Organisation de Coopération et de Développement Economiques
Organisation for Economic Co-operation and Development

29-Nov-2006

English - Or. English

ENV/JM/MONO(2006)35
Unclassified

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

CURRENT DEVELOPMENTS/ ACTIVITIES ON THE SAFETY OF MANUFACTURED NANOMATERIALS

Tour de Table at the 1st Meeting of the Working Party on Manufactured Nanomaterials

London, United Kingdom, 26-27 October 2006

JT03218801

English - Or. English

OECD Environment, Health and Safety Publications
Series on the Safety of Manufactured Nanomaterials

No. 2

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Environment Directorate
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT
Paris, 2006

About the OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 30 industrialised countries in North America, Europe and the Asia and Pacific region, as well as the European Commission, meet to co-ordinate and harmonise policies, discuss issues of mutual concern, and work together to respond to international problems. Most of the OECD's work is carried out by more than 200 specialised committees and working groups composed of member country delegates. Observers from several countries with special status at the OECD, and from interested international organisations, attend many of the OECD's workshops and other meetings. Committees and working groups are served by the OECD Secretariat, located in Paris, France, which is organised into directorates and divisions.

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

This publication was produced within the framework of the Inter-Organisation Programme for the Sound Management of Chemicals (IOMC).

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

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 38th 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], the 39th Joint Meeting recommended that the OECD Council consider the establishment of a Working Party as a subsidiary body of the Chemicals Committee, to address the health and environmental safety implications of manufactured nanomaterials. The OECD Council agreed to establish a Working Party on Manufactured Nanomaterials on 14th September 2006 as a subsidiary body of the Chemicals Committee.

The ***1st meeting of the Working Party on Manufactured Nanomaterial (WPMN)*** was held 26-27 October in London. An earlier version of this document was originally provided to the meeting as background information in considering a Draft Programme of Work and its implementation. 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 such as the United Nations Educational, Scientific and Cultural Organization (UNESCO) and the International Organisation for Standardisation (ISO) (section II).

As a result, the WPMN recommended that the document be forwarded to the Chemicals Committee, which agreed that this document be declassified. This is published 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.

TABLE OF CONTENTS

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

Background

1. The main objective of the 1st Meeting of the Working Party on Manufactured Nanomaterials (WPMN) was to agree a draft programme of work, for 2006-2008. This was subsequently forwarded to the Chemicals Committee which approved the draft programme of work at its 40th meeting held 15-17 November 2006.

2. The purpose of an agenda item at the 1st meeting of the WPMN (the tour de table) was to give each delegation the opportunity to describe recent or planned national initiatives and/or events related to the safety of nanomaterials. This was intended to facilitate the development of the draft Programme of Work by allowing delegations to share their experiences and preoccupations with respect to safety. This was also an opportunity to identify possibilities for future co-operation and co-ordination. Delegations responded to this item by providing the information in this document.

Headings for the Tour de Table

3. The information from delegations is organised, when possible, under the headings identified below, while recognising that not all delegations are able to supply information under each heading. It is to be expected that there will be considerable variation amongst delegations as to the issues they wish to address, so there is some flexibility in the way the information is provided.

Please identify work completed, underway or planned in your country or organisation, which relates **to activities in the chemicals regulatory area on health and environmental safety aspects of manufactured nanomaterials:**

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.

REPONSES FROM DELEGATIONS

AUSTRALIA

Current Developments in Australia on the Safety of Manufactured Nanomaterials

(Provided 4 September 2006)

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

The Australian Government is currently developing its response to the paper "Options for a National Nanotechnology Strategy" delivered by its National Nanotechnology Strategy Taskforce to the Australian Industry Minister on 30 June 2006. The report recommends an integrated package of nine elements: (1) establish a dedicated federal office responsible for developing and coordinating the implementation of a national nanotechnology strategy; (2) health, safety and environmental issues (HSE); (3) community awareness and public engagement; (4) metrology and standards; (5) coordination of whole of government activities across Federal and State jurisdictions; (6) international cooperation; (7) industry infrastructure; (8) industry development; and the (9) commercialisation and application of nanotechnology research. The Minister expects to release the finalised strategy as part of a national manufacturing industry initiative in early 2007. The Taskforce report can be viewed at www.industry.gov.au/nano_options_report.

2. Developments related to voluntary or stewardship schemes

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS), the national regulator of industrial chemicals, issued a voluntary call for information to importers and manufacturers of nanomaterials.

http://www.nicnas.gov.au/publications/chemical_gazette/pdf/2006feb.pdf

NICNAS is seeking information on uses and quantities of nanomaterials imported or manufactured for industrial uses, and use in cosmetics and personal care products. Nanomaterials used exclusively as therapeutic goods, pesticides or food additives do not fall within the scope of NICNAS, and are consequently outside the voluntary call for information.

The information will assist in understanding which nanomaterials are available on the market or close to commercialisation, and help focus our efforts to ensure the adequacy of the regulatory scheme to assess nanomaterials. NICNAS is following-up the call for information with particular industry sectors and will then analyse the information and publish a report. To date, approximately 15 companies have indicated that they introduce (import and/or manufacture) nanomaterials for commercial purposes. Introduced nanomaterials include metal oxides for use in surface coatings, cosmetics and as catalysts; and acrylic latexes, pigments and silica for use in surface coatings.

3. Information on any risk assessment decisions

The Therapeutic Goods Administration (TGA) conducted a review of the scientific literature in relation to the use of nanoparticulate zinc oxide and titanium dioxide in sunscreens. The review can be found at: http://www.tga.gov.au/npmeds/sunscreen-zotd.htm

Food Standards Australia New Zealand (FSANZ) has not yet received any applications to consider the regulation of any nanomaterials in the Australia New Zealand Food Standards Code.

4. Information on any developments related to good practice documents

The Office of the ASCC commissioned a review of the potential OHS implications of nanotechnology. The review report, which includes a detailed examination of the potential toxicology of nanoparticles, is derived from a detailed review and analysis of worldwide literature and consultation with nanotechnology stakeholders. The report entitled "A Review of the Potential Occupational Health and Safety Implications of Nanotechnology" has been published and is available on the ASCC website http://www.ascc.gov.au/ascc/AboutUs/Publications/ResearchReports/AReviewofthePotentialOccupationalHealthandSafetyImplicationsofNanotechnology.htm

Standards Australia has established a Committee on Nanotechnology (NT-100). This committee provides Australian input to the International Standards Organisation (ISO) for the development of international nanotechnology standards and good practice documents.

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

In preparation for developing a strategy to address HSE issues, the National Nanotechnology Strategy Taskforce commissioned a report from the National Academies Forum (a coalition of Australia's four learned Academies) on the environmental, health, safety and legal aspects of nanotechnology. It suggests areas of nanotechnology where little risk is present (such as electronics), and suggests further R&D be undertaken in areas where greater risk is possible (such as nanomaterials). The report will be considered as part of the Government's response to the Taskforce report. The National Academies Report can be viewed at www.industry.gov.au/nano and follow the links.

In addition, Australia's research community has established a network called NanoSafe Australia to link together toxicology researchers and assess the potential of nanotechnology to impact on human health, worker safety and the environment. NanoSafe Australia, which brings together nine HSE-related research organisations around Australia, is currently preparing a Position Paper on "Current OH&S best practices for the Australian nanotechnology industry", as well as assessing nanotoxicology skills available in Australia.

Australia's National Measurement Institute is offering a service for calibrating standard reference powders and nanoparticle samples to ensure that nanoparticle measurements are made on a consistent basis throughout Australia and in line with international measurement practices.

6. Information on any public/ stakeholder consultation

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BELGIUM

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;

At present there is no regulation specifically addressing nanomaterials in Belgium.

In Belgium, the Public Federal Service (Ministry) for Health, Safety of the Food Chain and Environment will be the leading competent authority to assess and manage risks in connection with handling and use of nanomaterials and this according to the existing regulations. However, currently no legislation activities are underway to address it specifically as there is no definition of "nanomaterials" in place under the current legislative framework. The issue was raised several times during the ongoing negotiation of the REACH proposal and Belgium is waiting for a further initiative to be taken at the EC level.

The interface 'environment and health' has already considered nanotechnology as a potential action point for the upcoming yearly work programmes.

A working group will be established under the frame of the Cooperation Agreement Act for Environmental policy: this group will be informed in first instance about developments at international level (eg. OECD). As a second goal, collection of scientific information would allow the Belgian CA to decide how to best answer to the potential safety concerns linked to the production and use of nanomaterials for human health and the environment.

2. Developments related to voluntary or stewardship schemes;

At present very little information is available about the presence of nanomaterials on the Belgian market. Therefore, it is envisaged during 2007 to carry out a "market" survey by convening the related sector (from R&D to manufacturers and down stream users). Those stakeholders will be invited to participate in declaring the purpose/extent/concerns of their current research and development of products/articles.

3. Information on any risk assessment decisions;

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

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

In Belgium we would like first to collect information during the survey planned in 2007 and thereafter develop good practice documents based on best available practice, as more specific knowledge concerning nanomaterials and situations for guidance-request are first needed.

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

No specific research programme is in place (to be confirmed by the planned survey) but the Scientific institute for Public Health has initiated a "think-tank" to develop a specific project. A budget has been foreseen to support the initiative throughout the Federal Public Service Public Health and Environment

which covers several domains of application for the nanomaterials (cosmetics, medicines/vaccines, pesticides, biocides, amongst other things).

6. Information on any public/ stakeholder consultation.

The working group referred in point 1 will be extended to stakeholders including NGOs and industrial federations.

CANADA

REGULATORY DEVELOPMENT IN CANADA

Federal government actions

A Federal Working Group has been established to develop a federal action plan for a coordinated and consistent approach to the regulation of nanotechnology in Canada. The plan includes four major themes:

- Terminology and nomenclature;
- Identifying the state of nanotechnology in Canada;
- Identifying science gaps and approaches to filling them; and
- Communication strategy (internal, public, industry).

The Working Group will work to ensure:

- Development of consistent approaches to testing, assessment and management of nanomaterials;
- Cooperation in research and testing of nanomaterial properties and effects;
- Adequate resourcing of Canada's participation in international activities (*e.g.*, OECD, ISO); and
- No duplication of efforts with respect to developing the necessary science to assess substances and products of nanotechnology.

A Federal Workshop on the Health and Environmental Implications of Nanoproducts (March 2006) brought together senior regulatory program managers, hazard and risk evaluators, and researchers to discuss regulatory science needs for nanotechnology.
Primary recommendations from the meeting included:

- Formation of federal working group on regulatory science issues;
- Enhancement of partnerships and linkages with stakeholders to generate new scientific information;
- Development of risk management strategies and foresight capacity;
- Engagement in relevant, key international activities, in particular OECD and ISO; and
- Development of a communication strategy for government, the public and other stakeholders.

Regulatory approach for nanomaterials under the Canadian Environmental Protection Act

A regulatory regime for nanomaterials, targeting mainly industrial substances, is being considered by the New Substances Program of Environment Canada and Health Canada. Approval of the proposed regime is pending from senior management and from multi-stakeholder consultations.

The current proposed regulatory regime is outlined as follows:

- **Phase 1 (fall 2006- fall 2008)**
  - Inform industry that "new" nanomaterials are subject to notification under the New

Substances Notification Regulations.
    - Nanomaterials with unique structures and not listed on Canada's inventory of chemicals currently on the market, the Domestic Substances List, can be considered "new".
    - Notification required if specified trigger volumes are reached.
    - Information to be submitted will be initially the same as for regular chemicals and polymers.
  - Develop a voluntary program to obtain data from industry to build a knowledge base on "new" and "existing" nanomaterials.
  - Work with international partners to develop appropriate property and effects testing methods.
  - Consider amendments to the Canadian Environmental Protection Act to facilitate assessment and management of all nanomaterials if necessary.

