAS has published an article updating NICNAS nano-related activities and an advisory to inform and educate industry of its obligations when introducing cosmetics containing new nanomaterials, such as carbon fullerenes, into Australia in the December NICNAS Matters, which is widely distributed to companies and stakeholders.

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

DEEWR has also established a Nanotechnology OHS Measurement Reference Group to help develop Australian nanomaterial measurement capability. Members are nanoparticle measurement experts, occupational hygienists, nanotechnology risk managers and OHS regulators.

Table 4: Australian Government actions responding to the Monash Report

Triggers identified in the report		Actions
'New' nano substances or products	✓	Products and chemicals are each regulated differently, depending on the risks associated with each. Regulatory agencies are consulting with stakeholders and commissioning reviews to determine whether any nanoforms should be treated differently to the usual form of a substance and also to understand whether any hazards might be present.
Current definitions of weight or volume	✓	The current thresholds for weight and volume in some regulations and legislation are being reviewed to determine whether they need amending to accomodate the different nature of nanomaterials.
Knowledge of the presence of nanomaterials	✓	Regulators are working to ensure that applicants indicate, at the time of application, size characteristics of ingredients/chemicals in products where those materials possess certain characteristics that could represent additional safety concerns.
Risk assessment protocols	✓	Regulators have sufficient flexibility within their current risk assessment protocols to consider issues specifically relevant to nanotechnology and nanomaterials. National and international guidelines applicable to risk assessment protocols are not, and are not intended to be, prescriptive or restrictive in nature. Within the flexibility of risk assessment protocols, regulators routinely adapt their analytical methods or risk assessment methodologies in order to accommodate the specific challenges presented by, and the characteristics of, the material or product under assessment. Australian Government agencies are continuing to address the adequacy of current arrangements in consultation with bodies such as the National Measurement Institute, other international regulators, and international bodies such as the OECD.
Research and development exemptions	✓	Regulatory agencies are reviewing current research and development exemptions, where they apply, to take account of the potentials risks of relevant classes of nanomaterials. This will provide a basis for considering amendments to the regulations.
International standards	✓	Regulatory agencies utilise international standards or guidelines only where they are relevant to Australia's regulatory environment. Guidelines are not intended to be prescriptive, and adoption does not constrain regulators from adapting their risk assessment methodologies and requirements to accommodate the specific issues presented by a given material. Agencies are currently working with their overseas counterparts and international partners to promote consistency in managing risks associated with nanomaterials, where they exist.

AUSTRIA

Highlight of developments since the 4th meeting of the WPMN

As a governmental project a **National Action Plan on Nanotechnology** lead-managed by the Federal Ministry of Agriculture, Forestry, Environment and Water Management (BMLFUW) has been initiated. Relevant stakeholders (ministries, agencies, NGOs, occupational health organizations, the Austrian Chamber of Commerce (WKO) and research institutions) are included to address potential risks and benefits and define measures to minimize potential risks as well as to enhance the utilization of potential benefits.

The development of the National Action Plan is performed by four Working groups:

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

Issues regarding consumer protection and communication to the public will be addressed by each working group.

First Announcement & Call for Abstracts for the **4th International Conference on the Environmental Effects of Nanoparticles and Nanomaterials** at the University of Vienna, from Sun 6th- Wed 9th September 2009. The conference will be hosted by the Department of Environmental Geosciences. For further information please visit http://nano2009.univie.ac.at

Work completed, underway or planned

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

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

A **platform ("Österreichische Nanotechnologie-Plattform")** of relevant ministries, agencies, NGOs, occupational health organisations, the Austrian Chamber of Commerce (WKO) and research institutions lead-managed by the Federal Ministry of Agriculture, Forestry, Environment and Water Management (BMLFUW) was established in autumn 2007. Its main purpose is the exchange of information as well as the discussion and planning of possible activities with a focus on risk assessment and risk management of nanomatierials as well as information for the public. In order to address these topics in a more fundamental way the Austrian Umweltbundesamt compiled the report "Statusbericht Nanotechnologie" (in German with an English summary) on the current status of developments in the European Union and the OECD. The report also includes recommendations for further actions for Austria. The report will be made publically available on the internet in the near future.

Bilateral exchange was intensified by participation at the 1st International Authorities Dialogue between Switzerland, Austria, Germany and Liechtenstein. Voluntary measures in risk management of nanotechnology and the creation of a network were discussed.

2. Developments related to voluntary or stewardship schemes

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

3. Information on any risk assessment decisions

No information provided

4. Information on any developments related to good practice documents

No information provided

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

The project **NanoTrust,** funded by the Austrian Federal Ministry for Transport, Innovation and Technology (BMVIT), is a research project to continually survey, analyse and summarise the state of knowledge regarding potential health and environmental risks of nanotechnology.

Research gaps will be identified and differing assessments will be made transparent. Dossiers on specific nanorelated topics are released.

EURO-NanoTOX is an open virtual center and national platform which is co-ordinated by the BioNanoNet Forschungsgesellschaft mbH and co-funded by the Federal Ministry of Science and Research (BMWF). It will elaborate strategies to conduct standardised toxicological in-vitro as well as in-vivo methods on nanostructered material. The main focus is human nanotoxicology and human risk assessment. Comparative studies will be organised.

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

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

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

A **Workshop on Aquatic Nanoscience & Nanotechnology** - bridging environmental nanosciences and nanotoxicology was organised in December 2007 by the working group "Nanoscience and Nanotechnology" of the German Waterchemical Society and the Department for Environmental Geosciences at Vienna University (contact person: Frank van der Kammer; Department for Environmental Geosciences, Vienna University).

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

EU-projects with Austrian participation within FP6:

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

NANOCAP: Nanotechnology capacity building NGOs,

Leadership: Drs. Jacques Cornelis van Broekhuizen, IVAM UvA BV, Amsterdam, Niederlande;

Austrian partner: ppm Forschung und Beratung, Linz (Günther Kittel).

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

POLYSOA: Polymers in Secondary Organic Aerosols (NEST Insight activity):

Austrian partner: Technical University of Vienna, Hans Puxbaum; already finished.

The Austrian Research Center GmbH- ARC, the Austrian Worker´s Compensation Board (AUVA) and the Österreichische Staub- und Silikosebekämpfungsstelle, Leoben, worked on a project

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

6. Information on any public/ stakeholder consultation

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

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

nanosafety questions from media and public are discussed with the partners of the dialogue process on nanotechnology.

Currently **NanoTrust** is working on an encompassing, annotated **bibliographic database (NanoLit)** on potential environmental and health risks as well as on risk governance, which will be made publicly available via the internet. Partners in this project are BioNanoNet Forschungsgesellschaft mbH and the Austrian Umweltbundesamt. Furthermore NanoTrust works as an information platform and takes part in the research on nanotechnology with own contributions from a technology assessment perspective.

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

CANADA

Highlight of Developments since the 4th Meeting of the WPMN

The following activities have taken place since the 4th meeting of the OECD Working Party on Manufactured Nanomaterials in June 2008:

- Following decisions made at the multi-stakeholder workshop held in September 2007, Environment Canada and Health Canada are planning the release of the information gathering survey, under the authority of Section 71 of CEPA 1999 in the Spring of 2009. The objective of this survey is to gather use pattern information, including volumes and sectors of use, and any relevant toxicological data already available for nanomaterials in commerce during 2008. See Section 2.

- Health Canada is leading the development of the "Nanoportal" website which will act as a gateway to the latest information on nanotechnology, similar to the "Bioportal". The target launch date for the Nanoportal is 2009/2010.

- On July 8, 2008 the Council of Canadian Academies' Expert Panel on Nanotechnology issued their report on the current state of knowledge of potential human health and environmental risks of nanotechnology. The panel acknowledged the current limited state of scientific knowledge regarding many nanomaterials and the need to develop and resource a strategic research agenda to improve our understanding of the risks associated with each specific class of nanomaterials. The panel concluded that although they believe it is not necessary to create new regulatory mechanisms to address the unique challenges presented by nanomaterials, existing regulatory mechanisms could and should be strengthened.

- In November 2008 the Canadian Food Inspection Agency (CFIA) conducted a Spotlight on Nanotechnology Expert Panel where Canadian leaders in the field of nanotechnology were invited to speak along with academic scientists specializing in nano-based applications in both the food and agricultural sectors. Representatives from Health Canada, Industry Canada and Environment Canada were invited to participate in the discussion following the presentations. Over 50 CFIA staff from all branches including Directors and Senior Analysts attended this 1/2 day event.

1. Regulatory Developments in Canada

Federal government actions

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

B. The proposed regulatory framework for nanomaterials under the *Canadian Environmental Protection Act, 1999* has been expanded to include both regulatory and research considerations. At this time, planned regulatory activities include:

Phase 1 (started fall 2006):

1. Continue work with international partners to develop scientific and research capacities (OECD, ISO).

2. Inform potential notifiers of their regulatory responsibilities under the current framework.

3. Develop initiatives to gather information from industry on the uses, properties, and effects of nanomaterials.

4. Consider whether amendments to CEPA 1999 or the NSNR would be needed to facilitate the risk assessment and management of nanomaterials.

Phase 2 (2008 – 2010):

1. Resolution of standard nomenclature and terminology by the ISO.

2. Consider establishing specific data requirements for nanomaterials under the NSNR.

3. Consider the use of Significant New Activity notices for substances already on the DSL.

C. Canada, through Environment Canada, is the lead for the ISO TC/229 WG1 Task Group on Nomenclature. This Task Group includes representatives from the United States, Japan, Germany, the Chemical Abstracts Service, and IUPAC, and includes regulators, industry, and academia. The Group is tasked with developing a nomenclature system which meets the needs of regulators, industry, and academia. Canada presented the Task Group's report on a nomenclature model for nano-objects at the ISO TC/229 meeting in November 2008 (Shanghai, China).

D. Canada, through NRC-CISTI (National Research Council – Canada Institute for Scientific and Technical Information) is developing, under ISO TC/229 JWG1, a taxonomy system for nanomaterials which involves an intelligent organization of terms used in various communities pertaining to nanomaterials (e.g., tubes, rods, nanoscale, etc). Also, Canada through NRC-SIMS (National Research Council – Steacie Institute for Molecular Sciences) is proposing to lead a project to develop definitions for core terms resulting from the taxonomy system.

2. Developments on Voluntary or Stewardship Schemes in Canada

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

Respondents will be required to submit information on:

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

Environment Canada and Health Canada are working toward harmonization and facilitated information exchange with the US EPA. The Canadian approach was informed by discussions within Steering Group 5 of the WPMN.

Nanotechnology Market Penetration in Canada

There is a limited understanding of the current Canadian market for nanotechnology. A formal use pattern survey has yet to be conducted and a product inventory is currently in progress. Industry Canada has performed preliminary investigations, and continues to monitor this emerging field.

In 2007, Industry Canada contracted a study in collaboration with Environment Canada, Health Canada, and the Canadian Food Inspection Agency, to investigate US companies exporting nanotechnology-related products to Canada. Analysis of all the data collected identified 63 US based companies which include Canada in their business, with 127 distinct product lines.

Industry Canada has examined its public website based company database and conducted independent web searching to identify Canadian companies engaged in nanotechnology. It's most recent update in February 2009 suggested that there are approximately 617 domestic companies or US headquartered companies that conduct business in Canada having some sort of involvement with nanotechnology, including finished goods, R&D, intellectual property, services, intermediates and primary producers of nanomaterials.

With the collaboration of Environment Canada, Industry Canada (February 2009) collected data on the current number of consumer products on the Canadian market that incorporate Nanotechnology-based components or technologies. Over 1100 products were estimated to be on the Canadian market, with 68% being imported into Canada from over 13 different countries. By way of example, products ranged from "stronger, more durable, lighter" sports equipment, to stain & wrinkle-free pants, antimicrobial clothing and appliances, or to cosmetics, sunscreens and drugs that claim deeper skin penetration.

3. Risk Assessment Decisions

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

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

4. Developments of Good Practice Documents

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

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

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

C. Industry Canada and a number of provincial partners, along with 9 other countries, are helping to fund the International Council on Nanotechnology's GoodWiki project being developed as an Internet-based collaboration platform and designed to enhance the ability of industry experts to exchange ideas on current good practices for the handling of nanomaterials in an occupational setting.

5. Research in Canada

Scientific research

Environment Canada supported two projects under the Strategic Grants Program of the Natural Sciences and Engineering Research Council (NSERC) which were approved in September 2007. The first project will focus on aqueous related research examining the fate and effects of nanomaterials on aquatic invertebrates, characterize their physiological effects, in addition to developing detection and characterization methodology. The second project will focus on the terrestrial fate of nanomaterials including toxicity to sentinel organisms (such as earthworms), particle transformation, and transport. Another objective of this research is to develop predictive tools generalized for nanoparticles.

In May 2008, a three-year joint Health Canada-Environment Canada project will focus on developing analytical tools and test methods for biomonitoring of nanomaterials in products covered under the *Food and Drugs Act* (e.g., pharmaceuticals, personal care products). Both invertebrate and mammalian cell lines will be studied by exposure to well characterized (e.g., physical chemistry) and representative nanomaterials on the OECD list of representative nanomaterials.

Environment Canada laboratories are also conducting some limited research on fate and ecotoxicity of nanomaterials in aquatic systems. A departmental research strategy is under development to focus on ecological and environmental research needs as mandated under the *Canadian Environmental Protection Act, 1999*. The objectives of the strategy are to build and improve upon research expertise and capacity for nanomaterials.

Health Canada is engaged in both in-house and collaborative research projects involving a range of different nanomaterials (e.g., nanoparticulates of zero-valent iron, gold, silver, TiO2, also carbon black, single walled carbon nanotubes, and C_{60} fullerenes). Testing includes pulmonary and cardiovascular injury; reproductive, developmental and transgenerational effects; exposure and tissue penetration, interactive effects with microorganisms, immune defenses, and genotoxicity. Alternative tests such as molecular (genomic/proteomic) and cellular in vitro techniques play an important part of the repertoire for such investigations. In line with goals for broader inter-departmental efforts, Health Canada is working with Environment Canada to enhance research capacity to support regulation of manufactured nanomaterials (i.e., in regulation, health and safety monitoring, ecotoxicology and benchmarking physical-chemical and toxicological characterization methods including ultra-fractionation systems for assessing nanomaterials in aqueous samples). Either directly or indirectly these research efforts contribute towards several of OECD's subgroups (e.g., SG1, SG2, SG3 and SG4, SG5 and SG-8) as well as priority testing and topics of the Molecular Screening Project (e.g., Thyroid signaling, Cancer epigenetics, Sensitization/Immunotoxicity, Developmental and Reproductive Effects, Developmental Neurotoxicity). Combined, they support international EHS and R&D efforts, the application of new tools for those priority nanomaterials identified by OECD countries and are consistent with directions that OECD and ISO work is taking.

The National Research Council of Canada is involved in research and development of nanotechnologies on a wide range of topics which probe our fundamental understanding of their physical and chemical properties to areas of fabrication and application. Research is ongoing to develop capabilities for measurement and characterization of nanomaterials and nanoscale features. Canada is actively involved in international R&D collaborations with the USA and other countries. The National Research Council of Canada-Taiwan partnership focuses on research projects which underpin and apply nanotechnologies, one of which involves the development of techniques and instrumentation for accurate primary calibration of nanoscale length for application in scanning probe microscopy. Cooperation and

harmonization of accurate measurement techniques and calibrations aid in establishing internationally-recognized client services and measurement capabilities.

The National Research Council of Canada (NRC) has launched R&D initiatives which support collaborative projects between Institutes (http://www.nrc-cnrc.gc.ca/institutes/index_e.html). These cross-Institute Programs in Nanotechnology exploit the multi-disciplinary strengths of the NRC with focus on fundamental R&D topics which underpin EHS research. One of the supported projects focuses on: airborne nanoparticles (nano-aerosols) that contribute to poor air quality. The NRC also launched collaboration with the Natural Sciences and Engineering Research Council of Canada (NSERC) and the Business Development Bank of Canada (BDC) offering opportunities for NRC scientists and Canadian academic researchers in nanoscience and nanotechnology to collaborate on large technology development-driven research projects in the critical areas of: Energy; Environment; and Information and communications technologies (ICT).

Policy research

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

6. Public and Stakeholder Consultations

None to report.