- **Phase 2 (fall 2008 - 2010)**
  - Resolution of standard nomenclature and terminology by ISO TC229.
    - The expectation is that a significant number of nomenclature issues will be resolved satisfactorily for regulatory purposes by 2008.
  - Establishment of specific data requirements for nanomaterials under the current notification regulations.

VOLUNTARY PROGRAM IN CANADA

A voluntary initiative would focus efforts on obtaining information on nanomaterials from industry and on building a knowledge base to inform risk assessment and management approaches. The objectives of the program would include:

- Identification and assessment of "existing" nanomaterials in Canadian commerce.
- Facilitated acquisition of information in industry possession.
- Provision of guidance on appropriate testing to identify potential health and environmental impacts of nanomaterials.

The Canadian approach would be aligned with US, UK, and Australian approaches and, like the US and UK initiatives, would continue for two years as a pilot project. The current tasks in preparation for a Canadian voluntary program include:

- Developing a timeline for engaging industry, the public, and other stakeholders.
- Developing incentives to encourage notification during the voluntary program timeframe.

NANOTECHNOLOGY IN CANADA

There is a limited understanding of the current Canadian market for nanotechnology. A formal use pattern survey and product inventory has not been conducted for Canada. The number of companies involved in nanotechnology ranges from 50 to 100 depending on the source of information and the definition used to describe nanotechnology.

Current market knowledge points towards several sectors using nanotechnology and/or nanomaterials in Canada. These include:

- Electronics/photonics (*e.g.*, improved performance of electronic devices/microsystems)
- Transportation (*e.g.*, body mouldings on vehicles, ceramic coatings on ships)
- Sports equipment (*e.g.*, tennis rackets, ski waxes)

- Consumer products (*e.g.*, antimicrobial coatings on refrigerators)
- Industrial (*e.g.*, petrochemical catalysts)
- Fashion (*e.g.*, stain and wrinkle-resistant fabric treatments)
- Health and beauty (e.g, moisturizers, makeup, medical imaging)

RISK ASSESSMENT DECISIONS

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

- Industrial or commercial chemicals
  - No notifications or inquiries to date.
  - This suggests industry is treating nanomaterials as existing substances not requiring notification.
- Pharmaceuticals
  - As many as 5 nanomedicines have received approval from Health Canada under the current regulations and policies.
- Pesticide applications
  - Some inquiries have been made, but no notifications have been submitted.
- Food related applications
  - Some food related applications in the natural health product field are currently under review by Health Canada.
  - No notifications on food additives or food packaging have been received to date.
  - No notifications with respect to fertilizers, veterinary biologics, or animal feed have been received to date.

RESEARCH IN CANADA

Research on human health and environmental impacts in Canada is limited, but interest is growing.

- Environment Canada and Health Canada are supporting a research proposal addressing environmental fate of nanomaterials.
- The Natural Sciences and Engineering Research Council (NSERC) and the Canadian Institutes for Health Research (CIHR) are encouraging/requiring the inclusion of health and environmental impacts components for research proposals involving nanotechnology.

PUBLIC AND STAKEHOLDER CONSULTATIONS

- Environment Canada has not conducted any public or stakeholder consultations; however, a consultation will be part of the normal process in the development of a regulatory regime for nanomaterials.

DENMARK

(from Danish EPA)

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;

At present there is no regulation specifically addressing nanomaterials in Denmark.

In Denmark the Ministry of the Interior and Health has in 2006 initiated a survey examining whether the existing regulation in the different sectors (environment-sector; chemical sector, food-sector, pharmaceutical-sector, occupational environment sector, and health sector) would also cover risk related issues in connection with handling and use of nanomaterials. Although the work is not quite finished yet, it seems that the regulation in the different sectors would in general cover situations where nanomaterials are handled or used although there is no specific mentioning of nanomaterials as such. It is recognised, however, that in order to address aspects specifically related to nanomaterials there may be a need for adjustments in the regulation.

In general there seems to be no need for a new and a broad trans-sector regulation on nanotechnology but rather to focus on identification on areas in the present regulations where updating or adaptations may be required in order to consider specific aspects of nanomaterials.

In the summer 2006 the Danish Board of Technology published a report concerning environmental and health aspects of nanotechnology. The authors behind the report concluded that the existing regulation has to be further developed to specifically address the potential risks from nanomaterials. In the present chemical regulation and in REACH the tonnage levels for data requirement have to be reassessed because of the low weight of nanomaterials. Furthermore industrial use of nanomaterials should be subjected to approval from the authorities and it is proposed that the authorities provide specific risk assessment guidance and that obligatory risk assessment should be required from industry in case of possible environmental or human exposure to nanomaterials.

The different proposals in this report are at under discussion by the relevant authorities.

2. Developments related to voluntary or stewardship schemes;

There have been no developments related to formal voluntary or stewardship schemes in Denmark.

3. Information on any risk assessment decisions;

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

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

In Denmark we are not yet at a stage to develop good practice documents as more specific knowledge concerning nanomaterials and situations for guidance-request are needed. However, a future project (see below item 5) may give further valuable input in order to further evaluate the need and the areas/ situations where guidance or good practice documents may be relevant.

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

At the present time one research programme in Denmark is specifically designed to address human health. At the National Institute of Occupational Health a research group was established at the end of 2005 with focus on risks associated with fabrication and use of nanoparticles and nanoparticle products.

Further, a couple of research institutes have initiated the testing of nanomaterials in eco-toxicological test systems.

The Danish EPA has started a network for risk assessment and risk management of nanomaterials. The network includes authorities from different sectors and scientific institutions experienced in chemical testing and risk assessment. The network is meant to support the Danish work in relation to risk assessment and risk management in the EU and OECD.

Knowledge about use and exposure is as important as knowledge about the intrinsic properties of nanomaterials. Therefore the Danish EPA has initiated a project where the presence of nanomaterials in consumer and industrial products in Denmark are identified. This survey will contribute to the evaluation, to which degree humans may be exposed to nanomaterials in relation to handling and use of products.
Furthermore The Danish EPA is planning a project in collaboration with industry with the aim of identifying those industrial branches in which nanomaterials are used; how they are used, and how aspects concerning environment and human health are considered.

Although not yet fully established, the Danish EPA considers that knowledge exchange and cooperation with industry and research laboratories is important in order to obtain relevant knowledge for targeting the work concerning risk assessment and risk management of nanomaterials.

6. Information on any public/ stakeholder consultation.

The Danish Standards Association has started a network group for nanomaterials with various stakeholders (authorities, industry, universities, advisors etc) in relation to the standardization work concerning nanomaterials in ISO and CEN.

The Danish EPA is together with industry planning an open conference/workshop in 2007 for stakeholders (*e.g.* industry and NGOs) concerning issues in relation to use, handling and risk management of nanomaterials.

FINLAND

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 Finnish chemicals legislation is in a harmony with EU legislation. The REACH Regulation is expected to replace the current regulations in 2007.
No national developments related to nanomaterials exist at present.

2. Developments related to voluntary or stewardship schemes;

Not yet decided. Finland's National Board of Chemicals, a cooperation body representing chemicals control authorities and relevant associations of chemicals industry, trade and industry, is a candidate body for developing voluntary reporting or stewardship schemes.

3. Information on any risk assessment decisions;

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

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

The Finnish Institute of Occupational Health has initiated research on health effects of nanoparticles.
The Chemicals administration, especially in the fields of the Ministry of Social Affairs and Health and the Ministry of Environment are in the process of collecting and reviewing information on health and environmental hazards of nanomaterials. In recent conferences efforts have been made to integrate safety aspects of nanomaterials and development of technological innovations.

6. Information on any public/ stakeholder consultation.

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Additional Information

Recent conferences in Finland include the Finnish EU presidency conference "Nanotechnologies – Safety for Success", 14-15 September 2006. The conclusions of this conference acknowledged a need for harmonised regulatory system for the evaluation of risks of nanomaterials, a need for reliable reference materials, voluntary stewardship programs, and integration of safety and competitiveness in nanotechnologies.
The links for this and other meetings:
http://www.fmnt.fi/ntss
http://www.nanotech.net/ntne2006
http://www.nanotech.net
http://www.nano.jyu.fi/NanoscienceDays2006.html

Research in nanotechnology, basic and applied, is mostly technology oriented in Finland. For funding of the major research programmes in nanotechnology, see below. The Ministry of Trade and Industry is responsible technology and innovation policy, and it is supervising the work of Tekes, the Finnish Funding Agency for Technology and Innovation.

A number of nanoscience research programmes in Finland are or will be funded and co-ordinated by the Academy of Finland and Tekes.
TEKES: FinNano 2005-2009, in collaboration with the Finnish Academy. The FinNano programme's strategy work is carried out in five thematic groups, one of which the Safety and Standardisation Group.
The 2005-2007 part of the programme includes 15 research projects lead by research consortiums with co-operation with both international research organisations and industry. In addition, 18 company R&D projects have been launched. In total, the programme involves over 70 companies. In addition, there are about 50 other projects addressing nanotechnology.
http://akseli.tekes.fi/opencms/opencms/OhjelmaPortaali/ohjelmat/NANO/en/etusivu.html

The Academy programme (FinNano 2006-2010) will combine nanoscale research in chemistry, physics and biosciences. One of the objectives of the research programme is to take into account health, safety and environmental issues. In addition, the Academy is participating in the ERA-NET Nanosci-ERA project funded through the EU Sixth Framework Programme.
www.aka.fi/FinNano
http://www.mnt-era.net/MNT/

The working group for nanosciences of the Finnish Ministry of Education has proposed that the Ministry launch a development programme for 2007-2009 to support the nano programmes of the Academy and Tekes.

The Technical Research Centre of Finland, VTT, is participating in the EU Nanosafe 2 Integrated Project.

FRANCE

Current developments in France regarding the safety of manufactured nanomaterials

It is worth recalling first that France does not view manufactured nanomaterials in isolation but considers it essential to link their development, promotion and worldwide dissemination to the development, promotion and dissemination of nanotechnologies and the various products of such technologies. Consequently, it is essential not to lose sight of impacts other than those relating to health and the environment, namely the ethical aspects of nanotechnologies, in the broad sense of the term, and of course the issue of social utility. It is for this reason that France would like the OECD Committee for Scientific and Technological Policy (CSTP) to adopt this more general vision of nanotechnologies and would like the two bodies to conduct their work in close collaboration.

In 2005, the Ministry responsible for industry (Directorate-General for Enterprises – GDE), conducted a strategic study of nanomaterials, from a sustainable development perspective, which subsequently served as a basis for an action plan covering not only research and development (through support for collaborative projects) but also the international presence of France in this sector of activity. At the same time, the recommendation by the Ministry of Industry that industrialists think about their practices in terms of development and safety was followed up through the creation of a working party overseen by the ECRIN Association. While the work on standardisation now in hand within AFNOR's Technical Committee on Nanotechnologies will help to clarify the metrological aspects, the Ministries responsible for health (Directorate-General for Health), Labour (Directorate-General for Labour) and Ecology (Directorate for Pollution and Risk Prevention) advocate the need to examine the health and environmental risks that nanomaterials/nanotechnologies may pose within the general framework outlined above, obviously in a spirit of prevention and precaution. It is for this reason that by as early as 2005 they asked AFSSET to draw up a summary report on the current state of technical and scientific knowledge regarding the:

- Typology, chemical and physical properties, biological and health effects of nanomaterials;
- current and future field of application for such nanomaterials;
- metrological tools currently available or under development;
- data relating to (current or potential) exposure of the general public and workers, and in particular the relevant parameters for characterising such exposure;
- impacts on human health.

The seminar organised on 19 October 2006 at the initiative of the Minister for Health will bring the representatives of the Ministries and public health and safety agencies and institutes working in the field up to the same level of information.

1. Developments in the regulatory field

Strictly speaking, there have been no developments to date. However, recommendations have been issued

by both the Prevention and Precaution Committee (CPP)[1] and the French Agency for Labour and Environmental Health Safety (AFSSET)[2] regarding the need to take precautionary measures in the workplace and the general environmental, to list the nanomaterials produced or imported and to ensure that they are taken into account in the REACH Regulation. The reports referred to above were not sufficient, however, and on 29 June 2006 AFSSET was asked to draw up an additional report covering, in particular, the assessment of professional risks; the results of this additional study are expected in June 2007.

The Ministry responsible for health also sent submissions to the French Health Products Safety Agency - AFSSAPS (for drugs, medical devices, cosmetics), and to the French Food Safety Agency - AFSSA (for food products and drinking water). Work is currently in progress.

The aim of the inter-ministerial seminar of 19 October (see below) is to outline lines of action for government in the short, medium and long terms and, possibly, to propose some short-term measures.

2. Voluntary approaches or schemes

France intends to ask industry to provide information on the nature of the nanomaterials sold on the domestic market, as well as information regarding risks, exposure and types of use.

Some industries have developed and introduced their own systems to prevent worker exposure or releases to the environment.

The question needs to be asked whether it should be made mandatory for industry to provide information. How such an obligation could be introduced and applied needs to be studied.

3. Risk assessment decisions

At this stage in the development of nanomaterials, there are no particular requirements in force in France regarding the risk assessment of nanomaterials. In theory, however, regulations regarding the sale of chemical substances currently in force in France and the EU could be used to gather information on the risks posed by manufactured nanomaterials.

However, the ECRIN[3] association, whose founder members are the National Centre for Scientific Research (CNRS) and the Atomic Energy Commission (CEA) and whose aim is to promote relations between research laboratories and industry, currently oversees a working party on industrial practices in the manufacture, packaging and processing of nanomaterials. This association has created a "nanomaterials safety" site[4] and set up four working parties. The Association is also active in standardisation groups.

The co-ordinator of the European NANOSAFE2 programme is a member of the CEA.

4. Developing good practice guides

[1] Nanotechnologies, nanoparticules : quels dangers, quels risques ?
http://www.ecologie.gouv.fr/IMG/pdf/Nanotechnologies_juin_2006.pdf
[2] Les nanomatériaux, effets sur la santé de l'homme et sur l'environnement.
http://www.afsset.fr/upload/bibliotheque/367611898456453755693572842048/nanomateriaux.pdf
[3] http://www.ecrin.asso.fr
[4] http://www.nanomateriauxetsecurite.fr/

On 23 August 2006 the INRS was approached and asked to draw up a good practice guide for the protection of workers (operators) exposed to nanomaterials, as proposed by AFSSET in its July 2006 report (proposal X.6.).

5. Research programmes or strategies developed in response to the safety issues raised by nanomaterials for man and the environment

"Few public bodies in France are currently working on the issue of 'nanoparticles – health'. Although a number of laboratories are investigating the biological effects of ultrafine particles in air pollution, very few of them are currently addressing the impacts of man-made nanoparticles."[5]

Two research projects were accepted from call for tender 2005 PNSE/PST issued by the National Research Agency (ANR):

- In situ characterisation of the surface of ultra-fine aerosols;
- Toxicology of nanoparticles: influence of size, composition, and surface reactivity on lung and kidney effects.

In 2006, the ANR will endorse new projects on these same subjects and AFSSET will launch a project in 2006 to develop metrology.

A European project, NANOSAFE2[6], co-ordinated in France by the CEA, is designed to develop technological solutions to the problem of nanomaterials safety. NANOSAFE2 is divided into four separate components. The aim is to develop technologies to detect and track nanomaterials in the environment, since at present nanoparticles can be counted but cannot be readily identified. Two other goals are to develop methods for determining toxicity and limiting exposure to nanoparticles and their dispersal in the environment. Lastly, international standards must be proposed and information given to the public.

6. Public information/consultation and the parties concerned

6.1 Public debate

The Prime Minister has launched a national debate in which the views of experts will be set against the expectations of the public. The organisation of this debate has been entrusted to the Ministries of Research and Industry, and will also involve other Ministries.

In terms of exchanges and dialogue, mention should also be made of the work of the ECRIN Association, even though the public is not directly involved. A number of theme groups (clubs) have been set up, two of which, the Nanomaterials Club and the Risk Club, have organised two one-day workshops on the integrated approach to risk management (9 November 2004 and 23 March 2005).

Lastly, as part of public communications, the Cite des Sciences et de l'Industrie is currently organising a travelling exhibition entitled "Nanotechnologies and Society". This exhibition sets out to explaining nanotechnologies to the public, to present its applications and potential and to inform discussions and research regarding the risks relating to its use.

There have also been several initiatives in France aimed at stimulating or organising debate. In 2005,

[5] Afsset report, *op. cit*, pp. 61 - 63.
[6] http://www.nanosafe.org/

following selection of the "Minalogic" project proposed by the city of Grenoble as part of the Poles of French Competitiveness programme, the Communal Community of the Grenoble conglomeration ("La Métro") sought to bring together a group of experts to analyse procedures for consulting the inhabitants of Grenoble about technological choices involving their city and to secure their active participation in decisions taken by local authorities. The mission report was published in September 2005[7]. We understand there is nearly no possibility for debating the validity of these technologies.

Other ideas about how the public debate might be enhanced will very probably emerge from the inter-ministerial seminar due to be held on 19 October.

6.2 Associations concerned with nanotechnologies

Since 2002 in Grenoble, Pièces et Mains d'Oeuvre (PMO) has been gathering critical information on nanotechnologies, which it publishes on its Internet site[8], and organising public debates. It has recently published an introduction to nanotechnologies as well as an opuscule stating "that the nanotechnologies (and beyond the "converging technologies"), are not a scientific project, but a political and philosophical. A project of eugenics and of artificialisation of life"[9].

Furthermore, Vivagora[10], an association founded in 2003 by two science journalists, organises an annual series of debates to which scientists (from both the hard and human sciences), industrialists, political leaders, associations and the public are invited. In 2006, the third series of debates is devoted to nanotechnologies (who are the players, what promises do nanotechnologies hold, what are the challenges?). The recommendations to emerge from these exchanges of points of view will be presented at the concluding conference in September 2006.

In addition, the RISE association (Réseau International Santé Environnement)[11], created in 1995, holds annual meetings aimed at promoting public debate on environmental health issues. In 2006, these meetings are to be devoted to the challenges of nanotechnologies.

The Entreprises pour l'Environnement (EpE) association [12] is holding a "public consultation" on nanotechnologies at the end of October.

Other information

Benefits

The Prevention and Precaution Committee (CPP) recalls that the direct and indirect benefits of developing nanotechnologies for society and individuals are currently unpredictable. Once it is possible to identify these benefits, they must be systematically examined in relation to the risks they potentially pose.

Ethical and societal issues

[7] "Démocratie locale et maîtrise sociale des nanotechnologies, les public Grenoblois peuvent-ils participer aux choix scientifiques et techniques ?" http://sciencescitoyennes.org/IMG/pdf/NanoGrenoble_rapport_final_05_09_22.pdf
[8] http://www.piecesetmaindoeuvre.com/
[9] « Minime introduction aux nanotechnologies » http://pmo.erreur404.org/Introduction_aux_nanos.pdf ; « nanotechnologies / Maxiservitudes », édiction de L'Esprit frappeur.
[10] http://www.vivagora.org
[11] http://www.rise-asso.org/
[12] http://www.epe-asso.org/index2.php

The Dupuy-Roure report[13] provides a robust presentation of these issues and the report by Roure, Gorichon and Sartorius[14] discusses one specific aspect of nanotechnologies, namely radio labels.

The CNRS Committee on Ethics for the Sciences (COMETS) is also preparing, in collaboration with the National Consulting Committee on Ethics (CCNE) for health and the life sciences, an opinion on the ethical issues relating to the development of nanotechnologies, which are addressed to the research community.

Under the heading "Taking account of societal aspects", the Prevention and Precaution Committee (PPC) recommends that:

- research bodies should be encouraged to develop programmes on the social and ethical implications of nanotechnologies;
- the awareness of researchers and laboratory workers should be raised with regard to the ethical implications of nanotechnologies and the challenges it poses to society. In this respect, it is important to support "partnerships" (or to create a forum for discussion) between researchers and actors from civil society (both directly and through trade unions, associations, etc.).

Synergy and co-operation

We feel that it is essential to pool knowledge at the international level to prevent risks arising from nanomaterials: this effort must be conducted at the international level in order to go beyond issues relating solely to intellectual property, industrial confidentiality and patents, and to work together in the general interest. The OECD can play a role in this respect.

GERMANY

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

A study on regulatory gaps and options is currently undertaken by the Federal Environment Agency (UBA). This study examines European and German chemical and environmental legislation. However, currently no legislation activities are under development due to lack of scientific methods to measure exposure and effects of nanomaterials appropriately

2. Developments related to voluntary or stewardship schemes;

At present very little information is available about the occupational exposure to nanoparticles, the risk management, and safety measures applied in industry. A questionnaire about the identity of nanoparticles produced, the production method and use pattern, the production volume, the number of exposed workers, and the already applied safety measures should be developed. This questionnaire should be answered by industry. Next to information on occupational exposures, nanoparticles of major concern can be identified.

[13] Les nanotechnologies : Ethique et prospective industrielle. http://lesrapports.ladocumentationfrancaise.fr/BRP/054000313/0000.pdf

[14] Les technologies de radio-identification (RFID) : enjeux industriels et questions sociétales. http://lesrapports.ladocumentationfrancaise.fr/BRP/054004451/0000.pdf

When more precise data on possible health effects become available the completed questionnaire can be used to improve guidance for a safe handling and use of nanoparticles. [In cooperation with the association of the German chemical industry (VCI) the Federal Institute for Occupational Safety and Health (BAuA) is finalising such a survey for the German industry. The results might form the basis for an European action and should be extended to OECD countries.]

In addition a voluntary reporting scheme by industry to authorities is considered an interesting approach to be informed regularly about produced and commercialized nanoparticles.

3. Information on any risk assessment decisions;

Not applicable due to lack of information

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

A "Code of Good Practice" is considered an important tool to inform about what can be seen as good technical standard. Since some technical information is available at the industrial companies BAuA cooperates with the VCI (German chemical industry association) in this field.

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

At present there is uncertainty about the risks of nanomaterials. Especially nanoparticles are in the focus of discussion. Research is generally considered to be necessary to finally produce recommendations for production and use of nanomaterials which is safe for human health and the environment, to set exposure limits and to make risk assessments, that take into account the current practice of assessing particles and chemical substances in general. Thus it is of high importance to structure the diversity of research ideas, to set priorities and to make sure that the research is not limited to fundamental research, but especially is appropriate to enable authorities to set exposure limits, to perform comprehensive risk assessments, to protect the environment, etc. Thus the BAuA (Federal Institute of Occupational Safety and Health) works together with BfR (Federal Institute for Risk Assessment) and UBA (Federal Environment Agency) on the development of a German research strategy, that considers health issues of workers and consumers and the environment issues.