CZECH REPUBLIC

Highlights of developments since the 4th meeting of the WPMN

- A questionnaire study „Inventory of Workplaces with Nanomaterials in the Czech Republic: Public Health Aspects / Stages „2008“ and „2009 and onward“
- Publication of the brochure „Nanotechnologies in the Czech Republic 2008“
- Enhancing the awareness of public health authorities towards growing use of nanomaterials and the associated public health risks through education in seminars, local conferences, and short courses
- Large number of research projects on nanomaterials and nanotechnologies has recently been funded in the Czech Republic, however, none of them addresses predominantly health, safety, and environmental aspects of NM.
- An international conference EuroNanoForum will be held in Prague on June 2-5, 2009

Work completed, underway or planned

1. National Regulatory developments

No developments

2. Developments related to voluntary or stewardship schemes

No developments

3. Information on any risk assessment decisions

No developments

4. Information on any developments related to good practice documents

No developments

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

A. Inventory of Workplaces with Nanomaterials in the Czech Republic: Public Health Aspects (2008)

In June 2008, Chief Public Health Officer of the Czech Republic (Deputy Minister of Health) launched a questionnaire study aiming at identification of health risk of NM in the workplaces in the Czech Republic. The study was conducted jointly by the National Institute of Public Health and Regional Public Health Offices. The primary database of the workplaces to be addressed (both production enterprises and research institutions) was a list of organizations participating in the research projects funded by or through major national agencies (source of information: Nanotechnologies in the Czech Republic 2005). The questionnaire comprised of 7 sections: 1) Data about the enterprise/ institution; 2) Data about the manufactured/ studied/ used NM; 3) Data about the production or research activity; 4) Data about the potential exposure to NM; 5) Reported health effects; 6) Perception of the potential health risk on handling NM; 7) Occupational health services. The requested data was collected on site jointly by the public health officer and a person responsible for the workplace (Safety Officer, Head of Laboratory, etc.). In total, 104

filled in forms were collected and provided to National Institute of Public Health for evaluation. The Final Report (9 pg) was approved by the Chief Public Health Officer in November 2008.

B. Nanotechnologies in the Czech Republic 2008

In August 2008, the Czech Society for Novel Materials and Technologies (a non-governmental organization) compiled a brochure „Nanotechnologies in the Czech Republic 2008“. It provides structured information about a) all workplaces, both in production enterprises and research institutions, that participated in the research projects funded by or through major national agencies (b) all research projects currently running in the Czech Republic in the field of NM+NT. These projects cover e.g. fundamental research in physics and material engineering, industrial applications in various industries, biomedical applications for diagnostic or therapeutic purposes, environmental remediation, etc. However, only few of the projects were partially engaged in the health and safety aspects of using NM.

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

The National Institute of Public Health and Regional Public Health Offices set up to continue the project established in 2008, based on the updated database of workplaces and own investigational capacity. As in the 2008 stage of the project the key to the detection of a workplace was involvement in a research project, the majority of them were in the research institutions. Here we aim to collect more complete data on the production enterprises regardless of whether they are involved in research or not. The structure of the questionnaire will be identical to the previous one.

6. Information on any public/stakeholder consultation

No information

FINLAND

Work completed, underway or planned

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

No Information

2. Developments related to voluntary or stewardship schemes

No Information

3. Information on any risk assessment decisions

Finland is participating and following the regulatory developments at REACH CA- nano subgroup.

4. Information on any developments related to good practice documents

No Information

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

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

The University of Joensuu is participating the OECD Sponsorship Programme with aquatic ecotoxicoly testing of nano-silver and nano-iron as a part of the Nordic group.

6. Information on any public/ stakeholder consultation

No Information

FRANCE

Highlight of developments since the 4th meeting of the WPMN

Action at European level

- **Support by the French Presidency for the workshop held by DG SANCO in Brussels on 2-3 October 2008 on productive dialogue on nanotechnology safety**: this workshop brought together all stakeholders in the field. A status report was presented on European and international work, including that of the OECD. Some ten actions emerged from this discussion and have been placed on line.
  (http://ec.europa.eu/health/ph_risk/ev_20081002_en.htm)

- At the initiative of the French Presidency, in 2009 the European Public Health Programme includes a joint action (EC/Member States) on nanomaterial safety. France will co-ordinate this action with the interested Member States. The studies, which will be prioritised, will take into account European and international work (ISO and OECD).

Action at national level

- Drafting of legislative provisions contained in Article 37 of the draft programme act concerning the implementation of the Grenelle Environmental Round Table (Grenelle I), introducing an obligation to report any nanomaterials released on the market; www.senat.fr.

- Holding of a **national public debate** in 2009 on general options for developing and regulating nanotechnologies.

- On 10 July 2008, the National Consumer Council (*Conseil National du Consommateur*) was mandated to create a working group to discuss the means of providing simple and understandable consumer information on nanotechnologies, their benefits and potential risks and the precautionary measures required. It should issue its opinion by the end of the first quarter of 2009.

- The CNRS programme bringing together the Centres of Competence in Nanoscience and the CNRS Department of Human and Social Sciences (SHS) invited the scientific community to an interdisciplinary residential workshop on the **legal regulation of nanosciences and nanotechnologies** hosted by the Centre of Competence in Nanoscience of Île-de-France (*C'Nano IdF*). The workshop was held on 27-30 January 2009 and revolved around three broad themes in response to the proposals of the Grenelle Environmental Round Table and the recommendation adopted by the European Commission at the beginning of February 2008.

These three themes are as follows:

1. Incorporating the risks involved in nanoparticles and nanomaterials
2. Sources and techniques for setting standards in the field of nanosciences and nanotechnologies.
3. Patents in the field of nanosciences and nanotechnologies.

➢ **REPORTS AND OPINIONS**:

- **Opinion of the High Public Health Council** (*Haut Conseil de Santé Publique*) of 9 January 2009 on the **safety of workers exposed to carbon nanotubes** in which it recommends – pending a registration, evaluation and possible authorisation procedure and in line with the precautionary

principle – that the production of carbon nanotubes and their use in manufacturing intermediate products and consumer and health products be carried out under conditions of strict containment in order to protect workers from being exposed when these activities involve a risk of aerosolisation and/or dispersion. This recommendation also applies to research laboratories. The HCSP also made recommendations on the identification of potential exposure situations and nanosafety, along with recommendations on metrology research and risks.
http://www.nanonorma.org/ressources/documentation-nanonorma/hcspa20090107-ExpNanoCarbone.pdf

- **Report by the French Agency for Environmental and Occupational Health and Safety** (*Agence française de sécurité sanitaire de l'environnement et du travail,* AFSSET) on nanomaterials and **occupational safety** published in July 2008. It shows the need to establish good production practices in order to protect workers from exposure to nanomaterials, the dangers of which are largely unknown.

  http://www.afsset.fr/upload/bibliotheque/308470480642484657342914409116/18_nanomateriaux_avis_afsset.pdf

  The Agency is currently exploring nanomaterials-related risks to the general population and in the environment.

- **Recommendations for assessing the toxicity of medicinal products containing nanoparticles** have been finalised by the French Agency for the Safety of Health Products (*Agence Française de Sécurité Sanitaire des produits de santé*, AFSSAPS):

  http://afssaps.sante.fr/pdf/5/reco_eval_toxico_nano_particulaire.pdf

- The issue of **cosmetics** is currently being investigated, since the AFSSAPS is hampered by the failure of manufacturers to provide information and by assessment difficulties due to the lack of suitable metrological and toxicological methods.

- **Report by the French Food Safety Agency** (*Agence française de sécurité sanitaire des Aliments,* AFSSA) **on "Nanomaterials manufactured in water"** submitted in March 2008. (http://www.afssa.fr/Documents/EAUX-Ra-Nanoparticules.pdf)

  AFSSA highlights the need to implement a system for detecting and regulating the marketing of any product containing nanoparticles. In addition, given the still-fragmentary knowledge of what happens to free nanoparticles in porous environments, it also recommends measures to ban any use of nanoparticles that would involve direct injection into the water table. Furthermore, a number of avenues for research are suggested in order to supplement the information available.

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.

- Bills introduced following the work of the Grenelle Environmental Round Table

The regulation on chemical substances and preparations (REACH) does not cover substances produced in amounts of less than one tonne per year, nor the specific properties of nanoparticles, unless it has been shown that there is cause for special concern.

Article 37 of the "Grenelle I" Act is aimed at improving surveillance of emerging environmental and health risks and the information and protection provided to workers and consumers. The obligation to report quantities and uses should ensure this improvement.

Article 73 of a second bill providing for a national commitment on the environment ("Grenelle II") is aimed at promoting better knowledge of the reality of the market for substances containing nanoparticles (manufactured nanomaterials). It confirms implementation of the reporting obligation regarding the identification, quantities and uses of substances containing nanoparticles, proposes to take measures at the national level and emphasises the responsibility of industrialists, manufacturers, importers and marketers in assessing the dangers and risks of substances, preparations and products.

- Legislation protecting workers

Through an instruction dated 18 February 2008, the General Directorate for Labour (*Direction générale du travail*) reminded its units throughout the country of the legislation governing the prevention of occupational risks arising from exposure to chemical substances containing nanometric-sized particles.

Regarding the national legislation applicable to nanomaterials, it was emphasised that risk prevention in this field does not lie outside the scope of the regulations of the Labour Code, the provisions of which cover at the very least chemical risk prevention and possibly the special provisions applicable to CMR category 1 and 2 agents if the substance falls within their scope of application.

2. Developments related to voluntary or stewardship schemes

No Information

3. Information on any risk assessment decisions

- Survey

In order to learn more about the exposure of researchers and workers to manufactured nanomaterials, the French Agency for Environmental and Occupational Health and Safety (AFSSET), in response to a request that it identify the risks that might affect researchers and workers, conducted a detailed survey of 41 research laboratories and 178 industrial establishments (219 questionnaires); 39 questionnaires were returned, of which 13 from research laboratories and 26 from industrial establishments, for a response rate of approximately 16%.

Given the number of responses, the findings of this survey provide an initial glimpse of the situation but cannot be used to draw conclusions or identify general trends.

4. Information on any developments related to good practice

No Information

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

- Organisation of research efforts through consultation with the bodies involved in each aspect of risk assessment (characterisation, metrology, experimental toxicology and epidemiology, and ecotoxicology).

- At the National Research Agency (*Agence Nationale de la Recherche*): programmes devoted to Functional Materials and Innovative Procedures, and Chemicals for Sustainable Development, and identification of nanomaterial safety as a priority theme in the call for research proposals on "Contaminants, Ecosystems and Health".

- Incorporation of nanomaterials into the National Research and Innovation Strategy being developed by the Ministry of Research.

- Participation in various research projects funded by the European Commission (see Database of Steering Group 1 http://webnet.oecd.org/NanoMaterials).

- Implementation of a prospective cohort for the epidemiological monitoring of researchers and workers exposed to nanomaterials (see Database of Steering Group 1).

- The National Institute for the Industrial Environment and Risks (*Institut National de l'Environnement Industriel et des Risques*, INERIS) is developing activities in the field of environmental exposure and metrology (participation in the EU's Nanosafe 2 and a number of OECD working groups).

6. Information on any public/stakeholder consultation

➢ Nanoforum of the *Conservatoire National des Arts et Métiers* (CNAM)

The forums continued during 2008 and the themes were broadened to include governance issues. Last October, a session was devoted to "nanoparticle risks and the protection of exposed workers".

The discussions were widely disseminated, in particular through the review *Le Journal de l'Environnement* (www.journaldelenvironnement.net).

A consensus is emerging to change the Nanoforum's format; rather than continuing a monographic approach by sector of activity, which might be too repetitive, methodological issues would now be explored using concrete examples.

The case of "nano-silver" has been chosen as the theme for these cross-cutting discussions in the next three sessions: since it involves a number of industrial sectors (textiles, IT, medicine, cold chain, etc.), this material is a suitable basis for analysing situation-management methods. Three sessions are planned in 2009:

- 2 April: What are the tools and indicators available that would be useful for conducting a benefit/risk analysis in the case of nano-silver?

- 4 June: What must be done to meet the information needs of the various stakeholders concerned by the production and use of nano-silver?

- 10 September: What governance arrangements are most appropriate for determining the rules for using nano-silver in specific situations?

International Industrial Health Forum

This event organised by the Ministry of Employment in Paris on 3-4 November 2008 constituted the high point of the French EU Presidency in the field of occupational health and safety. It brought together many French and European stakeholders involved in prevention policy, such as institutions,

public and private bodies, social partners and businesses. One of the workshops was devoted to emerging risk management as illustrated by the case of manufactured nanoparticles.

Additional information

- IFCS

A full day was devoted to this issue at the most recent Intergovernmental Forum on Chemical Safety (IFCS) held in Dakar in September 2008. The second International Conference on Chemicals Management (ICCM-2, the steering body of SAICM, the Strategic Approach to International Chemicals Management) this coming May will also address this topic. During the IFCS, France held a side event on the fundamental issues posed by nanotechnologies, beyond health and environmental risks. A document to stimulate thinking on this issue is available on the IFCS site: http://www.who.int/ifcs/documents/forums/forum6/f6_se_beyond.doc.

GERMANY

Highlight of developments since the 4th meeting of the WPMN

The NanoDialogue was initiated by the Federal Government and a so called “NanoKommission” was established where stakeholders from authorities, industry, trade unions and NGOs tried to get a common understanding on opportunities and risks of nanotechnology. The NanoKommission had the mandate to develop a report within 2 years by the end of 2008. Three working groups discussed important aspects of the development of nanotechnology:

The first Working Group "Opportunities for Health and Environment" concentrated on the question: How can the use of nanomaterials contribute to sustainable economic and social development in Germany, in particular to environmental/health and consumer protection? The Working Group wanted to identify and describe selected nanoproducts or applications which deliver a special benefit for the environment or for consumers. These opportunities were checked concerning their sustainability throughout their life cycle, at least qualitatively.

A second Working Group was called "Risks and Safety Research" and consequently dealt with the possible risks posed by nanomaterials, especially the gaps in our knowledge, which we need to fill as soon as possible. The aim was to develop a programme for future safety research plus suggestions for concrete projects. Since many products containing nanomaterials are already on the market and we expect a further increase in the future, this working group had to assess the risks for some selected nanomaterials based on present knowledge.

In order to provide preventive protection to employees, consumers and the environment, a third Working Group developed “Guidelines on the Responsible Use of Nanomaterials". The group started the work on a Guideline for worker protection and worked on basic principles on which all Guidelines should be based and on indicators to monitor their implementation. The aim of Working Group 3 was that industry and user companies adopt these Guidelines as a “Code of Good Practice”.

The results of the “NanoDialog” were presented at a final conference in November 2008 giving advice to politicians and information to the public. The “NanoDialog” will continue for additional two years.

The English translation of the report 2008 will be available soon. The German version is available www.bmu.de.

The NanoDialog Project is part of this action plan.

Since 2007, the "Nano Initiative - Action Plan 2010" gives a framework across all government departments. The leading Ministry “Education and Research” (BMBF) has started this initiative, together with six others (Environment (BMU), Labour and Social Affairs (BMAS), Food, Agriculture and Consumer Protection (BMELV), Defense (BMVg), Health (BMG) and Commerce and Technology (BMWi)). ***Work completed, underway or planned***

1. Any national regulatory developments

No Information

2. Developments related to voluntary or stewardship schemes

No Information

3. Information on any risk assessment decisions

No Information

4. Information on any developments related to good practice documents

No Information

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

In the year 2008 the BAuA together with partners from Europe [European Agency for Safety and Health at Work, Spain, the Institut National de Recherche et de Sécurité pour la prévention des accidents du travail et des maladies professionnelles (INRS), France, the Centralny Instytut Ochrony Pracy - Państwowy Instytut Badawczy (CIOP-PIB), Poland, and the Instituto Nacional de Seguridad e Higiene en el Trabajo (INSHT), Spain] finalised the report "Workplace exposure to nanoparticles and ultra-fine particles" in the framework of the EU-OSHA-Topic Centre Risk Observatory. The report will be published online in 2009.

Research Project (Results available: July 2009)

Toxicokinetics of titanium dioxide nanoparticles

Nanotechnology offers a great promise in many industrial applications. However, little is known about health effects of manufactured nanoparticles, the building blocks of nanomaterials. Mammalian and in vitro studies have raised concerns about the toxicity of titanium dioxide (TiO_2) nanoparticles. There is an ongoing discussion that inhaled nanoparticles may translocate from epithelial deposition sites of the lungs to systemic circulation. Therefore this research project addresses the tissue distribution of inhaled TiO_2 particles (4nm particle and P25) 1h, 24h, 1 week and 1 month after application in rat. Using quantitative bio-kinetic analysis of radiolabeled inhaled TiO_2 particles the retained part in selected organs and tissue including excrements will be investigated. Healthy adult Wistar Kyoto rats of both genders are exposed by intratracheal inhalation to vanadium V-48-radiolabeled TiO_2 nanoparticles. A complete V-48 balance of all organs, tissues, excretion and remaining carcass will be performed at each time point.