The Federal Ministry of Education and Research (BMBF) started in March 2006 the project “NanoCare”. In this project the ministry, together with Industry, supports research to assess risks in handling new nanomaterials in their life cycle. Another project called INOS, supported by BMBF, is investigating the effects of nanoparticles at the research and development stage on people’s health and the environment. The aim is to create a scientifically-based data set where anyone can find information about the potential risks of nanoparticles. In the joint project TRACER the potential of Carbonanotubes concerning applications and toxicological risks will be investigated to tap the full potential of this material.

6. Information on any public/ stakeholder consultation.

The Federal Ministry for Environment (BMU) together with the Federal Environmental Agency (UBA) and the Federal Institute of Occupational Safety and Health (BAuA) initiated a dialogue to assess synthetic nanoparticles in the work place and in the environment with a workshop in October 2005. This dialogue is continued by the BMU in September 2006 with a conversation with high-ranking experts on chances and risks on nanotechnology. In this conversation succeeding activities will be considered.
Expert-Meeting “Nanotechnology - Applications, Trends and Risks” (BfR), 28.03.2006
Expert-Meetings “Nano sealing sprays” (BfR), 07.04.2006, 23.05.2006, 05.07.2006

Delphi survey about risks of nano-technological applications in the areas of food, cosmetics and commodities (BfR), 03/2006 – 12/2006
Consumer conference on perception of nanotechnology (BfR), 04/2006 – 01/2007

ITALY

Short Review of the Iniziatives in the Field of Nanotecnology and Nanomaterials in Italy
(National Institute of Health, Italy)

While at the public and private levels in Italy there is a general consensus on the need to face the challenges posed by nanotechnology, the current situation in the research and regulatory area on health and safety aspects of nanomaterials is characterized by a general scarcity of initiatives at both public and private levels.

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

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

Policy oriented discussion on the necessary approach for the development of research strategies and programmes to address health and risk implications of manufactured nanomaterials results still very scarce.

Specific research studies concerning mainly toxicological experiments *in vitro* on some type of nanomaterials are currently underway in a limited number of small groups of people in some universities, research centres, or institutes, but they are conducted with limited ambitions and poor co-operation/co-ordination among them. This category includes a very recent project proposed by the National Institute for Occupational, Safety and Prevention (ISPESL) to the Ministry of Health on the aspects of occupational exposure to nanomaterials, but focused on nanotubes (yet to be financed).

Environmental safety aspects appear not yet taken into consideration.

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

The only exception which may be considered is an initiative taken by the association AIRI (Italian Association for Industrial Research) and its division NanotecIT (Italian Centre for Nanotechnology) aimed to provide a census of the public and private organizations involved in nanotechnology in Italy (www.nanotec.it).

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

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

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

The role of public research is still fundamental. All major public research organisations (CNR/INFM, INSTM, INFN, ENEA)[15] and universities are involved. Relevant resources are dedicated to this field and various initiatives have been put in place to improve the effectiveness of the efforts.

In particular 7 centres of excellence dedicated to nanotechnology have been established in the last years at various Italian universities, while 5 high technology clusters (structures financed by the government to promote particular technologies in different Italian regions), have activities related to nanotechnology; one of them is specifically focused to nanotech.

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

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

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

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

Moreover, the Italian standardization organization (UNI) has recently activated a commission on nanotechnologies, which is oriented to follow essentially the ISO and CEN activities in the same field.

In conclusion it seems that most of research efforts in Italy are focused on industrial development and application of a variety of nanomaterials.

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

JAPAN

Current developments on the safety of manufactured nanomaterials
(As of October 2006)

1. Any national regulatory developments on human health and environmental safety including

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

recommendations or discussions related to adapting existing regulatory systems or the drafting of laws/ regulations/ guidance materials;

In the existing regulatory system, the Chemical Substance Control Law obliges manufacturers to notify the government about nanomaterials if they are new chemicals subject to the law, and some notifications concerning fullerene derivatives have been submitted under the small quantities exemption of the new chemical notification.

The Ministry of Economy, Trade and Industry (METI) has just had a preliminary discussion on the health and environmental safety issues of manufactured nanomaterials as one of the emerging issues to be addressed in the near future within the framework of chemical management in METI's Policy Council on Chemical Issues. However, no proposal regarding concrete measures restricting manufactured nanomaterials has been put on the table yet.

2. Developments related to voluntary or stewardship schemes;

The Japanese Government does not have any voluntary reporting scheme on health and environmental safety issues of manufactured nanomaterials at this stage. However, METI has just started a preliminary survey on safe handling of nanomaterials at manufacturing sites and research laboratories.

3. Information on any risk assessment decisions;

The Japanese Government does not have any risk assessment decisions regarding manufactured nanomaterials.

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

The Japanese Government has just started a programme on safety nanomaterial project "Evaluation of the Potential Risks of Manufactured Nanomaterials based on Toxicity Tests with Precise Characterization" that is mentioned hereinafter. It could lead to develop guidance documents relating to good practices for appropriate handling methods of manufactured nanomaterials in the workplace, such as at research institutes and at sites of production fields.

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

The Japanese Government does not have any strategies designed to address human health and/ or environmental safety aspects of nanomaterial.
However, in the fiscal year 2005, four national institutes, namely The National Institute of Advanced Industrial Science and Technology (AIST), the National Institute of Health Science (NIHS), the National Institute for Environmental Studies (NIES), the National Institute of Materials Science (NIMS), and some universities have jointly conducted research and surveys to facilitate 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 assessment for promoting the public acceptance of nanotechnology and its economic effects by the funding of the Ministry of Education, Culture, Sports, Science and Technology (MEXT). The survey team has issued a report which contains a series of recommendations to public institutes, the private sector and the government.

These survey results may possibly be used as a guide for future national measures by the government. In the fiscal year 2006, by the MEXT funding, the project named "The multidisciplinary experts panel for nanotechnology implication" has 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 nanotechnology implication for health, environment and social acceptance." The additional objective is the establishment of the researchers' network on nanotechnology implication.

METI has launched a five-year project named "Evaluation of the Potential Risks of Manufactured Nanomaterials based on Toxicity Tests with Precise Characterization." The project focuses on toxicity test protocols (mainly an inhalation test) and a risk assessment methodology of manufactured nanomaterials, based on developing:

- characterization methods/apparatuses and sample preparation protocols for nanomaterials themselves and for organs or cells etc. which contains nanomaterials;
- inhalation test apparatus for nanomaterials;
- non-invasive in vivo imaging protocols and apparatus to measure biological reductive ability;
- biological reaction profiles of in vitro tests;
- methods of evaluation of protective equipment (*e.g.* mask), and also based on surveillance of amounts and types of nanomaterials released from/inside facilities.

Fullerene and carbon nanotubes are given priority in this project. Literature research of nanomaterials toxicity, together with social and legal scientific studies is also implemented.

Also, MHLW conducted a preliminary project in 2005, and has launched a subsequent three-year project named "Research on the hazard characterization and toxico-kinetic analysis of manufactured nanomaterials for the establishment of health risk assessment methodology" led by NIHS from 2006. The project has been focusing on detecting methodology of nanomaterials in the biological samples, ADME analysis, long-term health implication using experimental animals, and development of transpulmonary experiment system.

The National Institute of Occupational Safety and Health, Japan (JNIOSH) is planning to start a research program in order to assess exposure to nano-materials and study the effective management of their risks, especially concerning health issues at workplaces, from fiscal year 2007.

The National Institute for Environmental Studies (NIES) has started both in vitro and in vivo toxicology research to evaluate health effect potencies of nanomaterials including nanostructured fibers. Besides, NIES has been investigating effects of atmospheric nanoparticles on respiratory and circulation systems for the last 2 years using chronic inhalation chambers for small rodents.

6. Information on any public/ stakeholder consultation.

The Japanese Government has not implemented public or stakeholder consultation focusing on safety issues of manufactured nanomaterials. However, in the above mentioned survey, a series of workshops in which public and members of NGOs actively participated were conducted by national institutes and recommendations have been developed based on the outcomes of these workshops. Furthermore, METI's Policy Council on Chemical Issuers is open to the public, and representatives of environmental NGOs and other stakeholder organizations participate in the conference.

REPUBLIC OF KOREA

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

The Korean Government established the National Strategic Nanotechnology Development Plan in 2001. It also enacted a law for promoting the development of nanotechnology in 2002. Although the law contains a provision on the requirement of the assessment on the impact of nanotechnology on the economy, society, culture, ethic and environment, any further sub-regulation/guidance to address negative impact on human health and environment by nanotechnology has not yet followed.

2. Developments related to voluntary or stewardship schemes;

The Korean Government does not have any voluntary or stewardship programs on human health and environmental safety issues of nanomaterials and nanotechnologies.

3. Information on any risk assessment decisions;

The Korean Government does not have any concrete information for the hazardous decisions on human health and environmental safety issues of nanotechnology/nanomaterials.

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

In Korea, the issues on the risk assessments for nanomaterials and nanotechnologies are currently emerging in sectors of government, academic societies and NGOs.

- Ministry of Environment, Ministry of Science & Technology and Food & Drug Administration has organized working groups, respectively, for the research on these issues.
- International Symposium on 'Toxicology of Nanoparticles" was held on 13 May, 2003, sponsored by the Korea Toxicology Association.
- Korea Institute of Science & Technology Evaluation and Planning (KISTEP) organized a Task Force Team including NGOs on May 2006, and started a research entitled 'Societal Impact Analysis by the Nanotechnology Development'.

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

The Korean government realized the importance of the issues on potential risks of nanotechnology/nanomaterials and initiated researche or plans to support researche through relevant ministries.

Ministry of Environment (MOE)
MOE has been conducting the Ecotopia-21 project since 2001 to promote the development of environmental technologies with the annual budget of approximately USD 100 million. Currently research plans to address the risks of nanotechnology/nanomaterials have been developed and are waiting for approval under the Ecotopia-21 framework. The final goal of the research plans is to support the establishment of infrastructure necessary to minimize potential risks derived from the manufacture, distribution and disposal of nanomaterials and nanomaterials-containing products. The research subjects proposed include 1) testing and standardization of measurement methods for nanomaterials, 2) (eco) toxicological assessment of nanomaterials, 3) environment exposure and fate of nanomaterials, and 4) risk management of nanomaterials.

Ministry of Science and Technology (MOST)
MOST is conducting a research project named "Environmental implications assessment of nanomaterials" in 2006. The objectives of the project is to evaluate the health and environmental impacts of nanomaterials through literature surveys and laboratory experiment and to formulate proposals to address these problems

Korea Food & Drug Administration (KFDA)
KFDA will start a series of researches on the toxicology of nanomaterials from 2007 to 2011 with the objectives of the development of a toxicological evaluation system of nanomaterials and establishment of related guidelines for the area of food and medical products.

** To be noted that activities conducted by other related ministries such as the Ministry of Labor and Ministry of Industry & Resource were not reflected here.*

6. Information on any public/ stakeholder consultation.

The Korean government has not conducted any public/stakeholder consultation so far.

NEW ZEALAND

Current developments in New Zealand on the Safety of Nanomaterials

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

If a nanomaterial has one or more hazardous properties[16], it would be regulated by the Environmental Risk Management Authority (ERMA) under the Hazardous Substances and New Organisms (HSNO) Act 1996. The Ministry for the Environment administers the HSNO Act and monitors the performance of ERMA. Hazardous substances that are regulated under the HSNO Act include toxic substances, pesticides, dangerous goods (such as petrol and liquefied petroleum gas), explosives and cosmetics.

The Ministry for the Environment and ERMA consider that there is significant scope within the HSNO regime to regulate nanomaterials that meet the definitions for hazardous substances on a case-by-case basis. ERMA intends to establish over the next 18 months or so a formal position on the regulation of nanomaterials under the HSNO Act. Specific data requirements for risk assessment of nanomaterials will be developed that 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

There is further provision under the Health and Safety in Employment (HSE) Act 1992[17] if nanomaterials do not fall under the HSNO Act due to being a manufactured article (excluded from the HSNO Act) or being non-hazardous as set out in the HSNO (Minimum Degrees of Hazard) Regulations.

[16] These are defined in the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001.

[17] http://www.osh.govt.nz/law/

The HSE Act is sufficiently general in its definition of a "hazard" that it would be applicable to any substance that has health consequences. The HSE Act provides a general duty on all employers to provide a safe place of work, and sets in place a hazard identification and management system that requires anything that could be hazardous to workers to be systematically identified and assessed to determine whether or not it is a significant hazard. If the hazard is found to be significant, the employer must take steps to eliminate, isolate or minimise the hazard.

There are also monitoring provisions under the HSE Act which requires an employer to monitor the employees' exposure to the hazard. However, in order for the hazard identification and management system to be effective, first the health effect and the technology for assessing the hazard and controlling it must evolve.

Residues of nanomaterials in foods are controlled by either the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2006[18] if contamination arises from use of pesticides or veterinary medicines, or the Food Standards Code[19] established by Food Standards Australia and New Zealand (FSANZ) for other sources of food contamination. Both pieces of legislation are able to cope with this new technology when the need arises.

2. Developments related to voluntary or stewardship schemes

There are currently no voluntary or stewardship schemes.

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[20]) must be notified to ERMA as a condition of the Cosmetic Products Group Standard[21]. 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

There are currently no research programmes underway to address human health and/or environmental

[18] http://www.nzfsa.govt.nz/policy-law/legislation/food-standards/mrl-2006/nzmrlfs2006-consolidation.pdf
[19] http://www.foodstandards.gov.au/thecode/foodstandardscode.cfm
[20] 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.
[21] http://www.ermanz.govt.nz/appfiles/orgctrl/pdf/HSR002552Con.pdf

safety aspects of nanomaterials. The Foundation for Research Science and Technology has called for research proposals in its "Creating Opportunities Through New Physical Technologies" portfolio[22] that investigate the environmental and socio-economic uncertainties associated with nanotechnologies.

6. Information on any public/stakeholder consultation

No public/stakeholder consultation has been conducted on safety of nanomaterials.

Additional Information

The Ministry of Research, Science and Technology (MoRST) is producing a "Nanoscience & Nanotechnologies Roadmap" on directions for research and policy associated with the responsible development and management of nanoscience and nanotechnologies in New Zealand[23]. MoRST has also established the Navigator Network[24] to identify emerging science trends and innovations, particularly in biotechnology and nanotechnology.

The Bioethics Council prepared a report on nanotechnology to the Minister for the Environment in 2003[25]. This report looked at the potential ethical, cultural and regulatory implications of nanotechnology. The Bioethics Council have indicated that they will continue to investigate the cultural, ethical and spiritual implications of nanotechnology as part of their "future watch" function.

The Agribusiness and Economics Research Unit at Lincoln University is conducting research on public attitudes to nanotechnology[26].

NORWAY

1. Any national regulatory developments on human health an environmental safety including recommendations or discussions related to adopting 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 EC.

2. Developments related to voluntary and stewardship schemes

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

3. Information on any risk assessment decisions.

No risk assessments on specific nanomaterials have been conducted in Norway.

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

[22] http://www.frst.govt.nz/research/NPT.cfm
[23] http://www.morst.govt.nz/current-work/roadmaps/
[24] http://www.navigatornetwork.net.nz/
[25] Bioethics Council (2003) *Report on nanotechnology to the Minister for the Environment*. http://www.bioethics.org.nz/publications/nanotechnology-sep03/nanotechnology-sep03.pdf
[26] Andrew J. Cook, John R. Fairweather (2005) *Nanotechnology - Ethical and Social Issues: Results from New Zealand focus groups*. http://www.lincoln.ac.nz/story_images/1330_RR281_s4140.pdf

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 since 2002 had a research program called NANOMAT, for nanotechnologies and new materials, which also support research on health and environmental effects. The Council published in 2005 a report where questions related to human health, environmental safety, ethics and social aspects on nanotechnologies and new materials are discussed. In 2006 the Council has worked on a national strategy for nanoscience and nanotechnology. It is expected that the strategy will be adopted soon.

6. Information on any public/ stakeholder consultation.

The report from the Research Council of Norway has been presented on an open meeting.
The work on the national strategy has also been an open process and a draft strategy has been put out for public hearing.

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;

In the area of legislation development many institutions cooperate with us, mainly in the form of requiring comments, suggestions. There have been no external incentives in the area of nanomaterials.

2. Developments related to voluntary or stewardship schemes

Because of a strict regulation in the area of chemical production we do not develop voluntary schemes. In general there are only a few opportunities in chemical industry for stewardship schemes

3. Information on any risk assessment decisions;

Analyses of risk assessment are systematically carried out the results are attached to the "Safety report" which is periodically offered to the governmental institutions. So far, we have performed only a few trials with nanomaterials at the laboratory scale; therefore no risk assessment decisions have been made.

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

Documents related to good practice have not been developed in Istrochem, o. z. yet, but there are activities, other documents, which substitute for Good practice documents. Actually there is no reason for using accredited methods in the area of nanomaterials because of the small number and scale of our trials.

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

In the scope of our interest in nanomaterials we have been monitoring the available information. We have not met any restriction in use of nanomaterials in the area of rubber compounds filler or formulations of

herbicides and so we have not carried out programmes of evaluating impact on health or environment

6. Information on any public/ stakeholder consultation.

Our activities are described in the reports submitted to the governmental institutions, part of information in them is provided to public on the principle of the law of free access to information. Information and news about our company are also published in newspapers, television, etc. At present most of our interests on nanomaterials are considered as a company secret.

Unfortunately no convenient document, paper or textbook describing the impact of nanomaterials on health, on environment is available. If such documents exist we would be able to consider the effects of nanomaterials more carefully.

SWEDEN

Swedish activities in the chemicals regulatory area on health and environmental safety aspects of manufactured nanomaterials:

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;**
   -

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.**

Completed:

- *Seminar on "Nanotechniques-possibilities and risks*", Organized by Royal Swedish Academy of Engineering Science, Swedish Governmental Agency for Innovation Systems, Swedish Research Council, Public and Science and Swedish Society of Toxicology, May 19th, 2006

Ongoing:

- *Network on Risk assessment of Nanomaterials*, organized by Swedish Chemicals Inspectorate
- *Network on Standards for Nanomaterials*, organized by Swedish Standards Institute

Planned:

- *Seminar on the topic "Nanotoxicology and risk assessment"*, Organized by Swedish Society of Toxicology and Institute of Environmental Medicine, Karolinska Institutet, November 27th, 2006

SWITZERLAND

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

Swiss Action Plan "Risk evaluation and management of synthetic Nanoparticles 2006-2009"
In February 2006 the Swiss Federal Office of Public Health and the Swiss Federal Office for the Environment started to work on an action plan on safety aspects of synthetic nanoparticles. The following topics will be covered:

- Support precautionary measures with respect to occupational health in R&D and industry
- Support and strengthen stakeholder awareness for self-control principles (code of conduct)
- Promotion of risk and safety research projects (university, industry)
- Promotion of harmonized definitions, characterization methods and validated test guidelines for hazard and risk evaluation and for assessment in cooperation with OECD, ISO and EU
- Promotion of an inventory on the usage of nanoparticles in Switzerland and development of exposure-scenarios (Comparison with exposures to airborne ultra fine particles, *e.g.* combustion dust)
- Adaptation of the existing legislation in Switzerland, if necessary
- Dialogue with stakeholders (science, industry, politics, NGO, public, etc.)

All activities will be worked out and implemented in coordination with other national and international initiatives.

For more information see (French and German only): www.umwelt-schweiz.ch/nanotechnologie

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

Several Research projects have been initiated:

NanoRisk - Safety and Risks of Carbon Nanotubes (CNT)
Project leader: Swiss Federal Laboratories for Materials Testing and Research (EMPA) St. Gallen
The aims of this project are:

- to present the international status quo of existing knowledge and uncertainties regarding safety and risk issues of CNT;
- to perform research to obtain toxicological in vitro data for hazard identification;
- to identify the toxicomechanism of CNT
- to perform a foresight of which potential problems can arise in order to be able to take precautionary measures already in the R&D process

Nano-Inventory
Project leader: Institute for Occupational Health Sciences (IST) Lausanne
Aim: the principlal aim of this study is to estimate the prevalence and extent of nanoparticles in the Swiss industry as well as the potential for exposure to engineered nanoparticles for workers. A "Nano-Inventory" will be created. It will show the number of companies from different industrial branches, the type of

particles used and the number of potentially exposed people. Some information will be gathered on emissions towards wastewater and air.

3. Information on any public/stakeholder consultation

PubliFocus on "Nanotechnology"
Project leader: Swiss Centre for Technology Assessment TA-SWISS
Aim: A publifocus is a participation model developed by TA-SWISS to produce early input for serious debate on the possible consequences of technological progress. The opinion expressed by randomly chosen participants from the public are collected in a report. Publifocus meetings do not produce any recommendations; nor do the results claim to be representative for Switzerland as a whole. They do, however, represent the public's view of that technology and give concrete indications of areas where future action might be necessary.
For more information see: http://www.ta-swiss.ch/e/them_nano.html

UNITED KINGDOM

Summary of UK Work on Health and Environmental Safety Aspects of Manufactured Nanomaterials

National regulatory developments on human health and environmental safety

Individual UK Departments and Agencies have undertaken reviews of the adequacy of existing regulations with regard to the potential risks posed by engineered nanoscale materials. In very general terms, conclusions are two-fold: (1) while there is no legislation specifically relating to nanotechnologies, Departments and Agencies have generic legislation that applies to engineered nanoscale materials and enables the relevant agency or local authority to take prompt action if products pose a risk to health, safety or the environment; (2) however, until we have data on which to determine the nature of any risks posed by nanomaterials, it is not possible to assess the full extent to which the implementation of current regulations addresses any potential risks.

The overall approach UK approach is to gather evidence on which to base a decision on the most appropriate form of control. Our research and Voluntary Reporting Scheme (VRS) are the key methods of gathering evidence and are detailed below.

Developments related to voluntary or stewardship schemes

Following consultation, the UK Government has introduced a Voluntary Reporting Scheme for engineered nanoscale materials[27]. The scheme is run by Defra, started in September 2006 and will run to September 2008. The scheme is voluntary and did not require legislation.

The scheme is targeted at any company or organisation involved in manufacturing, using, importing or managing wastes consisting of engineered nanoscale materials.

Information requested includes any data on: physico-chemical, toxicology, ecotoxicology and risk management practices, a data reporting form has been provided.