Research Project (2009-2011)

Developing of Test procedures for Nano-Silver and Titanium Dioxide

The project aims at determining the environmental toxicity to soil and sediment species and environmental behaviour.

6. Information on any public/ stakeholder consultation

The analysis of nanotechnology coverage in German print media was the subject of a research project conducted by the Federal Institute for Risk Assessment (BfR) in 2008. The results: In the media coverage nanotechnology is not presented as a risk technology; most articles stress the benefits of this new technology. The analysis revealed that nanotechnology is not currently a subject of controversy in the

German print media. 70 percent of the articles examined focussed on the positive sides to nanotechnological products and processes. The reports mainly concentrated on applications of nanotechnologies in medicine and in information and communication technology, potential increases in sales revenues and new jobs through the development of nanotechnological products and processes. The articles mostly examine the scientific and economic aspects. Hence, most of the stakeholders, who are quoted in them, are representatives of scientific bodies and companies. Up to now, representatives of political circles and non-governmental organisations have only played a minor role in media coverage.

7. Additional information

There are two research projects by the Federal Environment Agency, available in German. Please find below the English abstracts:

The top priority of the research project "Environmental Relief Effects through Nanotechnological Processes and Products" was to identify and quantify, to the extent possible and by means of selected examples, the environmental and sustainability opportunities and risks associated with this rapidly developing line of technology. Environmental relief potentials are understood here to include not only environmental engineering in the narrower sense (end-of-pipe technologies), but also and specifically process, production, and product-integrated environmental protection. The project consisted of four stages:

1. Analysis of products and processes already on the market or soon to be made available and application

2. Examination and initial qualitative assessment of each of the products and processes with respect to its potential for environmental relief (or burden, as the case may be)

3. In-depth life cycle analysis and assessment of four selected processes or products as compared to conventional processes or products (Manufacture of solderable surface finishes on printed circuit boards, MW carbon nanotube application for foils in the semiconductor industry, Lithium batteries for energy, storage, Ultradur® High Speed plastic)

4. An appraisal of nanotechnology employment effects.

Applications of nanomaterials in environmental protection (UFOPLAN Ref-No. 3707 61 301/05)

Golder Associates GmbH, Celle, Dr.-Ing. Sonja Martens, Dr. Bernd Eggers, Thorsten Evertz

Following comprehensive research nanomaterials or products which were either still in a research/development status or are already available in the marketplace were identified for the water and air sectors.

Based on life cycle assessments for two case studies, it was checked how the potential benefits and impacts on the environment for nanotechnology products or processes compare with those for conventional solutions. The first case study deals with the solar treatment of water contaminated with tetrachloroethylene, comparing nanoscale titanium dioxide (photo-catalysis) and a photo-Fenton process. The second case study on air filtration compares a passenger car cabin-air filter with nanofibres and a conventional filter.

JAPAN

Highlight of developments since the 4th meeting of the WPMN

- The Ministry of Health, Labour and Welfare (MHLW) issued a notification for exposure prevention in the workplace in February, 2008. According to the report of a committee, which was established to discuss safety of nanomaterials in occupational settings, MHLW revised the notification in March, 2009. MHLW also established another committee on safety of manufactured nanomaterials in consumer products, and the committee is issuing a report shortly.
- In November 2008, Ministry of Economy, Trade and Industry (METI) organised an expert meeting focusing on the voluntary safety measures for handling nanomaterials by manufactures. A study report was published in March 2009.
- In June of 2008, the Ministry of the Environment (MOE) established an expert committee on potential risk of manufactured nanomaterials to health and environment through exposure in the ambient environment. The committee discussed the possibility of the environmental exposure of manufactured nanomaterials and the control methods for them, and published the guideline on the environmental sound management of manufactured nanomaterials in March 2009.

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

Japan has no safety regulation focusing on size of chemicals at this moment. In terms of the existing regulatory system, the Chemical Substance Control Law obliges manufacturers/importers to notify the authorities all newly developed chemical substances they manufacture/import. Some notifications of manufactured nanomaterials (e.g. fullerene derivatives) have been observed in the small quantities exemption notification scheme[1] under the Law.

2. Developments related to voluntary or stewardship schemes;

Although Japan has no voluntary/stewardship scheme on health and environment safety of manufactured nanomaterials so far, METI organised a study group on industries' voluntary activities for safety production of nanomaterials (see 4. in detail).

3. Information on any risk assessment decisions;

Japan has no risk assessment decision on manufactured nanomaterials so far.

[1] Newly developed/imported chemicals up to one tonne in total can pass through a simpler regulatory procedure with prior notification to the authorities.

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

The Ministry of Economy, Trade and Industry (METI) conducted a preliminary survey on safety handling of nanomaterials at manufacturing sites and research laboratories. The survey reviewed existing good practices both in domestic and overseas sites and compiled them into a report in 2007 (in Japanese). The report proposed a draft basic guideline, which gave some ideas for sound handling of nanomaterials to manufacturers and laboratories.

In November 2008, the Ministry of Economy, Trade and Industry (METI) organised an expert meeting focusing on the safety measures introduced by nanomaterials manufactures in voluntarily basis. Experts form industries made presentations on their voluntary activities for safety production of nanomaterials. Afterward, a study report was discussed and was published on March 31, 2009. Those meetings are open to the public. In the study report, manufacturers' voluntary management of nanomaterials for manufacturing, use and disposal is highlighted. The report also stressed the necessity of information collection and transmission by both governments and industries.

The Ministry of Health, Labour and Welfare (MHLW) issued a notification for exposure prevention in the workplace in February, 2008. According to the report of a committee, which was established to discuss safety of nanomaterials in occupational settings, MHLW revised the notification in March, 2009.

In June of 2008, the Ministry of the Environment (MOE) established an expert committee on potential risk of manufactured nanomaterials to health and environment by the exposure in the ambient environment. The committee discussed the possibility of the environmental exposure of manufactured nanomaterials and the control methods for them, and published the guideline on the environmental sound management of manufactured nanomaterials in March 2009, respectively.

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

The promotion and the social acceptance of nanotechnology has been considered as an important issue, and the R&D for the social acceptance of nanotechnology has been focused on as a strategic Science and Technology Priority in the 3rd Science and Technology Basic Plan in Japan.

Also, The Cabinet Office established a committee that coordinates research and development policy on nanotechnology. One of its targets is to establish an information infrastructure to accelerate innovation, by facilitating research and development of nanotechnology and research for public acceptance of nanotechnology in a focused and strategic manner.

Four national institutes[2] and some universities jointly conducted surveys on public acceptance of nanotechnology. They focused on 1) risk assessments of nanomaterials, 2) health issues of nanomaterials, 3) environmental issues of nanomaterials, 4) ethical and societal issues of nanotechnology, and 5) technology and economic assessment for promoting the public acceptance of nanotechnology. The survey was funded by the Ministry of Education, Culture, Sports, Science and Technology (MEXT). The survey team issued a report in 2006, which contains a series of recommendations to public institutes, the private sector and the government. In fiscal year 2006, funded by MEXT, a project named "The multidisciplinary experts panel for nanotechnology implication" was started. The project is composed of the above institutes and the university researchers, and focuses on "what are preferential tasks with reference to clarifying the

[2] The National Institute of Advanced Industrial Science and Technology (AIST), the National Institute of Health Science (NIHS), the National Institute for Environmental Studies (NIES), and the National Institute of Materials Science (NIMS).

nanotechnology implication for health, environment and social acceptance." The additional objective is the establishment of a researchers' network on the implications of nanotechnology.

METI launched a five-year programme on the "Evaluation of the Potential Risks of Manufactured Nanomaterials based on Toxicity Tests with Precise Characterization" in 2006, which focuses on toxicity test protocols (mainly an inhalation test) and a risk assessment methodology of manufactured nanomaterials. The programme aimed at: establishing preparation methods of test samples; developing methods for measuring shapes and sizes of tested nanomaterials, for testing toxicity, and for analysing exposure; publishing such results in the form of manuals; carrying out risk assessment on typical of nanomaterials; and proposing a risk management policy with formulating risk assessment documents. Fullerenes and carbon nanotubes (CNTs) are given priority as targeted nanomaterials. Literature survey on nanomaterials toxicity and social acceptance studies are also conducted. The programme is coordinated by the National Institute of Advanced Industrial Science and Technology (AIST), which also conducts much of this research in cooperation with the University of Occupational and Environmental Health and other universities. The New Energy and Industrial Technology Development Organisation (NEDO, and R&D funding organisation) evaluates the progress of the programme and is to explore a possible next phase. Under the aegis of this programme, AIST together with OECD and NEDO organised an international symposium on the "Risk Assessment of Manufactured Nanomaterials"[3] in April 2008, which attracted more than 500 attendees. It was held back-to-back the OECD Tokyo workshop on the Sponsorship Programme for the Testing of Manufactured Nanomaterials.

MHLW conducted a preliminary project in 2005, and launched a subsequent three-year project led by NIHS from 2006. The project has been focusing on detecting methodologies of nanomaterials in biological samples, ADME analysis, dermal exposure experiments, long-term health implication analysis using genetically modified animals, and the development of a transpulmonary/inhalation experiment system. In addition to this project, other research projects have been adopted to strengthen research on nanomaterials, including inhalation toxicity tests and dermal toxicity tests. In fiscal year 2007, MHLW conducted a survey on manufactured nanomaterials used in consumer products. The volume and uses of nanomaterials used in Japan were surveyed and the summary of the results are available in English as well. MHLW also established two committees on safety of manufactured nanomaterials. Those committees discuss safety of nanomaterials in occupational settings and in consumer products, respectively. The first committee has issued the report in November, 2008, and the second one is issuing the report shortly as well.

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

In 2006, the National Institute for Environmental Studies (NIES) launched a nanotoxicology programme where both in vitro and in vivo toxicities of nano-structured particulate materials are to be revealed. The programme includes (1) interaction of nano-fibers including CNT with cell membranes, (2) transepithelial and transpulmonary migration of nanoparticles, (3) in vitro and in vivo toxicity assay of nanomaterials using heat-treated asbestos as reference samples. Some in vitro studies on toxicity of nano-carbons and nanotubes have been completed. (4) The preliminary experiment for generation of inhalable carbon nanotubes has been successfully completed. NIES is planning an acute inhalation study on nanotubes and nano-metals.

[3] http://www.aist-riss.jp/projects/nedo-nanorisk/nanorisk_symposium2008/index_e.html

6. Information on any public/ stakeholder consultation

Japan has not implemented any official public/stakeholder consultation programme focusing on the safety aspects of manufactured nanomaterials. However, during the survey that was concluded in 2006 (see 5.), a series of workshops were organised, in which the public and NGO members actively participated.

NETHERLANDS

Activities on risks of nanotechnology in the Netherlands

Cabinet view on nanotechnologies

In November 2006 the Dutch government issued a cabinet view on nanotechnologies. The aim of this cabinet view is to indicate whether the frameworks necessary for responsible developments are adequate or in need of adjustment or revision. This assessment will be made on the basis of the main areas of Opportunities, Dealing with Risks, Ethical and Legal Issues, Research Agenda, Coordination and Support base and Communication. The view can be briefly summarised as follows: nanotechnologies are new technologies that are already the subject of a great deal of research worldwide and that are being increasingly applied. It is important that the Netherlands participates in this, not only by keeping up with the development of knowledge in the field but also by securing a position in the vanguard. Furthermore, we must be alert to the possible risks that nanotechnologies entail. The Netherlands will only be able to take optimum advantage of the opportunities by dealing cautiously and carefully with the associated risks.

Based on this cabinet view a.o. the following actions have been taken:

- An **interdepartmental working group** on possible risks of nanotechnology has been established, which will produce an action plan for both applications and risks of nanotechnology (June 2008) and a document for the Government on the risk strategy by the end of 2008.

- A **national observatory**, called the Risks of Nanotechnology Knowledge and Information centre (KIR nano) was established in 2007 at the National Institute of Public Health and the Environment (RIVM). KIR nano is a result of the Dutch action plan which includes proposals on research, innovation, legal aspects, risk management, and communication to the public at large. 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 signaling function is put into practice by participating in national and international networks (e.g. OECD WPMN, REACH CASG Nano, ISO, SCENIHR, EFSA, SETAC, WHO/FAO) and bringing experts together into national expert panels on different topics (environment, food, consumer products, medical applications, and workers). In this way, KIR nano acts as an information exchange platform without performing research itself. Until now, the focus was on engineered, free, insoluble and non biodegradable nanomaterials and their possible toxicological and ecotoxicological risks. As a first achievement, a report giving an overview of risks for man and the environment and knowledge gaps in the entire field of nanotechnology was published. An English translation will be available on www.rivm.nl in the near future.

KIR nano is involved in the following EU FP-7 projects:

- EU Observatory Nano (work package on health, safety and environment and work package on legislation)
- NanoImpactNet (work package on risk assessment and work package on environmental exposure)
- FramingNano

The Netherlands Nanotechnology Initiative (NNI), arising from the NanoNed consortium which is active in the area of possible applications of nanotechnology, made a Strategic national Research Agenda (SRA). See below for more information.

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

The Netherlands participate in the REACH CA Subgroup on nanomaterials.

The current opinion in the Netherlands is that the present regulatory framework in principle gives a good coverage; different aspects of production and products are at the same time subject to various Community provisions. Therefore, although there is no legislation specifically relating to nanotechnologies, the generic legislation applies to engineered nanosized materials and in the case of REACH places the responsibility on industry to ensure safe use of nanomaterials.The legislation in principle also enables authorities to take prompt action if products pose a risk to health, safety or the environment. But since many knowledge gaps have been identified, and no data on which to determine the possible risks are available, it is not possible to assess the full extent to which the implementation of current regulations addresses any potential risks. In short the legislation is adequate but the implementation of it is inadequate due to lack of specific measures, parameters or control devices. The Netherlands is working on a case study with nanosilver. In this study a Chemical Safety Report is made for nanosilver and it is discussed if data gaps can be filled with data for silver salts (not nano). The questions that arise will be used to develop a screening model to assess the risks of nanoparticles.

Developments related to voluntary or stewardship schemes

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

Information on any developments related to good practice documents

The SER (Dutch Socio Economic Council which consists of representatives from business labour union. and academia) has written an advice on good practice on workplace exposure of nanomaterials. Publication is foreseen in the near future.

The Netherlands subscribes the Code of Conduct for responsible Nanosciences and Nanotechnologies Research, adopted by the EC (press release IP/08/193, Brussels, 8 Feb 2008).

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

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

In 2008, a working group of the Ministries of Agriculture (food), Health (consumer goods, medicine), Labour (working conditions), Economic Affairs, Environment (substances) and Transport, Public Works and Water Management prepared a paper which addresses the risk management strategy on nanotechnologies (focusing first on nanoparticles). This paper is discussed with stakeholders (Business, NGO’s United Trade Unions) amended and sent to the Dutch parliament.

A strategic national research agenda (SRA) including a "risks section" has been drafted by the Netherlands Nanotechnology Initiative (NNI) and has been published in September 2008. Beginning 2009 a large research proposal was designed reflecting the priorities set in the SRA. The National Observatory (KIRnano at RIVM) coordinated the design of the theme risk analysis. A decision whether this proposal will actually be co-funded by the Dutch government is expected before autumn 2009.

The Netherlands will participate in the Sponsorship Programme developed by the OECD WPMN and be a co-sponsor of the performance of toxicological testing for the development of a risk assessment dossier for cerium oxide and for the performance of a study focussing on dosimetry.

Information on any public/stakeholder consultation

The Dutch cabinet view on nanotechnology includes the foreseen installation of a so called "broad commission" with stakeholders from both science and the public. Individual actions to start a public debate have already been undertaken e.g. between employers' organizations, NGOs and the government.

The SER (Dutch Socio Economic Council which consists of representatives from businesslabour union. and academia) has been asked to comment on a study regarding the exposure to nanoparticles in the workplace. The advisory report of SER has been published at March 31, 2009.

NEW ZEALAND

Highlight of developments since the 4th meeting of the WPMN

- At least three substantial research projects are now underway that investigate aspects of risks associated with manufactured nanomaterials.
- A symposium will be held in April to discuss the positive potential and the possible consequences of nanotechnologies in a New Zealand context. The event will bring together an invited audience of policy makers, researchers, NGOs and business people.
- A Nanotechnology Officials Group has been established to coordinate nanotechnology regulatory and related activities across the New Zealand government.