[27] See: http://www.defra.gov.uk/environment/nanotech/policy/index.htm#voluntary

The purpose of the scheme is to develop a better understanding of the properties and characteristics of different engineered nanoscale materials, so enabling potential hazard, exposure and risk to be considered. The building of an evidence base in this way will allow for a more informed debate about the nature of appropriate controls in the shortest time frame.

Information on any risk assessment decisions

We have not conducted any risk assessments or taken any risk assessment decisions.

Information on any developments related to good practice documents

Three 'Good Practice Guides' are being developed by the British Standards Institute (BSI) to meet immediate UK industry needs regarding health & safety issues around nanotechnologies:

- **Guide to Safe Handling and Disposal of Free engineered Nanomaterials**
  To provide good practice guidance, based on current knowledge, on the measures that should be adopted by businesses and others that are engaged in the manufacturer, processing or handling of free, engineered nanomaterials to ensure that workers and others, including members of the public are not unnecessarily exposed to such materials. *To be developed as a PD (Published Document)*

- **Guide to Specifying Nanomaterials**
  To provide manufacturers and end users with guidance on how to prepare comprehensive specifications for engineered nanomaterials to ensure the delivery of product that performs in a reproducible manner. This will help to assure consistent performance of the end products in which such components are used. The guide will be appropriate for use by Technical Managers and others responsible for specifying materials. *To be developed as a PD (Published Document)*

- **Good Practice Guide for Labelling of nanoparticles and products containing nanoparticles (PAS)**
  To provide industry and consumers with appropriate technical information to enable them to make informed choices and to reduce the need for the regulation of nanotechnologies. To be developed as a PAS (Publicly Available Specification)

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

The UK Nanotechnology Research Coordination Group (NRCG) was established in 2005 to develop and oversee the implementation of a cross-Government research programme on the potential human health and environmental risks posed by free engineered nanoscale materials.

The NRCG's first research report[28], published in November 2005, sets out a programme of nineteen research objectives to characterise the potential risks posed by free engineered nanoscale materials.

These objectives have been taken forward by five Task Forces set up under the NRCG. Their objectives are grouped under the following inter-related work areas:

[28] See: http://www.defra.gov.uk/environment/nanotech/research/pdf/nanoparticles-riskreport.pdf

- metrology, characterisation and standardisation
- exposure, sources, pathways and technologies
- human health hazard and risk assessment
- environmental hazard and risk assessment
- social and economic dimensions of nanotechnologies.

The Task Forces have developed action plans to progress the nineteen objectives and a progress report will be published on 19 October 2006[29].

Information on any public/stakeholder consultation

The UK Government's programme of public engagement[30] on nanotechnologies is centred on three projects – Nanodialogues, the Nanotechnology Engagement Group, and Small Talk – which aim to elicit and understand people's aspirations and concerns around the development of these technologies.

We have additionally established a Nanotechnologies Stakeholder Forum, which enables key stakeholders from industry, academia and civil society organisations to learn about and discuss each other's views, as well as Government activities, on appropriate controls and research.

Additional information

The UK Government has commissioned a study to analyse the potential environmental benefits of nanotechnologies with regard its key policy challenges, including climate change and sustainable energy. The project will additionally identify potential barriers to the development and realisation of environmentally beneficial nanotechnologies, including how Government can help in this respect. The project is expected to report its conclusions by March 2007.

The UK Government has been working with the European Commission and other Member States to reach agreement on the interpretation of nanomaterials in the context of the current Notification of New Substances Regulations (which implement Directive 67/754/EEC), the Existing Substances Regulation (EC) No 797/93 and the forthcoming REACH Regulation). These discussions resulted in agreement that:

- Whether a nanomaterial is a new or existing substance is related to the substance identification: So far substance identification is done on the basis of the information on chemical structure, purity, the chemical name (IUPAC and CAS) and the supporting spectral and analytical data. When a nanomaterial is derived from an existing substance, the Existing Substances Regulation 793/93 (ESR) applies. There are certain caveats to this.

- Nanomaterials having specific properties may require a different classification and labelling compared to the bulk material.

- The European Commission will invite industry to provide a number of dossiers on different representative nanomaterials, to show what kind of data is available, how risk assessment is being performed and how the risks are controlled.

[29] See: http://www.defra.gov.uk/environment/nanotech/research/pdf/nanoparticles-riskreport.pdf
[30] See: http://www.defra.gov.uk/environment/nanotech/research/pdf/nanoparticles-riskreport.pdf

UNITED STATES

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 Nanoscale Science, Engineering, and Technology (NSET) Subcommittee's Nanotechnology Environmental and Health Implications (NEHI) Working Group provides for exchange of information among agencies that support nanotechnology research and those responsible for regulation of nanotechnology-related products. The Working Group also seeks to facilitate research and other activities that support responsible development of nanotechnology.
The NSET Subcommittee member agencies are active participants in national and international standards development activities, including those of ISO Technical Committee on Nanotechnologies (TC 229), American National Standards Institute- Nanotechnology Standards Panel and ASTM International's Nanotechnology Committee (E56).

The Food and Drug Administration (FDA) has initiated an internal Task Force on Nanotechnology that will, among other considerations, examine regulatory approaches to manufactured nanomaterials.

The Environmental Protection Agency (EPA) is developing guidance under the Toxic Substances Control Act (TSCA) in order for manufacturers of nanoscale materials to make the distinction between "new" and "existing" chemicals on the TSCA Inventory.

EPA has received and reviewed a number of new chemical notices for potential nanoscale materials under TSCA. EPA has permitted manufacture of these nanoscale materials under limited conditions.

2. Developments related to voluntary or stewardship schemes;

For new products using nanotechnology, USG agencies (including EPA, NIOSH, and FDA) have encouraged manufacturers to enter into discussions with the appropriate review authority early in the product development process, prior to submitting an application or notice for regulatory decision, so that potential issues of regulatory uncertainty or information needs can be identified and where possible addressed. These discussions are ongoing for a number of products that use manufactured nanomaterials.

EPA has established an Agency-wide workgroup to develop a stewardship program under TSCA that could complement EPA's regulatory authorities and to ensure the responsible development and commercial use of nanoscale materials.A key goal of the Program is to assemble and encourage the development of scientific information on hazards, exposure, risks, and risk mitigation practices to provide a sound scientific foundation to inform industry and EPA.

3. Information on any risk assessment decisions;

The National Institute for Occupational Safety and Health (NIOSH) has drafted and released for public review Current Intelligence Bulletin: Evaluation of Health Hazard and Recommendations for Occupational Exposure to Titanium Dioxide (http://www.cdc.gov/niosh/review/public/tio2/).

EPA has assessed a number of new chemical notices for potential nanoscale materials under TSCA.

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

In August NIOSH released a second edition of its best practices document for working with nanomaterials

"Approaches to Safe Nanotechnology: An Information Exchange with NIOSH" (http://www.cdc.gov/niosh/topics/nanotech/safenano/)

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

The NSET Subcommittee's NEHI Working Group has released a document entitled "Environmental, Health, and Safety Research Needs of Engineered Nanoscale Materials" that identifies EHS research needed to enable risk assessment and risk management of nanoscale materials (http://www.nano.gov/NNI_EHS_research_needs.pdf).

The U.S. National Institutes of Health (NIH), U.S. Department of Health and Human Services, established a "Health Implications Working Group" as part of a larger Tran-NIH Nanotechnology Task Force that encompasses unintentional exposures to manufactured nanomaterials and intentional exposures to nanodiagnostics and therapeutics. Currently, several million dollars of the NIH annual total expenditure of about $170 million on nanotechnology research is devoted to assessing health affects of manufactured nanotechnologies (see Annex A).

NIH's National Institute for Environmental Health Sciences (NIEHS) is leading a multi-institute/multi-agency program to investigate the effects of manufactured nanotechnologies on human health. NIH intends to broadly share research results.

Also under the aegis of NIH/NIEHS, and in collaboration with the U.S. Food and Drug Administration and the Centers for Disease Control's (CDC) National Institute for Occupational Health and Safety (NIOSH), the National Toxicology Program's Nanotechnology Safety Initiative is undertaking toxicological evaluations of specific engineered nanoscale materials. The U.S. Consumer Product Safety Commission (CPSC), EPA and the U.S. OSHA are also active participants in this initiative.

EPA's Science Policy Council is finalizing a White Paper that describes the science issues that EPA is addressing now, and will address in the future, regarding the potential environmental benefits and impacts of nanotechnology.

FDA has initiated research, in collaboration with NIST, to characterize certain particles used widely in commerce that are also used in drug products.

The U.S. National Institutes of Health (NIH), with co-sponsorship with other U.S. agencies (NIOSH and EPA), announced on 29 September 2006 a request for applications (RFA) on a research program on the physico-chemical properties of manufactured nanotechnologies. Further information on this RFA is at: http://grants.nih.gov/grants/guide/rfa-files/RFA-ES-06-008.html. The research that will be supported seeks to characterize the physical and chemical properties of nanomaterials and determine the interaction of these properties with a relevant biological system at the cellular, molecular and systemic levels.

EPA is developing a nanotechnology research framework for 2007-2012. In fiscal years 2007 and 2008, EPA will focus on the following high-priority areas: environmental fate, transport, transformation, and exposure; and monitoring and detection methods. Resulting data will be used to inform and develop effects and exposure assessment methods and identify important points of releases for potential management.

NIOSH Nanotechnology Research program (http://www.cdc.gov/niosh/topics/nanotech/research.html) addresses health hazard and safety aspects of nanotechnology in occupational settings.

NIOSH Interdisciplinary Field Team of nanotechnology researchers partners with nanotechnology companies to assess exposures to nanomaterials and effectiveness of engineering controls and personal protective equipment to reduce exposures to nanomaterials in the workplace.

EPA, the National Science Foundation (NSF), NIOSH, and NIH plan an expanded joint extramural research program addressing potential EHS implications of nanotechnology for human health and the environment.

NIOSH is supporting focused research on nanotechnology issues associated with worker safety and health as outlined in the NIOSH Nanotechnology Strategic Plan (available at www.cdc.gov/niosh/topics/nanotech/strat_plan.html) through intramural and extramural programs and international collaborations.

The NIH National Cancer Institute's Alliance for Nanotechnology Characterization Lab is developing a characterization cascade for use in preclinical evaluations of nanomaterials intended for cancer therapeutics.

NSF supports basic research directed at environmental, health, and safety impacts of nanotechnology development. NSF has funded hundreds of grants for such study to individual researchers, environmental centers and interdisciplinary groups.

See Annex A for a Chart summarizing research programs in the USG directed at environmental, health, and safety impacts of nanotech.

6. Information on any public/ stakeholder consultation.

The NSET Subcommittee sponsored a workshop in May 2006, with support from the EPA, on Public Participation in Nanotechnology.

EPA's Office of Solid Waste and Emergency Response hosted a symposium on July 12 -13, 2006 about nanotechnology and its influence in waste management practices.

FDA held a public meeting October 10, 2006 to consult with the public about the kinds of new nanotechnology material products under development and whether there are new or emerging scientific issues that should be brought to FDA's attention, including issues related to the safety of nanotechnology materials.

EPA's Office of Pollution Prevention and Toxics (OPPT) is holding scientific peer consultations in the fall of 2006 on materials characterization and risk management practices pertaining to nanoscale materials to support development of the stewardship program it is considering.

OPPT is also planning a pollution prevention conference to provide a forum to exchange information and ideas on the potential environmental and pollution prevention benefits of innovative nanotechnologies and nanomaterials.