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

It has been established that if a nanomaterial has a known hazard or risk, there are regulatory systems in place in New Zealand that can regulate, eliminate or manage this hazard or risk. Depending on the circumstance in how the nanomaterials is used or poses a threat, a nanomaterial would be regulated under:

- the Hazardous Substances and New Organisms (HSNO) Act 1996 by the Environmental Risk Management Authority (ERMA);
- the Health and Safety in Employment (HSE) Act 1992 by the Department of Labour;
- the Food Act 1981, via the NZ (Maximum Residue Limits of Agricultural Compounds) Food Standards 2008[4], and the Australia New Zealand Food Standards Code[5], by the NZ Food Safety Authority;
- the Fair Trading Act 1986 by the Ministry of Consumer Affairs.

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

ERMA intends to establish a formal position on the regulation of nanomaterials under the HSNO Act. Specific data requirements for the hazard and risk assessment of nanomaterials will be developed which will take into account international harmonisation efforts on regulatory requirements for nanomaterials.

Further information on the HSNO Act and ERMA is available from:
http://www.mfe.govt.nz/issues/hazardous/
http://www.ermanz.govt.nz/index.html

2. Developments related to voluntary or stewardship schemes

There are currently no voluntary or stewardship schemes.

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

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

3. Information on any risk assessment decisions

ERMA has not received any applications to import or manufacture a hazardous substance that contains manufactured nanomaterials. There have not been any applications to allow residues of nanomaterials in foods.

4. Information on any developments related to good practice documents

Cosmetics containing nanoparticles (other than zinc oxide or titanium dioxide[6]) must be notified to ERMA as a condition of the Cosmetic Products Group Standard[7]. The purpose of this provision is to provide information to inform technical review of such substances in the future, so that if necessary, the group standard can be amended to put in place controls relating to such substances. To date no notifications have been received from importers or manufacturers of cosmetics.

"Nanoparticle" is defined in the group standard as "a particle having three dimensions in the nanoscale and a diameter of less than 100 nanometres". This is an interim definition that can be readily revised when international consensus on definitions emerges.

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

Research investment decisions for 2008/2009 are now final.

The MacDiarmid Institute for Advanced Materials and Nanotechnology[8], a New Zealand Centre of Research Excellence, received renewed funding for a further six years commencing in July 2008. They have introduced a new research theme with this new funding that will look at biological applications and implications of nanotechnologies, which has the potential to investigate risk-related issues.

In addition to the MacDiarmid Institute, we are aware of at least three specific research projects that incorporate investigations of human health and/or environmental safety aspects of nanomaterials. One involves computational modeling that includes assessments of potential adverse effects of different types of nanoparticles. The second includes examination of potential toxicity of particular quantum dots in human cells and animal models. The third is a laboratory research project which was funded in 2008 to specifically examine the uptake of quantum dots by plants and subsequent environmental effects of these particles. This is a three year project.

6. Information on any public/ stakeholder consultation

No public/stakeholder consultation has been conducted on the safety of nanomaterials; however a symposium on nanotechnology is planned to be held in April 2009.

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

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

[8] http://www.macdiarmid.ac.nz

Additional Information

The Ministry of Research, Science and Technology (MoRST) is continuing to run a scanning network that identifies emerging science trends and developments[9]. Nanotechnology is an area of active interest.

The Bioethics Council will continue to investigate the cultural, ethical and spiritual implications of nanotechnology as part of their "future watch" function.

[9] http://www.morst.govt.nz/current-work/futurewatch/

NORWAY

Work completed, underway or planned

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

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

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

   For the time being there are no voluntary or stewardship schemes.

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

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

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

   Documents related to good practice have not been developed in Norway.

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

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

A national strategy for nanoscience and nanotechnology was adopted by the Council in autumn 2006 and forward to the Minister of Education and Research. NANOMAT will be hosting a major conference in Lillehammer June 15th-19th 2009. There will be presentations from several acclaimed researchers, also in the field of safety for human health and environment.

http://www.forskningsradet.no/servlet/Satellite?c=Nyhet&cid=1229697615365&p=1226993562811&pagename=nanomat%2FHovedsidemal

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

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

6. Information on any public/ stakeholder consultation

The Norwegian Board of Technology published a report in 2008 regarding Nanomaterials, risk and regulation (only in Norwegian). They also had a public meeting 12 March 2009 where the main topic was how the health and environment authorities deal with the uncertainties regarding nanomaterials in a regulatory context.

Additional Information

The Norwegian Institute of Occupational Health has established a network group together with The Norwegian Labour Inspection Authority and The Product Register related to occupational health aspects of nanotechnology.

SLOVAK REPUBLIC

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

There is exists the system of national legislation in Slovakia which protects the human health and environment from negative impacts of products. These legally binding instruments can be applied for protection of environment and human health in relation to the nanomaterials and nanotechnology. From our point of view it is urgent need and demand for internationally acceptable methodology for nanomaterials risks establishing and evaluation. The international exchange of information at the field of physical and chemical properties and environmental and health risks of nanomaterials is needed for better protection of our environment and human health, from possible negative impacts of nanomaterials and nanotechnologies.

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

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

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

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

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

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

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

There is no existing joint governmental strategy for nanomaterials in Slovak republic or specific overall research programmes in this area. However several strategies dealing partly with nanomaterials such as Economic development strategy, Research strategy and nanoparticles such as Sustainable development strategy or Health care strategy was worked out and approved by Government or Parliament. In this time we have not common specific strategy which is dealing with human health or environmental safety aspects of nanomaterials.

It was established the new governmental advisory body for nanomaterials. This body was created from stakeholders and experts of environment, health and economy ministries, experts from scientific institution and universities, stakeholders from producers and consumers associations. The main goal of this advisory body is work out the common strategy for nanomaterials. As a first step in Strategy preparation process, it was worked out the analysis of actual situation of existing nanomaterials at market. One of the most important results of this analysis is rapid increasing of sold products containing nanomaterials, which can causes the enormous increasing the potential risks of products or composites containing nanomaterials their presumable negative impacts to environment and public health.

At the field of research Ministry for the environment and Slovak academy of sciences sign up an agreement and create the working group for nanomaterials as an advisory body for research development at this area. Research institutions and universities have now issued a series of projects addressing aspects of further research on nanomaterials, including their health and environmental risks. Created working group for nanomaterials is used for exchange of knowledge and further cooperation between national authorities and producers of nanomaterials in Slovak republic. It was finalised project for mapping the existing producers and products containing nanomaterials in our market and for subscribing their possible negative impacts environment and human health.

One of the most important part of research at the field of nanomaterials are construction ceramics, such as silicon nitride, titanium nitride, boron nitride, silicon carbide and titanium carbide and colour pigments. Ultra fine nano scale powders for construction ceramics are prepared by chemical vapour deposition or sol – gel methods.

6. Information on any public/ stakeholder consultation;

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

SPAIN

Highlight of developments since the 4rd meeting of the WPMN

The project *NANOSOST: Towards a safety, responsible and sustainable nanotechnology*, has been granted by the Ministry of Science and Innovation.

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 SpRRC (Spanish REACH Reference Center), Institution under mandate of the Ministry of the Environment and Rural and Marine Affairs (MARM) supporting the Ministry on technical and scientific issues, has taken note and will follow further updates of the discussion within the REACH Competent Authorities (REACH CA) and its Sub-Group on Nanomaterials - in which MARM is a member - on how REACH applies to nanomaterials (Doc. CA/59/2008 rev.1, EC, Brussels, 16 Dec., 2008).

2. Developments related to voluntary or stewardship schemes

None.

3. Information on any risk assessment decisions

None.

4. Information on any developments related to good practice documents

Spain will follow the recommendations in *Code of Conduct for Responsible Nanosciences and Nanotechnologies Research* adopted by the EC (Press Release IP/08/193, Brussels, 8 Feb., 2008).

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

The Ministry of Science and Innovation has granted (January 2009) the project *NANOSOST: Towards a safety, responsible and sustainable nanotechnology*. The initiative is under the national program *Public-Private Cooperation* of the R&D+I National Plan 2008-2011, and is being conducted by a consortium of several Public and Private Institutions. The general objective is the generation of knowledge to guarantee a safety use of nanoparticles and nanostructured materials, from their production up to their final fate, and includes seven subproyects (*e.g.,* Chemical and Health Risk, Scientific Basis for Risk Assessment and Control, or Technical Basis Risk Management)

The Ministry of Environment and Rural and Marine Affairs has encourage, and will partially support, with the technical and scientific support from the SpRRC, the participation of Spain in the OECD Sponsorship Program to Test Manufactured Nanomaterials, by cosponsoring the testing of two types of nanomaterials (TiO_2 and dendrimers).

6. Information on any public/stakeholder consultation

None

Additional Information

Workshops and curses about Nanotechnology and Nanomaterials have started to program some dedication to EHS issues.

The international event *Trends in NanoTechnology* 2009 edition (TNT2009) will be held in Zaragoza (Spain, March 09-12, 2008).
http://www.nanospainconf.org/2009/index.php?conf=09

SWEDEN

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

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

2. Developments related to voluntary or stewardship schemes;

- No Information

3. Information on any risk assessment decisions;

- No Information

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

- No Information

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

1. The Swedish Research Council for Environment, Agricultural Sciences and Spatial Planning (Formas), a governmental research-funding agency related to the Ministry of Sustainable Development will finance a number of large initiatives with an annual grant not exceeding MSEK 5 per project for up to five years. At least one of these initiatives will be in the field of Nanotechnology – the hazards associated with new materials. The funding of Formas in the field of nanotechnology is intended for strong research environments with the focus on both the development of nanomaterials in the areas of relevance for Formas and on the potential risks for humans and the environment related to the use of nanomaterials. The sphere of responsibility of Formas is primarily within the area of risks, but since these risks will most likely are associated with both the type and field of application of the nanomaterial, development of nanomaterials and the risks should be closely coupled in the project. The proposed projects should be of interdisciplinary character. The intention of Formas is to support teams of researchers which are considered to have great development potential and the ability to develop new ideas in this strategically important field of research.

2. The Swedish Governmental Agency for Innovation Systems (Vinnova) is a State authority that aims to promote growth and prosperity throughout Sweden. Recently Vinnova started a program called “GreenNano” that links nanotechnology development with solving key environmental issues. The projects are late phase nanotech innovations, based on research mature enough to be tried in defined applications.

So far this is a small program, the call comprised 4 million euro in public funding and the program is funding only a few projects. A second call is under discussion.

The objectives are:

- Facilitate commercialization of nanotech
- Addressing a key societal concern – reduced environmental impact
- A further objective is to augment society-industry-academia interaction and involvement in nanotech. The Project teams consist of both academic and industrial actors
- A final objective is to legitimize nanotech by making the opportunities that nanotech present tangible, both for industry and top government policy.

3. The Government bill on research and innovation proposed increased support for strategic research areas. More specifically, during 2009 to 2012 the additional resources for the 24 strategic research areas will mean an increase of 1800 million Swedish kronor (SEK) to Sweden's higher education institutions (HEIs in the following). This call for grant applications includes 20 of these areas, where Nanoscience and nanotechnology is one of the 20 strategic research areas, and the level of increase in grants for the areas during the period will reach SEK 1315 million per year. Normally, at least two HEIs will be chosen for targeted initiatives in the respective areas.

The Government used three criteria in prioritising the strategic areas. Strategic initiatives should address:

- research that, in the long term, has the prerequisites to be of the highest international quality,
- research that can contribute towards fulfilling major needs and solving important problems in society,
- research in areas that have a connection to the Swedish business sector.

During the spring of 2009 the Swedish Research Council (Vetenskapsrådet), the Swedish Council for Working Life and Social Research (FAS), the Swedish Research Council for Environment, Agricultural Sciences, and Spatial Planning (Formas), the Swedish Energy Agency (Energimyndigheten), and the Swedish Agency for Innovation Systems (VINNOVA) will manage the call for, and review of, grant applications from Sweden's HEIs in all of the strategic research areas announced by the Government. Decisions concerning funding of the 20 areas covered by this call for applications will be made by the Government. The agencies can make recommendations to the Government to allocate resources for large national infrastructures within the framework of the strategic research initiatives.

6. Information on any public/ stakeholder consultation

A stakeholder consultation on use of nanomaterials in products on the Swedish market has been done during 2008. It was made by the Swedish Chemicals Inspectorate in co-operation with other authorities and trade associations.

Through interviews with persons given the task to observe the development of nanotechnology in their special field, by appeal through authorities and trade organisation newsletters to report nano-products, by shop visits and Internet searches and by a workshop the Swedish nanomarket was surveyed. Except for the carbon black containing products and electronic devices few products could be found that contain nanomaterials. About a hundred surface protection products, cosmetics and sport articles were noted and a few cases of other products.

SWITZERLAND

Highlight of developments since the 4rd meeting of the WPMN

- As an outcome of the Swiss Action Plan on synthetic Nanomaterials the so called "precautionary matrix for synthetic nanomaterials" has been published. This matrix allows screening nanomaterials for possible health, occupational and environmental risks during their production, use or disposal.

Work completed, underway or planned

1. Swiss Action Plan on Synthetic Nanomaterials

The action plan on synthetic nanomaterials was approved by the Federal Council on 9 April 2008. The package of measures pursues four objectives:

The action plan will create regulatory framework conditions for the responsible handling of synthetic nanoparticles. The development of a methodology allowing risk characterisation of nanomaterials based on existing knowledge will be a first goal. This methodology can be used by the industry to assess their products and for the decision on risk management measures. Only when the methodological foundations and well-grounded risk assessments of synthetic nanomaterials are available, can additional statutory framework conditions for the safe handling of synthetic nanomaterials be developed.

Possible risks for humans and the environment arising in the course of the manufacture, use and disposal of these nanomaterials cannot yet be conclusively evaluated, as the scientific and methodological basis is currently lacking. The action plan aims to foster research to narrow the knowledge gaps. The National Research Programme "Opportunities and Risks of Nanomaterials" that has been launched by the Federal Council on 28 November 2007 will contribute substantially to this aim.

Communication and public dialogue are key prerequisites for the rational engagement with nanotechnology, and should therefore be encouraged. Including the public, industry and science in the debate about the opportunities and risks of nanotechnology must be an integral part of its development.

The potential of nanotechnology for efficient use of resources and health protection is of major social and economic relevance. The collaboration of research and industry to invest is such applications of nanotechnology should be promoted. Existing Federal funding schemes can be used for funding.

Download Action Plan on Synthetic Nanomaterials: http://www.bafu.admin.ch/publikationen/publikation/00574/index.html?lang=en

2. Precautionary Matrix for Synthetic Nanomaterials

The first version of the precautionary matrix for synthetic nanomaterials has been published on 3 December 2008 by the Federal Office for Public Health and the Federal Office for the Environment.

Background

Synthetic nanomaterials are not dealt with specifically in present legislation. But in principle all areas of regulation implicitly include synthetic nanomaterials and nanoparticles. Responsibility for safe handling of synthetic nanomaterials lies with industry (producers, processors) and trade. However, up until now there have been no special regulations for synthetic nanomaterials either in Swiss or in European Union legislation. The scientific and methodological prerequisites (e.g. special testing requirements) are not yet in place to define requirements going further than the current general provisions to protect health and the

environment. In view of this general situation, the precautionary matrix was worked out based on the scientific and methodological knowledge available today.

Objective

The matrix is a screening tool to estimate the "nanospecific potential risk" of synthetic nanomaterials and of their applications for workers, consumers and the environment, based on parameters such as stability, reactivity and exposure or emission to the environment of nanomaterials. The matrix will be updated on a regular basis to include new scientific knowledge.

Potentially dangerous applications can be identified with the help of the matrix, and measures to protect health and the environment can be taken. In this way the precautionary matrix is an instrument, which can be used in the context of duty of care and self-supervision by trade and industry for the production, marketing and disposal of synthetic nanomaterials. The matrix comes with a structured approach to assess the potential risk, and allows the most important sources of risk to be identified.

Using a classification of risk potential should show what action is appropriate:

"Class A": The risks specific to nanomaterials can also be classified as low, without further clarification of the risks presented by nanomaterials.

"Class B": Possible risks specific to nanomaterials should not be excluded. Further clarification of the risks is needed, or if necessary risk reduction measures must be taken in relation to manufacture, use and disposal, with a precautionary approach in mind.