NIOSH invites public comments on its nanotechnology-related documents posted on NIOSH nanotechnology web-page (http://www.cdc.gov/niosh/topics/nanotech/), such as "Approaches to Safe Nanotechnology: An Information Exchange with NIOSH" (http://www.cdc.gov/niosh/topics/nanotech/safenano/).

NIOSH sponsored a workshop on nanotechnology and occupational safety and health hosted by the RAND Corporation on October 17, 2005. The workshop focused on policy and planning issues (as opposed to scientific issues) that are key to understanding the options available to NIOSH in formulating and implementing its strategic objectives to protect the safety and health of workers exposed to nanoscale materials (http://www.rand.org/pubs/conf_proceedings/CF227/).

Annex A

Research programs directed at environmental, health, and safety (EHS) impacts of nanotechnology development, and risk assessment of such impacts are a growing component of the U.S. National Nanotechnology Initiative. R&D leading to a detailed understanding of the health and safety impacts of nanotechnology for researchers, workers, consumers, and the public is a strategic priority within the NNI's Societal Dimensions Program Component Area, and is reported by agency in the table below. Note that the funding indicated in this table does not include R&D within other NNI Program Component Areas that is highly relevant to EHS implications but not primarily directed at those implications, such as fundamental studies of the interactions between engineered nanoscale materials and biological systems, development of improved instrumentation for measuring the properties of engineered nanoscale materials, or applications-oriented work that also produces information related to potential toxicity of nanoscale or nanostructured materials.

Budget for Environmental, Health, and Safety R&D, 2005-2007 (dollars in millions)			
	2005 Actual	**2006 Estimate**	**2007 Request**
NSF	20.9	22.1	25.7
DOD	1.0	1.0	1.0
DOE	0.5	0.5	0.0
DHHS (NIH)	2.7	4.5	4.6
DOC (NIST)	0.0	2.4	1.8
NASA	0.0	0.0	0.0
EPA	6.7	3.9	8.0
USDA (CSREES)	0.1	0.1	0.1
DHHS (NIOSH)	3.0	3.0	3.0
USDA (FS)	0.0	0.0	0.0
DHS	0.0	0.0	0.0
DOJ	0.0	0.0	0.0
DOT (FHWA)	0.0	0.0	0.0
TOTAL*	**34.8**	**37.5**	**44.1**

EUROPEAN COMMISSION

Contribution of the European Commission, relating to activities in the chemicals regulatory area on health and environmental safety aspects of manufactured nanomaterials:

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 Commission is performing a regulatory inventory, covering EU regulatory frameworks that are applicable to nanomaterials (chemicals, worker protection, environmental legislation, product specific legislation etc.). The purpose of this inventory is to "*examine and, where appropriate, propose adaptations of EU regulations in relevant sectors*" as expressed in Action 6d) of the Commission Action Plan. Preliminary findings indicate that the regulatory frameworks in principle give a good coverage; different aspects of production and products are at the same time subject to various Community provisions. However, many of the knowledge gaps (toxicity thresholds, test schemes etc) will need to be addressed to ensure implementation. Those knowledge gaps are in line with the ones earlier identified by EC and others and reported to the OECD.
In the chemicals regulatory area, EU competent authorities (CAs) have decided that:

a. The decisive criterion whether a nanomaterial is a new or existing substances is the same as for all other substances, *i.e.* whether or not the substance is on EINECS. When a nanomaterial is derived from an existing substance, article 7.1 of the Existing Substances Regulation 793/93 (ESR) on the updating of reported information applies.

b. Nanomaterials having specific properties may require a different classification and labelling compared to the bulk material, also when the nanoform is derived from a bulk substance.

c. They invite industry to provide a number of dossiers on different representative nanomaterials, to show what kind of data is available, how risk assessment is being performed and how the risks are controlled.

d. For the longer term, a review of the applicability of testing methods and risk assessment methods should be carried out. This should be done at international level (*e.g.* within the OECD chemicals programme) with active input from industry and contributions from the EU.

2. Developments related to voluntary or stewardship schemes;

The EC has not developed any voluntary or stewardship schemes at this stage. Issues regarding such schemes will be discussed in the chemicals CAs working group, also as a follow-up to 1.c. above. The UK has launched its voluntary reporting scheme in September 2006.

3. Information on any risk assessment decisions;

In relation to nanomaterials in chemicals legislation, risk assessment and management is implemented at this moment as for other chemicals in the framework of the current legislation on new and existing chemicals (see 1.a. above).
The EC Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) adopted an opinion on "The appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies" in March 2006 after the public consultation of the first version adopted in September 2005[31]. In essence, the SCENIHR scientific opinion states that "given […] uncertainties [concerning respectively hazard and exposure], the current risk assessment procedures require modification for nanoparticles." (p. 60).
Two new scientific opinions on risk assessment of nanomaterials are foreseen from the EC Scientific Committees, namely:

[31] http://ec.europa.eu/comm/health/ph_risk/committees/04_scenihr/docs/scenihr_o_003.pdf

- a scientific opinion from the SCENIHR on "the appropriateness of the risk assessment methodology in accordance with the Technical Guidance Documents for new and existing substances for assessing the risks of nanomaterials"[32].
- a scientific opinion from the Scientific Committee on Consumer Products on the safety of "nanomaterials in cosmetic products"[33];

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

The Commission is closely following the work in ISO and CEN. Both nanotechnology related Technical Committees in ISO (TC 229) and in CEN (TC 352) are currently working on the nomenclature and hence on the definition aspects taking also into account labelling issues. In ISO/TC 229, the working group on Health, Safety and Environment is proposing a Technical Report on "Current Safe Practices in Occupational Settings Relevant to Nanotechnologies". In addition, ISO (TC 146) on Air Quality one working group is preparing a technical report "Ultrafine nanoparticles and nano-structured aerosols – Exposure characterization and assessment"

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

As stated in Action Plan on Nanosciences and Nanotechnologies (N&N), the European Commission aims at reinforcing N&N research and development in the seventh framework programme for research, technological development and demonstration activities (FP7) and has proposed a significant increase of the budget compared to FP6.

It has also committed itself to boost support for collaborative R&D into the potential impact of N&N on human health and the environment via toxicological and ecotoxicological studies as well as developing appropriate methodologies and instrumentation for monitoring and minimising exposure in the workplace.

Future activities in FP7 are being drafted have taken into consideration external and internal inputs. The data gathered in an informal collection of inputs on (eco)toxicology provide valuable information to prioritise research on health and safety aspects of nanotechnology-based products. Additional information such as priorities identified in the SCENIHR opinion, external stakeholders comments (such as representatives from the Member States and the Advisory group on Nanotechnologies and Nanosciences) as well as internal discussions between different Commission services have also been taken into consideration when drafting the work programme for the first years. Based on the regulatory inventory work, additional detailed and prioritized research needs were identified. Dedicated calls are foreseen among the first actions of the FP7.

The Commission has dedicated up to now around 25 million € to nanotechnology research projects particularly focused on safety aspects (additional funds have been made available within nanotechnology projects with targets not specifically related to safety) and intends to continue rising the funds available for risk-related research activities.

The JRC has set-up a research activity on risk assessment of engineered nanomaterials. The activities in FP7 will focus on the development and harmonization of methods for nanotoxicity testing and encompass related studies on nanometrology and reference materials as well as the development of databases.
As with previous framework programmes, FP7 is open to the participation of virtually all countries in the world. The possibility of coordinated calls with third countries and other specific actions is foreseen.

[32] http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_q_008.pdf
[33] http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_nano_en.pdf

6. Information on any public/ stakeholder consultation.

As mentioned under 5), a collection of inputs on (eco)toxicology took place as input to shaping the future activities within FP7.

As mentioned under 3), the SCENIHR first Opinion on Nanotechnology was submitted to an Internet Consultation.

Several conferences on nanotechnology have been organised by different organisations throughout the EU and by recent EU Presidencies. The Finnish Presidency of the EU organized a conference on "Nanotechnologies: Safety for Success" in September 2006 to examine how to promote the safe, integrated, and responsible development of nanotechnologies. The conference confirmed safety as a prerequisite to the success of nanotechnologies, the need for stronger coordination and a clear road map as well as the usefulness of a sustained dialogue between stakeholders.

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

The European Group on Ethics in Science and New Technologies (EGE) is a high-level group of independent experts on ethics appointed by President Barroso. The EGE advises the Commission on ethical issues related to science and technology or other relevant EU policies. The Group is currently working on an opinion on ethics and nanomedicine that should be issued to the President by the end of 2006.

Several research projects funded by the European Commission are related to innovation, ethical aspects and societal implications of nanotechnology. Additional information can be found at http://cordis.europa.eu/nanotechnology/. Linked to the European Technology Platform on Sustainable Chemistry, several documents are becoming available such as a code of conduct on nanotechnology; a guide on safe manufacturing and for activities involving nanoparticles at workplaces; and detailed information on the characterisation of nanomaterials.

THAILAND

Current Developments on the Safety of Manufactured Nanomaterials:
Overview on recent and planned national initiatives and activities in Thailand[34]

National Nanotechnology Center (NANOTEC), National Science and Technology Development Agency (The Thai Science Park, Rangsit, Patumthani, Thailand)

Following the US National Nanotechnology Initiative (NNI) in 2000, the Royal Thai Government established the National Nanotechnology Center (NANOTEC) three years later under the umbrella of the

[34] Presented at the First Meeting of the Working Party on Manufactured Nanomaterials, 26-27 October 2006 in London by Lerson Tanasugarn, PhD, Department of Biochemistry, Faculty of Science, Chulalongkorn University, Bangkok 10330, Thailand. Mailing Address: Dr. Lerson Tanasugarn, P.O. Box 256, Bangkok 10400, Thailand. Office Telephone +662 218-5424, Office FAX +662 218-5418. Home Telephone +662 616-8080, Home FAX +662 616-8090. Email: lerson@lerson.org

National Science and Technology Development Agency (NSTDA), a non-governmental public institution. NANOTEC has a mandate to formulate a national nanotechnology strategic plan for Thailand as well as to establish nanotechnology operational plans, guidelines, and specific measures in order to foster nanotechnology generation and commercialization.

NANOTEC is centrally involved in R&D funding, conducting nanotechnology policy research, drafting nanotechnology manpower plans, and maintaining a nano-scale national testing laboratory. Many private companies rely on NANOTEC for state-of-the-art testing technologies such as Environment Scanning Electron Microscopy (ESEM), Atomic Force Microscopy (AFM), Scanning Tunneling Microscopy (STM), dynamic light scattering setup, and zeta potential measurement, to name just a few.

During the past three years, NANOTEC has initiated and supported various projects in the fields of semiconductor and optical device, nanocomposite, nanoscale surface coating, and nanoencapsulation of active ingredients.

Most nanotechnology-based industries in Thailand are still in their infancy. Notable products include: nanocomposite food packages, alcohol nanosensors, water-repellent fabric coating made of nanoparticles, nanoclay membranes for water treatment, and curcuminoid nanoliposomes (whitening) face creams. Other products in the pipelines include nanoalumina-doped ceramics-based artificial gemstones, nanochitosan-based slow-release drug vehicles, nanoparticle Organic Light Emitting Diodes (OLEDs), nanodye-sensitized solar cells, etc.

Owing to the global publicity of nanotechnology and the marketing success of the locally manufactured nano-fabrics/apparel and nano-encapsulated cosmetics, Thai consumers have slowly entered the age of nano-hype. The general public was led to believe that a product manufactured using nanotechnology must possess superior quality or features and therefore would deserve a higher price than similar counterparts without any nanotechnology on the label.[35] Typical consumers are not aware of any possible health risk arising from the use of nanotechnology-based products. Possible adverse effects of nanotechnology and nanoindustry on the environment are virtually unheard of.