For further clarification of risks, the investigations carried out by the manufacturer on human exposure, inputs into the environment and the effects of nanomaterials or – if applicable – data from the literature may also be used.

Download Safety Precautionary Matrix for Synthetic Nanomaterials: http://www.bag.admin.ch/themen/chemikalien/00228/00510/05626/index.html?lang=en

Developments related to voluntary or stewardship schemes

No governmental activity so far.

Information on any developments related to good practice documents

An important goal of the Swiss action plan is the development of a method based on existing knowledge to estimate health and environmental risks form production use and disposal of nanomaterials or its applications. The development of this so called "safety matrix" is ongoing.

Trade and industry are obliged to assess their products and applications as part of the existing provisions on self-supervision, if necessary to take measures to reduce risk, and to inform their customers of such measures. As employers they must take all the required measures to protect their employees. Corresponding instructions are being drawn up on the basis of the safety matrix.

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

The new National Research Programme "Opportunities and Risks of Nanomaterials" was launched by the Federal Council on 28 November 2007. The implementation plan defining the research focus is in preparation. The call for research projects is planned for spring 2009.

Some Federal agencies and universities have given safety research on nanomaterials a high priority.

Selected ongoing projects:

Title: *Nanoinventory*
Project leader: Michael Riediker, Institute for Occupational Health Sciences (IST) Lausanne (Michael.Riediker@hospvd.ch)
Duration: 2006-2009
Link:http://www.i-s-t.ch/fileadmin/users_datas/recherche/advancement_of_nanoinventory_www.pdf

Title: *Cytotoxicity of Nanoparticles*
Project leader: Wendelin Stark, Institute for Chemical and Bioengineering, ETH Zürich (wendelin.stark@chem.ethz.ch)
Duration: 2005-2008

Title: *Analysis of the human exposure to nanomaterials in Switzerland*
Project leader: Konrad Hungerbühler, Institute for Chemical and Bioengineering, ETH Zürich (hungerb@chem.ethz.ch)
Duration: 2006-2009

Titel: *Ecotoxicology of Nanoparticles: Biota-Nanoparticle-Pollutant Interactions in aqueous systems - Comparison of Black Carbon and Carbon Nanotubes*
Project leader: Bernd Nowack , EMPA Material Science and Technologies (nowack@empa.ch)
Duration: 2008-2011

Titel: *Interplay of lung cells and their cellular responses upon exposure to combustion-generated ultrafine particles and manufactured nanoparticles*
Project leader: Barbara Rothen-Rutishauser, Institute for Anatomy, University of Bern (rothen@ana.unibe.ch)
Duration: 2007-2010

Information on any public/ stakeholder consultation

Communication and promotion public dialogue is a goal of the Swiss action plan. It is planned to improve communication with the different stakeholders on possible risks and opportunities of nanotechnologies. Communication should allow opinion-forming which may influence technology development. On the other approaches to the safe handling of synthetic nanomaterials must be debated and discussed among the different stakeholders to be accepted and to be successful.

UNITED KINGDOM

1. Developments in the UK's Voluntary Reporting Scheme (VRS) for Manufactured Nanomaterials

A total of 13 submissions have been received since the launch of the VRS in September 2006, eleven from industry and 2 from academia. The VRS concluded its 2-year pilot phase in September 2008. Recommendations on next steps are being put to UK government ministers.

The VRS is targeted at any company or organisation involved in manufacturing, using, importing or managing wastes consisting of engineered nanoscale materials. Information requested included any data on: physico-chemical, toxicology, ecotoxicology and risk management practices.

In their recent report 'Novel Materials in the Environment: The case of Nanotechnology', the UK's Royal Commission on Environmental Pollution (RCEP) considered that reporting should be compulsory if it is to be effective and that, in addition, an 'early warning' checklist be developed so as to flag up areas of possible harm. The UK is exploring options for future reporting of nanomaterials.

2. Information on any developments related to good practice documents

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

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

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

3. Recently concluded projects

An outline scoping study to determine whether high aspect ratio nanoparticles (HARN) should raise the same concerns as do asbestos fibres.

This study was commissioned by Defra to review the existing literature and set out a research strategy towards determining whether the health concerns about HARN are well-founded. The work, carried out by the Institute of Occupational Medicine, identified many similarities between HARN and asbestos with regard to their physico-chemical properties and toxicological effects and concluded that there is sufficient evidence to suggest that HARN which have the same characteristics (diameter, length and biopersitance) as pathogenic fibres are likely to have similar pathology.

The results from the critical review were used to formulate a research strategy to investigate the potential hazard of HARN. The main components of this strategy are:

- **Hazard Identification:** The characterisation of the physico-chemical properties of HARN especially the length of the fibres and their biopersistence

- **Dose-Response Assessment:** Acute and chronic adverse effects of HARN; Cellular and molecular mechanisms of HARN toxicity investigated with in-vitro and in-vivo models

- **Exposure Assessment:** Identification and quantification of the routes (e.g. inhalation, dermal); the pattern and the intensity of exposure

- **The Risk Assessment of HARN:** Combining exposure and hazard to calculate the health risks from exposure to HARN.

The report makes recommendations on future studies to cover the identified information gaps.

The report was published in June 2008 and can be found at http://randd.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&Completed=0&ProjectID=15570.

Studies to identify the physico-chemical factors controlling the capacity of nanoparticles to penetrate cells

Two grants were made under this research topic funded by Defra.

The first project, being carried out by the Institute of Occupational Medicine, set out to scope the existing and required research into mechanisms of translocation of nanoparticles across the respiratory epithelium and the resulting possible toxic effects in and beyond the lung and to advise on the feasibility of achieving the following outcomes:

- Identifying which features of nanoparticles are important in particle-cell interactions, considering the potential role of surface chemistry, structure, mass, numbers, shape, surface area, surface charge and surface functionalisation

- Suggesting how nanoparticles may be modified to enhance or reduce their capacity to enter cells

- Suggesting how interactions between nanoparticles and cultured human cells might be studied.

The second project, experimentally based and being undertaken at Imperial College, London, set out to determine:

- Which (combination) of factors influence nanoparticle uptake and/or translocation by/into human alveolar epithelium - particle size, surface area, surface charge?
- The fate/cellular location of internalised nanoparticles and whether particle uptake is active or passive
- The influence of the lung lining fluid (lung surfactant) on these processes.

Reports from both studies are due to be published in early 2009.

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

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

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

A report from this study is due to be published in early April 2009.

The UK Government's Department of Health is in the process of commissioning work on:

- Carbon nanotubes and the asbestos/fibre structure activity relationship – Expected to commence January 2009 and last 3 years. The work will be carried out at Edinburgh University, supervised by Professor Ken Donaldson, costing £151,588
- Quantitative and kinetic measurements of carbon nanotubes transport across pulmonary epithelium using an isolated perfused rat lung preparation –Expected to commence January 2009 for one year. Work to be carried out at Cardiff University, supervised by Professor Ian Matthews costing £117,584
- Factors that may affect the nanotoxicology of hard materials for surgical applications – Expected to commence January 2009 for one year at the University of Bristol, supervised by Dr Charles Patrick Case, costing £121,322
- Nanoparticles and Atherothrombosis: Resolving the Paradox – Expected to commence January 2009 for 3years. Work to be carried out at Edinburgh University, supervised by Dr Nicholas Mills, costing £184,113

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

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

Total funding should be in the region of $8M.

4. Information on any public/ stakeholder consultation

The UK government has funded a consultation to assess the potential for a new organisation to coordinate public engagement on nanotechnologies, through multi-stakeholder debate and encouraging all organisations to play their part in minimising the risks and realising the benefits of nanotechnologies. The final report will be available in due course.

UNITED STATES

Highlights of developments since the 4th meeting of the WPMN

- EPA released an interim report on its Nanoscale Material Stewardship Program (January 2009)
- EPA issued several Consent Orders regulating new chemical submissions of carbon nanotubes under TSCA (Fall and Winter 2008)
- EPA issued a Federal Register notice reiterating that carbon nanotubes were subject to new chemical notification under TSCA (October 2008)
- EPA's draft *Nanomaterial Research Strategy,* issued in February 2008, underwent its 2nd peer review (December 2008)
- NIOSH issued interim guidance for medical screening and hazard surveillance for workers potentially exposed to engineered nanoparticles (February 2009) which is available at www.cdc.gov/niosh/docs/2009-116.
- OSHA posted a new web page on nanotechnology that highlights related OSHA standards, current and potential applications of nanotechnology, potential health effects and workplace hazard controls, as well as health and safety research priorities for nanotechnology (October 2008)

Work completed, underway or planned

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

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

EPA issued several Consent Orders regulating new chemical submissions of carbon nanotubes. A sanitized version of such a consent order is available. On November 5, 2008, EPA issued Significant New Use Rules (SNURs) for two new chemical substances identified as nanoscale materials. (http://www.epa.gov/fedrgstr/EPA-TOX/2008/November/Day-05/t26409.pdf.) To date, EPA has issued SNURs for less than 10 new chemical nanoscale materials. Because of confidential business information claims by submitters, EPA is unable to identify the chemical substance as a nanoscale material in every new chemical SNUR it issues for nanoscale materials. EPA will continue to issue SNURs for new chemical nanoscale materials in the coming year.

EPA issued a Federal Register notice on October 31, 2008, reiterating that carbon nanotubes were subject to new chemical notification under TSCA, http://www.epa.gov/fedrgstr/EPA-TOX/2008/October/Day -31/T26026.pdf.

2. Developments related to voluntary or stewardship schemes

In February, 2009, NIOSH issued interim guidance for medical screening and hazard surveillance for workers potentially exposed to engineered nanoparticles, which is available at www.cdc.gov/niosh/docs/2009-116/. The NIOSH interim guidance addresses the question of whether specific medical screening is appropriate for workers potentially exposed to engineered nanoparticles who do not display symptoms of disease. NIOSH concluded that at this time, there is insufficient scientific and medical evidence to recommend the specific medical screening of workers potentially exposed to engineered nanoparticles.

On January 12, 2009, EPA released its interim report on the Nanoscale Materials Stewardship Program. The program will continue through January 2010. EPA will issue a final report early in 2010. EPA stated in the report that it would consider how best to apply regulatory approaches under TSCA to address data gaps noted in the report.

3. Information on any risk assessment decisions

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

4. Information on any developments related to good practice documents

NIOSH has been developing a series of brochures and fact-sheets describing NIOSH recommendations and efforts in nanotechnology. The first brochure in this series, "Safe Nanotechnology in the Workplace: An Introduction for Employers, Managers, and Safety and Health Professionals," is available on the web at http://www.cdc.gov/niosh/docs/2008-112/pdfs/2008-112.pdf. First three fact sheets The Nanotechnology Field Research Team Update (http://www.cdc.gov/niosh/docs/2008-120/), NIOSH Nanotechnology Field Research Effort Fact Sheet (http://www.cdc.gov/niosh/docs/2008-121/), NIOSH Nanotechnology Metal Oxide Particle Exposure Assessment Study (http://www.cdc.gov/niosh/docs/2008-122/) were published in March, 2008. Additional nanotechnology fact sheets will be available at http://www.cdc.gov/niosh/whatsnew.html.

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

In 2008, NIOSH researchers have published several leading scientific papers pertaining to occupational health and safety of workers producing or using nanomaterials. These papers include:

- Schulte, P., Geraci, C., Zumwalde, R., Hoover., M., Castranova, V., Kuempel, E., Murashov, V., Vainio, H., Savolainen, K.(2008). Sharpening the focus on occupational safety and health of nanotechnology in the workplace., Scan. J. Work. Environ Health 34(6); 471-478.

- Shevdova, AA., Kisin, E., Murray, AR, et. Al (2008). Inhalation versus aspiration of single walled carbon nanotubes in C57BL/6 mice: inflammation, fibrosis, oxidative stress and mutagenesis, Am J Physiol Lung Cell Mol Physiol, 295: L 552-L565.

US-UK Collaboration

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

It is anticipated that the call (or solicitation) will ask applicants to propose conceptual models and similar predictive tools for environmental fate, behavior, interaction, bioavailability and effects focused on one or more classes of manufactured nanomaterials. They will also be asked to propose research to validate and refine the proposed model(s). In addition, researchers will be asked to develop novel

techniques for detection and characterization of nanomaterials in complex environmental and biological systems. The joint program aims to draw on complementary strengths in the UK and US to produce robust, validated models that accurately predict transport, fate and bioavailability of nanomaterials and their interaction with biological and ecological systems. The program will be strongly interdisciplinary in its approach.

It is anticipated that this collaborative research will generate valuable tools to support assessment of risks associated with the environmental release of manufactured nanomaterials. It is anticipated that the solicitations will be issued in February 2009.

New Research Centers

The US National Science Foundation and US Environmental Protection Agency are jointly funding two Centers for Environmental Implications of Nanotechnology (CEIN) one led by Duke University and the other led by the University of California-Los Angeles. The centers are dedicated to elucidating the relationship between a vast array of nanomaterials—from natural, to manufactured, to those produced incidentally by human activities—and their potential environmental exposure, biological effects, and ecological consequences.

The Duke-CEIN is a collaboration between Duke, Carnegie Mellon University, Howard University, and Virginia Tech, and investigators from the University of Kentucky and Stanford University. Other US academic collaborations include ongoing activities coordinated with faculty at Clemson, North Carolina State, Rice, and Purdue universities. The Duke-CEIN performs fundamental research on the behaviour of nano-scale materials in ecosystems that will provide guidance in assessing existing and future concerns surrounding the environmental implications of nanomaterials.

The UC-CEIN proposes to conduct predictive toxicological science for engineered nanomaterials in partnership with UC Santa Barbara, UC Davis, UC Riverside, Columbia University (New York), University of Texas (El Paso, TX), Nanyang Technological University (NTU, Singapore), the Molecular Foundry at Lawrence Berkeley National Laboratory, Lawrence Livermore National Laboratory, Sandia National Laboratory, the University of Bremen (Germany), University College Dublin (Ireland), and the Universitat Rovira I Virgili (Spain). The goal of the Center is to develop a broad based model of predictive toxicology premised on quantitative structure activity relationships and nanomaterial injury paradigms at the biological level.

6. Information on any public/ stakeholder consultation

NIST continues to leverage nanotechnology standards development work among other Federal programs, establish direct collaborations with other Federal agencies, and work with representatives from the risk assessment and regulatory communities represented by government, academia, industry, and the international community. Specific meetings at NIST with other agencies to strengthen collaborations on the characterization of nanomaterials and the development of reference materials have occurred with the NIOSH, U.S. FDA, and the National Cancer Institute's Nanotechnology. NIST continues to participate in and lead efforts on the development of nanotechnology standards in standard development bodies: ISO TC 229 Nanotechnologies, IEC TC 113 Nanotech. Stand. For Electrical and Electronic Products & Systems, ASTM E56 Nanotechnology, IEEE Nanotechnology Council Standards Committee, and the OECD Working Party for Manufactured Nanomaterials. NIST continues to participate as a member agency with the National Nanotechnology Initiative and provide service to the NEHI WG.

EUROPEAN COMMISSION

Highlight of developments since the 4th meeting of the WPMN

- On 10 February 2009, the European Food Safety Agency (EFSA) Scientific Committee adopted the scientific opinion on "The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety" after a public consultation. The text of the opinion will be available from the EFSA web site (http://www.efsa.europa.eu) in early March 2009.
- On 19 January 2009, the EU Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) adopted an update of the opinion on "The Risk Assessment of Products of Nanotechnology". The recently adopted opinion is part of an on-going process for evaluation of the risks of nanomaterials. The European Commission is considering inviting web-based comments on the issues addressed in this opinion followed by a scientific hearing in the coming months. The text of the opinion is available at: http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_023.pdf
- Since the establishment of the Competent Authorities Sub Group on Nanomaterials (CASG Nano) on 27 March 2008 it has had two official meetings and an informal workshop. The sub-group has established a work programme until 2012, based on the implementation deadlines under REACH. CASG Nano issued its first paper "Nanomaterials in REACH", which was endorsed by the REACH CA meeting on 16 December 2008. Further papers are expected during 2009.
- The deadline for pre-registration of phase-in substances under REACH (Registration, Evaluation, Authorisation of Chemicals) was 1 December 2008. By that time some 2.75 million pre-registrations of some 150,000 different substances had been received For further information consult the website of the European Chemicals Agency (ECHA); http://echa.europa.eu/home_en.asp and http://echa.europa.eu/doc/press/pr_08_59_publication_pre-registered_substances_list_20081219.pdf
- The European Commission organised on 13-14 November 2008 in Brussels a "Global Risk Assessment Dialogue", where nanotechnology products were prominently featured. The agenda, proceedings and presentations, may be accessed at: http://ec.europa.eu/health/ph_risk/ev_20081113_en.htm
- The European Commission organised on 2-3 October 2008 in Brussels the "2nd Annual Nanotechnology Safety for Success Dialogue Workshop". The agenda, proceedings, and presentations may be accessed at: http://ec.europa.eu/health/ph_risk/ev_20081002_en.htm
- The European Parliament has decided to issue an own initiative report in response to the Commission's Communication on "Regulatory aspects of Nanomaterials", which was adopted on 16 June 2008. The European Parliament is expected to have adopted its report at its session in April 2009.
- The projects selected under the first call for proposals of the 7th EU Research Framework Programme (FP7) are being launched.
- The second call for proposals in the 7th EU Research Framework Programme (FP7) was completed and the five proposals selected are in negotiation. The third call is closing on 31/3/2009 and addresses proposals on use, recycling and final treatment of nanotechnology based products as well as coordination on exposure scenaria to nanoparticles.

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

According to the Commission's Communication on "Regulatory Aspects of Nanomaterials", existing EU legislation covers in principle the potential health, safety and environmental risks in relation to nanomaterials. The protection of health, safety and the environment needs mostly to be enhanced by improving implementation of current legislation. The Commission and EU Agencies will therefore in the first place review current documents that support implementation, such as implementing legislation, standards and technical guidance with regard to their applicability and appropriateness to nanomaterials. The Communication is currently being discussed in the European Parliament. Their final opinion is expected to be adopted in April 2009.

The 2nd Annual Nanotechnology Safety for Success Dialogue Workshop led to the adoption of ten action points to be launched by Easter 2009. The workshop called for an increased coordination and exchanges between EU Member States, stakeholders, and regulatory bodies. Emphasis was also put on information and scientific knowledge gap filling.

The two European legislators (The European Parliament and the Council) are discussing amendments to the Cosmetics Directive and the Novel Foods Regulation. The discussions involve nanotechnology aspects. The discussions are still on-going and the results are therefore not yet known.

2. Developments related to voluntary or stewardship schemes

The European Commission has not developed any voluntary programmes or stewardship schemes. However, the Directorate General for Environment has requested a contractor to make a survey on what nanomaterials exist on the EU market and in what quantities. This will be followed up by a workshop in autumn 2009. This and general issues regarding information on nanomaterials are also discussed in the REACH CASG Nano.

3. Information on any risk assessment decisions

The European Commission has not taken any risk assessment decisions since the last Tour de Table document issued in June 2008 of relevance in the context of nanomaterials. Last year the European Commission requested the Scientific Committee on Emerging and Newly Identified Human health Risks (SCENIHR) to identify and assess new information and update the opinions on potential risks of products of nanotechnologies, in particular, with respect to characterisation, eco-toxicology and toxicology as well as exposure assessments, for further details see ENV/CHEM/NANO(2008)2).

SCENIHR adopted their opinion on 19 January 2009 and the abstract of the opinion reads:

"*This Opinion deals with the recent developments in the risk assessment of nanomaterials for both man and the environment. The in-depth characterisation of a manufactured nanomaterial on the basis of its physical-chemical characteristics is essential. Due to the size and material specific temporal evolution of some nanomaterials, potentially hazardous nanomaterials need to be characterised both 'as manufactured' and in the various possible forms 'as delivered' in biological systems, or to a human in a specific application, or to a particular ecosystem of concern. The characterisation 'as manufactured' provides information for the material safety data sheet of the product itself. The characterisation 'as used' in biological systems is needed as properties of nanomaterials may change considerably, notably the size distribution due to agglomeration/aggregation of the particles. An issue of specific importance is the properties of the nanomaterial as it is actually used in products and to which consumers may be exposed. For the risk assessment the latter characterisation is of highest relevance.*

Some specific hazards, discussed in the context of risk for human health, have been identified. These include the possibility of some nanoparticles to induce protein fibrillation, the possible pathological effects

caused by specific types of carbon nanotubes, the induction of genotoxicity, and size effects in terms of biodistribution. Knowledge is gradually becoming available on the behaviour of manufactured nanoparticles in the environment in terms of the development of possible fate scenarios.

For some nanomaterials, toxic effects on environmental organisms have been demonstrated, as well as the potential to transfer across environmental species, indicating a potential for bioaccumulation in species at the end of that part of the food chain. Although for some manufactured nanomaterials adverse effects were observed they should not be extrapolated to other manufactured nanomaterials. These observations indicate potential hazards which should be taken into consideration in the safety evaluation of manufactured nanomaterials. As there is not yet a generally applicable paradigm for nanomaterial hazard identification, a case by case approach for the risk assessment of nanomaterials is warranted.

One of the main limitations in the risk assessment of nanomaterials is the general lack of high quality exposure data both for humans and the environment. A differentiation between background and incidental exposure is generally difficult in real life situations as the methods employed mainly measure the presence of (nano)particles and do not generally discriminate between the different types of particles (manufactured or naturally occurring) that may be present. Currently, the risk assessment procedure for the evaluation of potential risks of nanomaterials is still under development. It can be expected that this will remain so until there is sufficient scientific information available to characterise the possible harmful effects on humans and the environment. Therefore the knowledge on the methodology for both exposure estimations and hazard identification needs to be further developed, validated and standardised".

The European Commission is considering inviting web-based comments on the issues addressed in this opinion followed by a scientific hearing in the coming months.

4. Information on any developments related to good practice documents

The European Commission's Code of Conduct (CoC) adopted on 7 February 2008 provides EU Member States, employers, research funders, researchers and more generally all individuals and civil society organisations involved or interested in nanosciences and nanotechnologies (N&N) research ("all stakeholders") with guidelines favouring a responsible and open approach to N&N research in the Community.

The CoC is complementary to existing regulations. It does not limit or otherwise affect the possibilities of Member States to grant a wider measure of protection with regard to N&N research than is stipulated in this Code of Conduct.

Stakeholders who adhere to the CoC should also be inspired, where applicable, by the principles set out in the Charter of Fundamental Rights of the European Union. The CoC will be regularly monitored and revised every two years by the Commission in order to take into account developments in N&N worldwide and their integration in European society.

For more information, please consult: ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/nanocode-recommendation-pe0894c08424_en.pdf

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

A High-Level Experts Group of Member States and FP7 Associated States has held their first meeting in February 2009. Research in the area of risk management, in particular the study of the impact of nanoparticles to health and environment, has been agreed as a priority.

Under the second FP7 call five proposals in the area of "Impact of engineered nanoparticles on health and environment" have been retained for negotiation. Proposals to be received under the third call will be assessed in April 2009.

The European Commission is working towards clustering the toxicology related projects in view of joint elaboration of common deliverables and strategic planning. The first meeting took place on 26 February 2009.

Research in Materials science

Within Framework Programme on Research (FP7), research on materials science supports the development of new multifunctional surfaces and materials with tailored properties for products targeting a wide range of applications. As has been the case since the first year, some topics specifically request the participants to consider including in the proposals research activities related to the safety of nanomaterials developed.

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

Several proposals coming from last year's call are currently under negotiation an have include this issue in their activities.

NMP-2008-2.1-2	**Processing and upscaling of nanostructured materials**

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

Finally, the research activities in the call for proposal for this year (deadline 17 February 2009) include also the specific call for attention to safety matters. Notably, it is specifically mentioned in the following topics:

NMP-2009-2.1-1	**Nano-structured materials based on graphene**
NMP-2009-2.2-1	**Oxide materials for electronics applications**
NMP-2009-2.4-1	**New biomass-based composite materials and their processing**

6. Information on any public/ stakeholder consultation

The Commission considers that dialogue is indispensable for emerging technologies such as nanotechnologies. Public trust in and acceptance of nanotechnologies are crucial for the long-term development. The Commission and a number of the Member States have also actively promoted multi-stakeholder dialogues on nanotechnologies, and numerous other outreach activities. These events have involved, depending on the special themes of the conferences, participation of public authorities, scientists, industry associations, consumers, environment and other non-governmental organisations. Furthermore these activities complement and are coordinated with various other activities at Member State level and by international organisations. Nevertheless, surveys have indicated that European public is not yet sufficiently aware of nanosciences and nanotechnologies. However, these surveys also show that public confidence in European public authorities' ability to ensure good governance for nanotechnology is higher in Europe than elsewhere.

The opinions from EU Scientific Committees, SCENIHR and SCCP are normally always submitted to public consultations before final adoption.

BUSINESS AND INDUSTRY ADVISORY COMMITTEE (BIAC)

PART I: CEFIC

Highlights

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

Background

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

Work Underway or Planned

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

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

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

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

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

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

Through its Long-range Research Initiative (LRI), Cefic sponsors health and environment safety research on nanomaterials. For example, one project led by Dr Otto Creuzenberg at the Fraunhofer Institute will test the suitability of OECD testing guidelines for nano zinc oxide and nano amorphous silicon dioxide particles and define a tiered testing strategy for these nanoparticles.

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

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

Stakeholder Engagement

In June 2008, Cefic organized an external stakeholder event. The aim was to facilitate an open and frank exchange of information so that industry, policy makers and other stakeholders can gain a better understanding about each other's point of view. Four chemical companies shared detailed information on four real-life nano-enabled products, discussing how and why nanomaterials work inside the product to improve its functionality and how they are tested for safety across their life cycle. This event will be followed up in the first half of 2009 with smaller, more focussed "stakeholder participative projects" where a maximum of 10-15 stakeholders will work together on pre-consulted projects. Possible projects currently under discussion include a review of the global chemical industry's Responsible Care® Program to assess how it addresses novel technologies, with a focus on nanotechnologies – and to make suggestions for adaptation where appropriate. Another is to look at ways of sharing appropriate information about nanomaterials and nanotechnologies with stakeholders. Questions include: what information should be provided to whom and in what form?

For further information please contact:

Johan Breukelaar, Director International Chemicals Policy, jbr@cefic.be

PART II: VCI

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

Principle documents:

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

Regulatory documents:

- Requirements of the REACH Regulation on Substances which are Manufactured or Imported also as Nanomaterials
- Guidance for a Tiered Gathering of Hazard Information for the Risk Assessment of Nanomaterials
- Guidance for Handling and Use of Nanomaterials at the Workplace
- Guidance for the Passing on of Information along the Supply Chain in the Handling of Nanomaterials via Safety Data Sheets

- Strategy Paper of the German Chemical Industry on the Standardisation of NanomaterialsDocuments on safety research:
- Roadmap for Safety Research on Nanomaterials
- Environmental Aspects of Nanoparticles

These documents have been discussed with the public as well as national and European authorities. The "Guidance for Handling and Use of Nanomaterials at the Workplace" and the "Guidance for the Passing on of Information along the Supply Chain in the Handling of Nanomaterials via Safety Data Sheets" have been developed together with stakeholders in dialogue activities. The "Roadmap for Safety Research on Nanomaterials" and the paper on "Environmental Aspects of Nanoparticles" have been developed together with representatives from science." The latter will be supported by a paper on results on research projects dealing with nanoparticle releases from end products.

In October 2008, BIAC and the German Federal Institute of Occupational Safety and Health (BAuA) hosted a workshop on "Exposure Assessment and Exposure Mitigation" (SG8) in the framework of the OECD Working Party on Manufactured Nanomaterials (WPMN). The workshop was sponsored by the German Chemical Industry Association (VCI) and discussed measurement techniques and measures for workplace safety.

www.vci.de

PART III: ACC

The American Chemistry Council Nanotechnology Panel (Panel) participated in and helped support the October 28-29, 2008 Workshop held at the Woodrow Wilson International Center for Scholars that focused on identifying appropriate materials characterization in nano-toxicity studies. Material characterization recommendations resulted from this workshop, and options were identified to implement the recommendations among researchers, research managers, and research publishers.

The Panel continued to support and participate in the voluntary EPA Nanoscale Materials Stewardship Program (NMSP). The Panel continues to discuss with EPA the further implementation of the basic and in-depth components of the NMSP, and the data to be generated by the contributions of BIAC to the OECD testing program. EPA and the Panel continue to discuss risk and exposure related research follow up activities.

The Panel continued to provide input to the reauthorization process of the US National Nanotechnology Initiative. NNI reauthorization legislation is expected to be re-introduced early in the new Congress. The Panel supports the NNI reauthorization and seeks to build upon the National Research Council review and recommendations for the NNI environment, health, and safety (EHS) program. Focusing on supporting increased funding and prioritization of EHS research at the federal level, the Panel continues to support the development of a "top-down" preparation of a roadmap for EHS federally funded research with progress markers clearly identified that are measurable over specified time intervals.

http://www.americanchemistry.com

PART IV: JCIA

Nanotechnologies are expected to bring benefits in a wide range of fields, as basic technologies for future industries. In particular, nanomaterials, which are produced by nanotechnologies, are expected to exhibit more specific functions than conventional materials.

However, there is also concern that nanomaterials as chemical substances may harm human health or the environment because of their extremely small grain size. In fact, some researchers in Japan have reported results of safety assessments which may not necessarily be valid.

Because of this situation, the Japan Chemical Industry Association (JCIA) raised this issue at the "New Chemical Issues Working Group(NCI-WG)" to Address New Issues in April 2008. The WG conducted a close examination and analysis in order to deepen its understanding and awareness of nanomaterials, and published the "Instruction Guidance" regarding Nanomaterials" in July, and the "Investigation Report regarding Nanomaterials" in December, both of which have been made public to the members.

In Japan, in response to a request from the public regarding the aforementioned concern, the relevant ministries have established committees to consider measures from various perspectives such as the protection of working environment and workers, safety of consumers, environmental impacts, and producers and importers. JCIA has been participating in these committees and offering opinions aggressively on what measures should be taken, from the standpoint of the chemical industry.

Also, as for OECD-related activities, the "Study Session on Research on the Utilization and Communication of Information for the Promotion of Public Acceptance" and "National Review Committee for the Standardization of Nanotechnologies" established by the National Institute of Advanced Industrial Science and Technology (AIST) as a follow-up group for such OECD activities respectively. JCIA has been actively participating and offering opinions as its project member since June and September 2008.

ENVIRONMENTAL NON GOVERNMENTAL ORGANISATION

European Environmental Bureau (EEB)

In February 2009 EEB has finalised it horizontal position paper on nanotechnologies and nanomaterials. The paper presents EEB's vision for responsible management and development of nanomaterials and explains how the vision can be put in practice through actions undertaken by EU policy and decision makers addressing EEB's demands for the sustainable governance of nanomaterials.

To date, the EEB has not been pleased with the European Commission's unfocused reaction to the development of nanomaterials. The following demands, if implemented, would provide a more credible, coherent and comprehensive approach to the governance of these novel technologies. Such an approach would enable the research community and industry to better target future applications of nanotechnologies within publicly agreed sustainability parameters.

EEB demands that no further market introduction be allowed for products containing manufactured nanomaterials which could lead to exposure of consumers or uncontrolled release in the environment in their use phase. Such a restriction should be put in place until appropriate impact and safety assessment tests are developed that provide scientific proof that these materials and products are adequately safe to human health and the environment. Those products already on the market should be regulated according to the REACH approach of "no data, no market", and should therefore be removed from commercial circulation.

The following additional demands would help establish a policy and regulatory framework on nanomaterials:

1. Develop a pre-market registration and approval framework

The fast-moving development of the types and uses of nanomaterials requires a regulatory framework that can anticipate the safe management of future applications in advance of their availability on the market. The framework should require registration of public and private research, test-based assessment and approval of near-market uses of nanomaterials. This information should then be put into a publicly available inventory that would serve to identify what possible future uses of nanomaterials could be developed, systematically assess what products are proposed for placement on the market and would help ensure swifter and more targeted management of these.

We therefore call on the European Commission to create a publicly available inventory for public and private research and demand test-based assessment and approval of materials in near-market-use stage.

This EU-wide inventory should be fed into by Member State level inventories, to avoid lack of harmonisation and duplication of efforts, while providing citizens important country-specific information immediately available in their national language.

2. Undertake public consultation on technological innovation, including nanotechnologies and nanomaterials

More attention has been devoted to technological innovation than to social innovation, including public participation in decision-making and the development of more democratic decision-making procedures. In light of increasing focus on innovation, and eco-innovation in particular, as a means of achieving competitiveness, more efforts are needed at EU and national levels to legitimately incorporate

public opinion in political decisions. For example, public opinion should be sought systematically on the needs for some innovations, as it should not be assumed that they will all deliver great enough social advantages to justify greater risk exposures.

Therefore, an EU-wide public debate, organised at the Member State level, is urgently needed to set clearer parameters for the current uses and future developments of these technologies and materials. The European Commission needs to work in collaboration with Member States in organising such a debate at the earliest possible moment.

EEB therefore urges the European Commission and the Member States to immediately undertake an EU-wide public debate on nanotechnologies and nanomaterials.

This should form part of a wider debate on technological innovation.

3. Put in place an adequate policy and regulatory framework before further market penetration occurs

Given that there is disagreement over the adequacy of existing legislation to address the potential impacts of nanomaterials, it is clear that the European Commission's regulatory assessment conclusions are not satisfactory and do not provide a solution to closing the regulatory gaps. Experience from REACH (the EU's most comprehensive chemicals legislation) has already shown the limitations of this legislation in dealing with nanomaterials. Moreover, that current implementing tools (e.g. test methods, communication of test results, etc.) do not apply at the nano level.

Taking the approach of amending existing legislation is leading to fragmented and incoherent governance, best illustrated with the current revisions of the Novel Foods Regulation and the Cosmetics Directive. Given that nanotechnologies and nanomaterials can be used in many different ways and in different types of products, a policy and regulatory framework which can address these various applications coherently and comprehensively is needed. This framework should also be able to address future developments, as detailed in our demand for a pre-market registration and approval framework.

EEB therefore calls for the development of a nano-specific policy and regulatory framework, addressing existing and future applications.

In an interim period, case-by-case amendments to legislation will need to continue, especially to more quickly bring nanomaterials into formal legislative mechanisms.

Such a comprehensive and coherent policy and regulatory framework would need the following:

- An immediate review and revision of existing legislation relevant to nanomaterials.
- The urgent and strict application of the REACH "no data, no market" approach to products containing manufactured nanomaterials that could lead to exposure of consumers or the environment.
- Required pre-market approval for all applications of nanotechnologies and nanomaterials as a central element of the policy and regulatory framework.
- Provide the necessary implementation tools for the coherent and comprehensive management of these technologies and materials. Particular focus and priority is needed on the development of testing methods to identify human health and environmental impacts.
- To develop robust safety assessment standards while recognising the serious limitations of our existing scientific capacity and knowledge to identify potential impacts.

- The Precautionary Principle, the Polluter Pays Principle, and sustainability objectives need to be the basis of the policy and regulatory framework. This would help to guide developments towards more societally beneficial (e.g. solar energy technology) uses than those with questionable benefits (e.g. stain-free fabrics).

- Clarity and coherence on the key aspects of nanomaterials definition, with focus on:

  - Size being defined from 0.3nm to 300nm;

  - Substances having nanomaterial-like properties to be included, even though they fall beyond the official size range;

  - All nanomaterials to be included in regulation, not just those that are insoluble or bioaccumulative, as well as aggregates and agglomerates;

- To immediately start work on the establishment of a mandatory EU label as an identification tool to be placed on products containing manufactured nanomaterials which could lead to exposure of consumers or the uncontrolled release in the environment. Such a label would work on an intermediate basis, before the EU-wide public debate is finalised and a regulatory framework is prepared reflecting the demands of the public on the appropriate identification tools. Public debates should also help to identify what other communication tools are useful to increase and improve public awareness of the issues.

4. Prioritise research funding on the functioning of natural and human systems with respect to possible impacts of nanomaterials on these

Currently, the vast majority of EU nanotechnology research funding focuses primarily on technological development, aimed at enhancing competitiveness and growth. This is unacceptable given the continuing unknowns about nanomaterials and that current product and safety testing does not extend to the nano level. EEB therefore calls for prioritisation of funding and the majority of research being directed toward environmental and human health aspects and strengthening social innovation on public participation in decision-making.

We therefore call on the European Commission to:

- Prioritise research funding in favour of eliminating knowledge gaps, over increasing funding in technological development. A sliding scale starting around 80% and reducing over time to around 15% should be reserved for the environmental, human health and social, economic and ethical implications of nanotechnology. All new projects receiving EU funding should be required to include sustainability assessment, public participation and decision making mechanisms.

- Clearly identify the limitations of existing safety assessment and management tools in relation to nanomaterials. This should be done in conjunction with the research on eliminating knowledge gaps on environmental and human health impacts. In this way, the research development priorities can be identified based on the gaps between current tools and the demand for existing and future uses of nanomaterials.

- Develop and implement a research strategy identifying a roadmap for improving knowledge leading to the safer development and use of nanomaterials in different applications.

- Further develop sustainability assessment of technologies tools, for their more systematic use in both research and product development. These should also be used in policy developments on innovation and eco-innovation, and sustainable industrial policy.

Additional Information

The full version of the EEB position paper can be found at http://www.eeb.org/publication/2009/090217_EEB_nano_position_paper.pdf\

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

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

The International Organisation for Standardization Technical Committee (ISO/TC) 229 - Nanotechnologies - was established in June 2005 with a UK secretariat and chair. It has held seven meetings to date - November 05 in London, June 06 in Tokyo, December 06 in Seoul, June 07 in Berlin, December 07 in Singapore, May 08 in Bordeaux, France, and November 08 in Shanghai. The next meeting will be in June 2009 in Seattle, USA. The committee currently has 40 members - 32 "P" and 8 "O". The first two documents developed by the committee were published in 2008: ISO/TS 27687 – Nanotechnologies – Terminology and definitions for nano-objects – nanoparticle, nanofibre and nanoplate; and ISO/TR 12885 – Nanotechnologies - Health and safety practices in occupational settings relevant to nanotechnologies

The TC structure consists of 4 working groups (WG), the first two of which are Joint Working Groups (JWG) with IEC/TC 113 (Nanotechnology standardization for electrical and electronic products and systems): Terminology and Nomenclature (JWG1, convened by Canada); Measurement and Characterization (JWG2, convened by Japan); Health, Safety and Environment Aspects of Nanotechnologies (WG3, convened by USA), and Material Specifications (WG4, convened by China). The work programme at the beginning of February 2008 contained 32 work items – 8 in JWG1, 13 in JWG2, 6 in WG3, and 5 in WG4 (Annex 1), with a further 3 New Work Item Proposals out for ballot. Of the existing work items, the most relevant to the WPMN are those in WG3, though both the terminology work, in JWG1, and the measurement and characterization work, in JWG2, have broad relevance.

The committee has established Task Groups to develop recommendations as to how it should address the areas of Nanotechnologies and Sustainability, Material Specifications, Nanomaterials Classification, and Consumer and Societal Dimensions of Nanotechnologies. Task Groups are disbanded once they have completed their work.

The TC works closely with the IEC (International Electrotechnical Commission) TC 113, chaired by the US, with Germany providing the secretariat. The two Technical Committees hold joint plenary meetings at least every two years, starting in December 2007. TC 229 also works closely with the CEN (European Committee for Standardization) TC in the area (TC 352 – Nanotechnologies, also chaired by UK), using the Vienna agreement where appropriate. Liaisons have been established with 15 other ISO TC's, with the OECD (Working Party on Manufactured Nanomaterials and Working Party on Nanotechnology), with the International Bureau on Weights and Measures (BIPM), with the EC Joint Research Centres (IRMM and Institute for Health and Consumer Protection, Ispra), with the Asia Nano Forum and with VAMAS.

Given the number of ISO and other committees and working parties with an interest in nanotechnologies standardization, and in particular in the development of test methods for measurement and characterization, a Joint International Workshop on measurement and characterization for

nanotechnologies was held in February 2008 in cooperation with IEC, OECD and NIST (US National Institute of Standards and Testing) to identify needs and to provide a forum for discussions on harmonization and coordination issues. Details of this workshop, including presentations and the final report, are available at http://www.iso.org/nanotech-workshop. One important outcome was agreement to establish a Nanotechnology Liaison Coordination Group to ensure coordination of activities and harmonization of deliverables amongst liaison organisations. This group held its first meeting in Bordeaux during the last week of May 2008, with the second meeting being held in Shanghai in November 2009.

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

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

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

Acceptance requires

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

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

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

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

Annex: ISO/TC 229 Work Programme at 30 June 2008

JWG1

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

JWG2

- *ISO/TS: The Use of Transmission Electron Microscopy (TEM) in the Characterization of Single-walled Carbon Nanotubes*
- *ISO/TS: The Use of Scanning Electron Microscopy (SEM) and Energy Dispersive X-ray Analysis (EDXA) in the Characterization of Single-walled Carbon Nanotubes*
- *ISO/TS: Technical Specification for the Use of UV-Vis-NIR absorption spectroscopy in the Characterization of Single-walled Carbon Nanotubes*
- *ISO/TS: Technical Specification for the use of NIR-Photoluminescence (NIR-PL) Spectroscopy in the Characterization of Single-Walled Carbon Nanotubes* ***– currently out for CD ballot***
- *ISO/TR: Use of Thermo Gravimetric Analysis (TGA) in the purity evaluation of Single Walled Carbon Nanotubes*
- *ISO/TR: Use of Evolved Gas Analysis-Gas Chromatograph Mass Spectrometry (EGA-GCMS) in the Characterization of Single-Walled Carbon Nanotubes*
- *ISO/TS: Use of Raman Spectroscopy in the Characterization of Single Walled Carbon Nanotubes.*
- *ISO/TS: Measurement Methods for the Characterization of Multi-Walled Carbon Nanotubes* ***– currently out for CD ballot***
- *ISO/TR: Guide to nanoparticle measurement methods*
- *ISO/TR: Guide to methods for nano-tribology measurements*
- *ISO/TS: Determination of meso-scopic shape factors of multiwalled carbon nanotubes (MWCNTs)*
- *ISO/IS: General framework for determining nanoparticle content in nanomaterials by generation of aerosols*
- *ISO/TS: Electrical resistance of carbon nanotubes using 4 probe measurement*

WG3

- *ISO/IS: Endotoxin test on nanomaterial samples for in vitro systems*
- *ISO/IS: Generation of nanoparticles for inhalation toxicity testing*
- *ISO/IS: Monitoring of nanoparticles in inhalation exposure chambers for inhalation toxicity testing*
- *ISO/TR: Guidance on physico-chemical characterization of engineered nanoscale materials for toxicologic assessment (Harmonized with WPMN list – woking closely with Noriko Oki on this to ensure that we complement each other's work and avoid duplication)*
- *ISO/TS: Guidance on safe handling and disposal of manufactured nanomaterials*
- *ISO/TR: Nanomaterial risk evaluation framework*

WG4

- *ISO/TS: Format for reporting the engineered nanomaterials content of products*
- *ISO/TS: Material specification - Nano-calcium carbonate, Part 1 – General requirements*
- *ISO/IS: Material specification - Nano-titanium dioxide, Part 1 – General requirements*
- *ISO/TS: Nanomaterial calcium carbonate (powdered form) — Part 2: Specifications for specific applications*
- *ISO/TS: Nanomaterial titanium dioxide (powdered form) — Part 2: Specifications for specific applications*

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

Three New Work Item Proposals are currently under consideration:

- Artificial gratings used in nanotechnology - description and measurement of dimensional quality parameters
- Guidelines for occupational risk managemen of nanomaterials based on a "control banding" approach.
- Guidance on labelling of manufactured nanoparticles and products containing manufactured nanoparticles

Preliminary Work on a nanomaterials nomenclature is being undertaken by a WG1 Task Group activity, which is led by Dr Andy Atkinson, from Canada.

Dr Peter Hatto, Chairman, 1 February 2009

SECTION III
REPORT FROM THE SECRETARIAT

This is intended to summarise progress on projects or events associated with the WPMN since the 4th meeting. It focuses on those activities which are not described in any other documents for the 5th WPMN. It is organised in two sections: **part one** describes WPMN activities/ events; and **part two** addresses internal OECD co-ordination as well as outreach work with other organisations and events.

PART I: WPMN ACTIVITIES/ EVENTS

SPECIFIC PROJECTS

Project 1: Development of a Database on Human Health and Environmental Safety Research

1. This project has developed a *Database of Research into the Safety of Manufactured Nanomaterials* as Phase 1 of its work. The database is intended to hold details of completed, current and planned environment, health and safety research projects on safety, which are to be updated (electronically) by delegations. This database is also to be an inventory of information on research programmes to help the other projects of the WPMN by identifying relevant research projects or storing information derived from the projects of the WPMN, including the sponsorship programme on the testing of manufactured nanomaterials. The database became available to delegations for their data population by editing the project information in the database and adding any other projects into the database through on-line interfaces in September 2008. SG 1 for this project is currently assessing the database to decide whether it is ready for public launch.

Project 2: Research Strategies on Manufactured Nanomaterials

2. This project developed a comprehensive list of research themes and compiled the current/planned research projects and the urgent and medium/long term research priorities. Based on these data, SG 2 presented its interim document report to the WPMN at its 4th meeting, which comprised research themes identified with wide current coverage already ("hot spots") and research themes less covered ("gaps"), and proposed possible research projects for international co-operation. As a follow-up to the 4th meeting of WPMN, the analysis reports have been declassified and made available on the public website. A web-based information sharing network for "hot spots" of research areas is under construction on the WPMN password protected website. The 4th WPMN meeting also decided that this project would be put on hold until the database (Project 1) becomes available for the research strategy analysis. The public launch of the Database is to be expected at or right after the 5th meeting of WPMN. A merger of Project 1 and Project 2 will be discussed at the meeting.

Project 3: Safety Testing of a Representative Set of Manufactured Nanomaterials

3. This project has launched the first phase of a "sponsorship programme" for testing a representative set of manufactured nanomaterials for specific endpoints. At the 4th WPMN, delegations committed to, or indicated an interest in, contributing to the 14 selected nanomaterials. Sponsors in the programme have been preparing Dossier Developments Plans for each nanomaterial to be tested. The

Korean workshop (described below) was an opportunity for sponsors to present their progress and discuss issues arising.

4. As a result of the Korean workshop, two new groups were established for the Sponsorship Programme: i) a Review Committee of DDPs was established to discuss any consistency or completeness issues within or across draft DDPs for consideration by sponsors and the WPMN; and ii) a Task Group on Integration of Alternative Methods was set up to encourage supplemental sponsorship efforts on alternative testing of the 14 representative nanomaterial in the Sponsorship Programme. The work of the Task Group will build on the work of project 7 (see below).

Project 4: Manufactured Nanomaterials and Test Guidelines

5. At the 4th WPMN, the steering group for this project presented the preliminary review of test guidelines related to physical chemical properties, effects on biotic system, degradation and accumulation, and health effects. Amongst other things, the review concluded that it was a high priority for SG4 to prepare guidance on sample preparation and dosimetry. The WPMN welcomed and encouraged SG4 to develop the guidance because that will also be useful for Sponsorship Programme and the experience from the programme will contribute to the improvement of the guidance development. In parallel, SG 4 started developing a comparison document on the use of pulmonary instillation studies and consideration of their advantages and disadvantages compared to studies using the inhalation route.

6. The 4th WPMN also suggested that the preliminary review of test guidelines be circulated to the Working Group of the National Co-coordinators of the Test Guidelines Programme. As a result, comments have been received from the National Co-ordinators of Canada, Germany, Japan, the Netherlands, the United States as well as an invited expert from ICAPO[1]. SG 4 is currently reviewing the comments received and will revise the text accordingly.

Project 5: Co-operation on Voluntary Schemes and Regulatory Programmes

7. This project analysed national information gathering programmes, whether voluntary or mandatory, to identify common elements relating to the risk assessment and risk management of manufactured nanomaterials. This project also conducted a survey on regulatory regimes for manufactured nanomaterials, which aims to identify various components of regulatory regimes which are or may be applicable to nanomaterials. The results of the survey will be presented at the 5th WPMN.

8. As an ancillary project to Project 5, the WPMN has sought possibilities for sharing and comparing the data on manufactured nanomaterials which has been received by delegations as part of their national reporting schemes. This would provide summary information on manufactured nanomaterials including the name; brief description of composition; description of the nature of any further information held on the material; reporting country; and contacts. This information could be shared via the password-protected web site. Delegations could also provide such information along with the submissions of current developments for the Tour de Table at each meeting.

Project 6: Co-operation on Risk Assessment

9. This project drafted a report which identifies critical issues presented by nanomaterials for risk assessment. SG 6 has been revising the document based on comments received by members. As a follow-up, SG 6 has been considering how to work more closely with BIAC and academia perhaps by holding a series of workshops to share experiences of risk assessment and to consider more harmonised approaches.

1. The International Council on Animal Protection in ***OECD*** Programmes (ICAPO)

Project 7: The role of Alternative Methods in Nanotoxicology

10. SG 7 held a face-to-face meeting on 22-23 September at the OECD headquarter. The main purpose of the meeting was to agree the next steps in implementing the operational plan and for contributing to the *Guidance Manual for Sponsors of the Sponsorship Programme*. The meeting included scientific presentations by experts and discussions on linkages with the Sponsorship Programme.

Project 8: Exposure Measurement and Exposure Mitigation

11. SG 8 held a "face-to-face" meeting on 21 October in Frankfurt Germany. This meeting was organised with support from BIAC and VCI. This was an opportunity to review the outcomes of the Workshop on Exposure Assessment and Exposure Mitigation on 20 October (described below) as well as for discussing the progress and outstanding issues with the projects: *Emission Assessment for Identification of Sources and Release of Manufactured Nanomaterials in the Workplace – Compilation of Existing Guidance*; and *Comparison of Guidance on Selection of Skin Protective Equipment and Respirators for Nanotechnology Workplace*. Another SG 8 meeting is scheduled for 26 February 2009 in Bethesda, Maryland (US). Amongst other things, it will discuss the next steps for moving forward with work on: i) consumer exposure, and ii) environmental exposure. This meeting will follow the NNI workshop on Human & Environmental Exposure Assessment.

PUBLICATIONS

12. Since the 4th WPMN, the following WPMN document has been declassified and made available on the public nanosafety website (http://www.oecd.org/env/nanosafety).

- *Current Developments/ Activities on the Safety of Manufactured Nanomaterials/ Nanotechnologies – Tour de Table at the 4th meeting of the WPMN (June 2008)*: This document provides information on current/planned activities related to the safety of manufactured nanomaterials in OECD member and non-member countries. It includes current activities related to nanotechnologies/ nanomatrials in other international organisations including the International Organisation for Standardisation (ISO) and the Intergovernmental Forum on Chemical Safety (IFCS). It also includes the report from the OECD Secretariat.

13. In addition, the following three documents have been circulated to the Chemicals Committee for approval for the declassification. Once they are approved, they will be made available on the public nanosafety website.

- *Compilation of Output Documents for EHS Research Strategies on Manufactured Nanomaterials*: This document provides the compilation of two outputs that have been produced during the course of the work of the project, and that can be useful to a wider audience; *i) List of Health and Environmental Safety Research Themes Relevant to Nanomaterials and ii) Analysis of the Frequency of Entries in the List of Current/ Completed as well as Planned Research Projects*. In particular, the second one includes the identification of the research themes with a high coverage already today ("hot spots").

- P*reliminary Analysis of Exposure Measurement and Exposure Mitigation in Occupational Settings*: This document provides preliminary analyses and recommendations as well as brief summaries of background documents.

WORKSHOP ON EXPOSURE ASSESSMENT AND EXPOSURE MITIGATION

14. The Business and Industry Advisory Committee to the OECD (BIAC) and the German Federal Institute of Occupational Safety and Health (BAuA) hosted the *WPMN Workshop on Exposure Assessment and Exposure Mitigation* on 20 October 2008 in Frankfurt Germany. The workshop was designed to improve the international consensus building in the field of exposure measurement, exposure mitigation and related risk assessment in the workplace which was the primary task of the Steering Group 8. The report of this workshop is expected to be publicly available in June.

WORKSHOP ON THE SAFETY TESTING OF MANUFACTURED NANOMATERIALS (BUSAN)

15. An OECD *Workshop on the Safety Testing of Manufactured Nanomaterials* was hosted by the Korean delegation on 19-21 November in Busan, Korea. The main objective of the workshop was for "sponsors" to describe and agree their plans for the testing of each of the 14 nanomaterials. These plans outlined the specific details when and where the testing are undertaken and by whom. They also described which methods are used in the tests. The workshop was an important opportunity for sponsors to describe their progress, including the status of their plans, while serving as a chance to resolve any outstanding issues. This helped to ensure greater consistency in the plans for testing the 14 nanomaterials.

16. As a way of facilitating communication amongst sponsors in order to share information and take advantage of developing a common understanding from consideration of other testing programme, the workshop suggested introducing something along the lines of "a wiki" based system to post DDPs as a part of the clearinghouse. The Secretariat has explored the possibility of using "wiki" technology within OECD and prepared a plan.

17. The OECD Workshop was preceded by the Symposium on Environment, Health and Safety Aspects on Manufactured Nanomaterials, which took place on 18th November at the same venue in Busan, Korea. This event was organised by the Korean Government under the auspices of OECD's WPMN.

PART II: CO-ORDINATION AND OUTREACH

18. The WPMN has worked to co-ordinate its programme with other activities addressing nanotechnologies. It is important to build strong communication for identifying synergies and avoiding duplicative work. Co-ordination has two main levels: i) internal including the activities of other subsidiary bodies of the Chemicals Committee (such as the WTN) and OECD's Working Party on Nanotechnology; and ii) externally (with other international and /or national initiatives). As a result, there is strong communication with other international organisations such as the IOMC participating organisations (*i.e.* FAO, ILO, UNEP, UNIDO, UNITAR and WHO), as well as UNESCO and IFCS.

INTERNAL CO-ORDINATION WITH OTHER OECD BODIES

Projects of the WPMN

19. There are clearly many linkages among each of the projects of the WPMN. In particular, the newly launched Sponsorship Programme for the Testing of Manufactured Nanomaterials was designed to build upon the work already achieved by Project 3 and Project 4. It also expects to benefit from the discussions of Project 7 on alternative testing in nano toxicology. In fact, those projects and the Sponsorship programme are complementary to each other. Progress on the sponsorship programme will depend on the work of SG4 and SG7.

20. The Workshop for Sponsorship Programme (Tokyo, 24-25 April 2008) was a crucial opportunity for SG3, SG4 and SG7, and thus the participants of SG3, SG4 and SG7 were encouraged to participate in this workshop to ensure the linkage between those projects and the Sponsorship Programme.

Co-ordination with other activities of the Chemicals Committee

21. The work of the Working Group of Test Guideline Coordinators (WNT) is of particular interest as it is relevant (in particular) to the work of SG3 and SG4. The WNT Secretariat has been informed, on a regular basis, of progress in the WPMN. At the 4th meeting, the WPMN agreed to circulate a document "*Progress Report of Project 4 "Manufactured Nanomaterials and Test Guidelines"* which includes preliminary draft of the review of OECD Test Guidelines to the WNT to obtain their comments. Six delegations to the WNT provided written comments which included both editorial and substantial items.

22. The Working Group on Pesticides (WGP) conducted a Survey of Pesticide and Biocide Regulatory Authorities on their Activities Related to Nanomaterials and the result is available in document [ENV/JM/PEST(2008)23]. At its 23rd Meeting (4-5 November 2008), the WGP had an agenda item to discuss Nanomaterials as pesticides. It was noted that i) FAO will inform colleagues about OECD work – in support of Codex conference on nano and food safety, ii) WPMN Secretariat invited to future WGP meetings; iii) Governments encouraged to update the WPMN Database on Human Health and Environmental Safety Research with research project information. In addition, the US delegation proposed to establish an ad hoc network of pesticides and nanomaterials.

23. The Task Force on Hazard Assessment is considering the revision of OECD's guidance on grouping of chemicals. One of the areas under consideration is the possibility to apply the concept of grouping to manufactured nanomaterials, with the aim to fill data gaps by read-across or trend analysis. To address this issue, the Joint Meeting (Chemicals Committee) strongly supported making linkages with the WPMN The Task Force will meet 26-27 March to agree the next steps.

24. At the same time, the Working Group on Chemical Accidents, the Task Force on PRTRs (Pollutant Release and Transfer Registers), the Task Force for the Safety of Novel Foods and Feeds have all expressed interest in aspects of the work of the WPMN. The secretariat has given an update of the work of the WPMN to these groups at their most recent meetings.

OECD's Working Party on Nanotechnology (WPN): Background, highlights and progress

25. The Working Party on Nanotechnology (WPN) is a subsidiary body of the OECD Committee for Scientific and Technological Policy (CSTP). Its role is to advise CSTP on policy-relevant issues within science, technology and innovation which are related to the responsible development of nanotechnology.

26. The establishment of the WPN was partly motivated by governmental awareness of the rapid increase in public nanotechnology R&D investments globally. While private forecasts suggest huge socio-economic opportunities for nanotechnology applications, many aspects of the underlying developments are still poorly understood. WPN is working to increase the understanding of nanotechnology in the policy environment, including business and research, and to develop policy advice relevant to nanotechnology.

27. The WPN is currently finalizing work related to the Work Programme for 2007-08 as indicated below. Some project areas will be continued in 2009-10 under its renewed mandate.

28. ***Indicators and statistics*:** Measurement of nanotechnology inputs, outputs and impacts suffer from a lack of internationally agreed statistical definitions. This project has identified and analysed available indicators and statistics on nanotechnology, and drafted a framework for the future collection of such data.

Key Outputs:

- A final version of the report "Nanotechnology: An Overview" is in the process of de-classification to be published by early March on the WPN website.
- The next draft version of the statistical framework will be available at the next WPN meeting in June 2009.

Future work:

- The work on statistics and indicator monitoring will continue in 2009 under the project area: Monitoring and Benchmarking Nanotechnology Developments.
- The work on the framework will continue in 2009 under the project area: Statistical Framework for Nanotechnology.

29. ***Companies and Business Environments:*** Nanotechnology may engender new types of business models and require tailored policies and research partnerships, an area which the WPN is investigating. This project has complemented the statistical work with a large number of company case studies across several nanotechnology application areas, sectors and countries.

Key Outputs:

- An internal WPN workshop on challenges in the commercialization of nanotechnologies was held in October 2008 in Helsinki, Finland.
- The final version of the report "Nanotechnology: impacts on companies, business environments and policy" will be available by early March. It will be published as an OECD monograph.

Future work:

- This work will continue in 2009 under the project area: Addressing Challenges in the Business Environment specific to Nanotechnology. This work will focus on key challenges in commercialization, as identified by the previous company case studies, in selected application fields. Challenges under consideration for closer investigation include those related to R&D and human resources, financial issues, value chains and production.

30. ***International scientific co-operation*****:** Nanotechnology is a highly multi-disciplinary area, leading to potential challenges in collaborative research. This project has developed a web-based list of national nanotechnology research facilities, networks and portals to facilitate international collaboration in science and technology.

Key Outputs:

- The information will be published on the WPN website.

Future work:

- This work will be further developed in 2009 under the project area: Fostering International Scientific Co-operation in Nanotechnology. It will be informed by the workshop of the CSTP on International S&T Co-operation to Address Global Challenges (March 25-26th 2009, Paris).
- A policy round table on International Scientific Co-operation in Nanotechnology is proposed for 2009, Portugal having volunteered to host the event.

31. ***Outreach and public engagement:*** Given past experiences with other emerging technologies, and the unfamiliarity of nanotechnology amongst many stakeholder groups including the public, the WPN sees benefit in an exchange of experiences in nanotechnology outreach and public engagement activities. This project is seeking out examples of good practice in nanotechnology communication with the public and promoting discourse between policy makers on public engagement principles and methodologies.

Key Outputs:

- A survey of national experiences of challenges and practices was undertaken using two questionnaires on nanotechnology-specific public engagement, outreach and communication.
- The analysis of the questionnaires, a conference and a WPN workshop in Delft, the Netherlands in October 2008 all led to the development of methodology for public engagement and a set of eight "points for consideration" by policy makers when planning and managing or commissioning public engagement activities.

Future work:

- This work will continue with delegations using the methodology and reporting back their experiences. It will happen under the project area of Monitoring and Benchmarking Nanotechnology Developments.

32. ***Policy dialogue***: Engaging in a policy dialogue between countries is important for the support of coordinated and responsible policies that take into account the risks and challenges involved. This project has reviewed national policy systems for the responsible development of nanotechnology with the purpose of engaging countries in a dialogue on topical issues of high concern for policy.

Key Outputs:

- A survey of science and technology policy approaches in nanotechnology was undertaken, the results of which are reported in DSTI/STP/NANO(2008)18. The document is in the process of de-classification to be published by early March on the WPN website.

Future work:

- This work will continue in 2009 under the project areas on (i) Policy Roundtables on Key Policy Issues related to Nanotechnology and (ii) Monitoring and Benchmarking Nanotechnology Developments (see below).

33. ***Global challenges:*** Nanotechnology may offer opportunities to address some pressing global challenges. The first of these to be examined by the WPN relate to the provision of clean water.

Key Outputs:

- A one-day workshop on "Nanotechnology and the Global Challenge of Access to Clean Water" at the Nanotech Northern Europe Conference in Copenhagen in September 2008 (http://www.nanotech.net/).
- A draft report was presented to WPN in December 2008, identifying the technologies, policies and challenges; pointing to other organisations and enterprises addressing the global water challenge; reporting on short case studies of the water industry and nanotechnology research and development activities.

Future work:

- The report on water will be finalised in 2009. A second global challenge may begin to be addressed in the second half of 2009.
- The WPN is working with WPMN towards organising the conference on "Potential Environmental Benefits of Nanotechnology", with the US EPA, in July 2009 in Paris.

34. ***Policy Roundtables on Key Policy Issues related to Nanotechnology:*** This is a new project area for the WPN, following on from its work on Policy Dialogue and other projects in 2007-2008. Policy roundtables agreed to date by the WPN are:

- International Scientific Co-operation in Nanotechnology, host: Portugal.
- Economics of Nanotechnology, September 2009, in collaboration with France.
- Risk Governance Issues in Nanotechnology 2009: Austria. The Secretariat of the WPN will seek input from WPMN on this when any further details are available.

35. ***Monitoring and Benchmarking Nanotechnology Developments:*** This is a new project area for the WPN, following on from its work on (i) Policy Dialogue, (ii) Outreach and Public Engagement and (iii) Indicators and Statistics. In addition to the work already mentioned above under those headings, it is proposed that pilot national policy case studies be undertaken if resources allow.

36. The fifth meeting of the WPN will be held 10-12 June 2009.

OTHER INTERGOVERNMENTAL ORGANISATIONS

37. OECD continues to work closely with other intergovernmental organisations on its work on manufactured nanomaterials and nanotechnologies. OECD is a Participating Organisation (PO) of the Inter-Organization Programme for the Sound Management of Chemicals (IOMC), which also includes FAO, ILO, UNEP, UNIDO, UNITAR and WHO. UNDP and the World Bank are observers. The OECD secretariat has kept these other organisations up to date with the work of the WPMN through the IOMC.

38. As reported at the 4th WPMN, the OECD also worked (during 2008) with the secretariat of the Intergovernmental Forum on Chemical Safety (IFCS). OECD prepared papers for a session on nanotechnology at Forum VI (15-19 September 2008) in Dakar). The papers include a summary of the activities of the WPMN and the WPN and a summary paper of nanotechnology activities of each of the PO of the IOMC. These papers were translated into the six languages of the UN and are available on the IFCS web site[2].

39. OECD has currently been working with the secretariat of SAICM and will participate in its 2nd International Conference on Chemicals Management (ICCM2) which will include a session on "nanotechnology and manufactured nanomaterials". This will be held 11-15 May 2009 in Geneva, Switzerland. The information on ICCM2 is available at SAICM website[3].

Co-ordination with Standardisation Organizations

40. Close co-ordination with the International Organisation for Standardization (ISO) has been established since the beginning of the WPMN. To illustrate the co-ordination, a "co-ordination paper" was

2. IFCS Forum VI website http://www.who.int/ifcs/documents/forums/forum6/report/en/index.html

3. http://www.saicm.org/index.php?content=meeting&mid=42&def=1&menuid=9

jointly prepared by the OECD Secretariat and the Chair of the Technical Committee 229 of ISO (ISO/TC 229) based (in the case of the WPMN) on the Programme of Work 2006-2008. As the new Programme of Work 2009-2012 has adopted by the Joint Meeting, the OECD Secretariat and the Chair of ISO/TC 229 have updated the document.

41. It has been recognised by participants of both bodies that there is a need for co-ordination to avoid duplication and take advantage of potential synergies. The development of the *Guidance Manual for Sponsors* and the *Guidance on Sample Preparation and Dosimetry* are examples where collaboration has been of particular value. A number of delegates, who participate in both bodies, have played an important role in co-ordination, for example, by aligning terminology or information on testing methods. Current activities under ISO/TC229 are found in the written submission from the Chair of ISO/TC229 in Section II.