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 of August 2006, nanosafety and nanoethics were new agendas being considered in the forums of local ISO and TIS (Thai Industrial Standard). So far no concrete development has been reported.

Back in 2004, the newly drafted NANOTEC strategic plan called for a national policy body to handle nanosafety issues. This established policy body then initiated a drafting of a nanosafety and nanoethics guideline in 2005. Due to bureaucracy red tape stemming from governmental changes and budgeting delays, the drafting has yet to commence. The following description is therefore a tentative plan on how the guideline should be drafted.

[35] Nano-hype may present an opportunity for unscrupulous businessmen to deceive the public. For example, a certain Thai cosmetics product advertised as containing nano-particles was found a few months ago to contain virtually no particle of which the diameter is smaller than 200 nm. In this particular case, the manufacture voluntarily withdrew such claims and advertisement before the Food and Drug Administration (FDA) and the Consumer Protection Board could take any legal action.

By the beginning of 2007, NANOTEC expects to commission Chulalongkorn University to draft the nanosafety and nanoethics guideline that covers nanotechnology research, development, manufacturing, transport, usage, consumption, and the treatement/disposal of wastes arising from any of the mentioned activities. The resulting guideline will be the first step towards specific standards as well as nanosafety and nanoethics laws and regulations. The drafting is to be completed in 9 months at a budget of approximately US$100,000.00.

Chulalongkorn University, the oldest and most endowed higher education provider in Thailand, is well-known for its multidisciplinary faculties. In addition to the project director with over 15 years of policy research management experience, the guideline drafting team consists of a technologist who is an associate professor in nanoparticle engineering, an economist who is an associate professor of economics and former director of policy research at the National Electronic and Computer Technology Center (NECTEC), a political scientist who is an assistant professor in public administration and specializes in logic, an associate professor in consumer protection law, and two lecturers in environmental protection law. The team is assisted by 3 research assistants and a panel of Project Advisors consisting of a dozen experts in various fields including public health, environmental protection, and ethics, plus representatives from the private sector such as the Federation of Thai Industries (FTI).

During the first couple of months, the drafting team will gather and consolidate relevant information on similar activities worldwide. Safety information will also be compiled. After consulting with the Project Advisory Panel and NANOTEC, the first draft of the guideline will be introduced to 6 focus groups that represent the industries and other stakeholders: (1) electronic manufacturers, (2) catalyst, adsorbent, chemical, and petrol industries, (3) adhesive, sensor, surface finish, medical equipment, automobile, sporting goods, defense, household appliances manufacturing industries, (4) food, pharmaceutical, and cosmetics industries, (5) university academics in various fields, (6) consumers and nongovernmental organizations (NGOs). The revised draft guideline will then be presented at a public hearing and to the panel of Project Advisors. After any necessary revisions, the guideline will come into force when it is sanctioned by the National Nanotechnology Committee.

In addition to the nanosafety and nanoethics guideline itself, the project will also produce a policy recommendation (such as the strategy for nanosafety research) for the various agencies involved. The raw data gathered during the drafting will become part of the knowledge base that subsequent activities can rely upon. It is expected that NANOTEC will continually monitor the global development and update such knowledge base after the guideline has been drafted. The guideline should be revised at least once every other year.

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

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

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

During the past couple of years, NANOTEC as a funding agency has urged researchers to add the safety aspects to all nanomaterial R&D grant proposals. For example, nanoparticle-coated fabrics under development were subject to wash-water contamination tests. Nano-titanium dioxide (TiO_2) coated fish tanks were tested for toxicity to fish and skin creams containing titanium dioxide nanoparticles were tested for skin penetration through model (pig) skins. Safety data should be available though NANOTEC after the research works are completed. Nevertheless, there has never been a research program specifically designed to address human health and/or environmental safety aspects of nanomaterials as such.

It is expected that the policy recommendations mentioned in Item (1) above will address nanosafety strategy at the national level.

6. Information on any public/ stakeholder consultation.

It was mentioned in Item (1) above that six groups of stakeholders would be consulted as focus groups during the formulation of the nanosafety and nanoethics guideline for Thailand.

The problem that has been anticipated is: the lack of nanosafety knowledge and understanding in almost all sectors will make it difficult for the drafting team to choose who would be invited as members of each focus group. An option to be explored is the mass education on nanosafety and nanoethics at the beginning months of the guideline drafting period. At present we are discussing how this education can be carefully accomplished without causing fear and resentment towards nanotechnology in the general public.

Additional information

About NANOTEC (http://www.nanotec.or.th)

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

BIAC

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;

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2. Developments related to voluntary or stewardship schemes;

BIAC supports the actions being taken by the US Environmental Protection Agency (EPA) and the UK Department for Environment, Food and Rural Affairs (Defra) to establish a voluntary reporting system as a means of building an evidence base to allow for more informed discussion and decisions about appropriate regulatory controls. BIAC believes that existing laws provide the component authorities with full authority to address environmental, health and safety implications of nanotechnology. (TSCA Authority White Paper, March 2006 *Attached)* Recently the American Bar Association Section of Environment, Energy and Resources prepared and made available a series of white papers reviewing the adequacy of six US environmental laws, and provided a seventh paper on innovative management systems. The six papers review each of the core domestic environmental laws and consider how each can be effective to address issues regarding nanomaterials and nanotechnology. The papers are available at http://www.abanet.org/environ/nanotech.

In March 2006, the International Council on Nanotechnology (ICON) commissioned researchers at the University of California at Santa Barbara to perform a comprehensive survey of industry practices for handling nanomaterials. Work on the project was completed in two phases. The Phase 1 report, Current Knowledge and Practices regarding Environmental Health and Safety in the Nanotechnology Workplace, released on October 18, 2006, offers a comprehensive review of all existing "best practice" development efforts. The Phase 2 effort surveyed a broad range of companies internationally to determine current practices. One of the major goals of the final report is to identify critical needs for the standardization and implementation of safe practices in the nanotechnology industry worldwide so that current practices can evolve into globally adopted best practices. The final report is currently in draft form and will be released on November 13, 2006.

As part of its ongoing product stewardship activities, the American Chemistry Council's (ACC) Nanotechnology Panel prepared a survey consisting of questions related to the production, handling, transportation, disposal and use of engineered nanomaterials. The survey requests information the areas of definition of nanomaterials, environmental controls, personal protection procedures, waste handling, environmental release and product stewardship practices. A summary of results is anticipated in late 2006 or early 2007.

3. Information on any risk assessment decisions;

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

The German Chemical Industry Association (VCI) has finalized a position on the legal coverage of nanoparticles and nanoscale substances together with recommendations on the safe handling in February 2006. In spring 2006 VCI started a survey in cooperation with the German Federal Institute for Occupational Safety and Health (BAuA) to determine the use of nanomaterials within the German chemical industry and to gather information on the exposure scenarios and safety measures applied. From the results of that survey, VCI and BAuA will jointly develop a best practice guidance for the safe handling of nanomaterials at the workplace.
In order to support the development of globally harmonized data requirements for carrying out risk assessments, VCI has published in September 2006 a proposal for a tiered data gathering as basis for further discussion on risk assessment with the authorities.
The German mirror group of the ISO Technical Committee 229 Nanotechnologies has prepared an issue sheet to sketch the SHE relevant issues in analytic procedures and analytical conditions for nanotechnologies standardization.

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

The Nanomaterials Occupational Safety & Health Consortium (NOSH) consists of international companies, government agencies from the US and UK and NGOs with the purpose of developing methods to generate consistently nanoscale materials and to well characterize the aerosol, to develop portable prototype equipment that can monitor nanomaterials in occupational settings, and to measure barrier efficiency of filter media to specific engineered nanoparticles. The Consortium has published some of its work and more publications are under development.
Policy in Japan (METI) includes:

A) Government will collect safety information data about Nanotechnology (Nano Tech) as follows:
1) Need for standardization of measurement technology etc. as a base of safety investigation.
2) Collect updated safety information about Nano Tech without any specific regulation.
3) Many of test methods for existing chemical substances can be applied.
4) The actual circumstances of Nanomaterials should be researched as quickly as possible, such as existing circumstances and exposure volume.

B) Industries are expected to conduct self risk assessment of Nanomaterials.
1) Industries are needed to conduct risk assessment of their own Nanomaterials because there is no legal framework on Nanotechnology at present.
2) Industries are also expected to do aggressive safety research of Nanotechnology from the standpoint of CSR.

VCI/Dechema have collected a list of research activities concerning exposure, characterization methods and toxicological testing of nanomaterials. Together with scientists from universities and applied research institutes a joint Working Group "Responsible Production and Use of Nanomaterials" of the German Society for Chemical Engineering and Biotechnology (DECHEMA) and German Chemical Industry Association (VCI) has listed and prioritized research needs for a roadmap and link with the 7th European R&D Framework Programme that has been disseminated to authorities on national and European level. Most of the highest priority issues are meanwhile covered by several research projects of the chemical industry and institutes - especially by the project "NanoCare" dealing with methodology, toxicology, hazard evaluation and exposure assessment. NanoCare is jointly federal and industry funded and coordinates industry and academia activities.

6. Information on any public/ stakeholder consultation.

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ENVIRONMENTAL DEFENSE

Environmental Defense and DuPont Framework for Responsible Nanomaterials Development

On September 1, 2005 Environmental Defense, an environmental non-profit organization and DuPont, a global science company, entered into a partnership agreement to develop a framework for the responsible development, production, use and disposal of nano-scale materials. The intent of this framework is to define a systematic and disciplined process that can be used to identify, manage and reduce potential environmental, health and safety (EH&S) risks of engineered nanomaterials across all lifecycle stages .The process for development and evaluation of the framework will include engagement of a wide range of

stakeholders for input and feedback as a proactive, practical and adaptable framework is developed. Development of the framework will also include a demonstration of the framework and publication. A draft framework document is expected in February of 2007.

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

International Organization for Standardization (ISO)

Summary of the status of ISO/TC 229, 3.11.06

ISO/TC 229 - Nanotechnologies - was established in June of 2005 and has held two meetings - November 05 in London and June 06 in Tokyo. The next meeting will be in Korea in December. The committee currently has 36 members - 28 "P" and 8 "O". The TC structure consists of 3 working groups - Terminology and Nomenclature (convened by Canada), Measurement and Characterization (convened by Japan) and Health, Safety and Environment (convened by USA). There are 2 work items in development - an ISO/TS (technical specification) - terminology for nanoparticles (led by Dr Mark Gee from NPL, UK), and an ISO/TR (technical report) on occupational safe practices regarding nanotechnologies (led by Dr. Vladimir Murashov from NIOSH, USA). The committee has recently received a new work item proposal for an "Endotoxin test on nanomaterial samples for in vitro test systems", which is currently the subject of a ballot amongst members. The TC is expecting a number of new work item proposals on different subjects, including standards relevant to the characterization of carbon nanotubes, by the time of the next meeting. Currently the TC is undertaking a survey of standardization needs of members, the questionnaire for which was distributed at the beginning of August. This will provide information for the development of the TC Business Plan - due for delivery by the next meeting - and for coordinated road maps for the different working groups.

The TC works closely with the CEN TC in the area (TC 352 – Nanotechnologies, also chaired by UK), using the Vienna agreement where appropriate, and looks forward to developing a strong working relationship with the newly formed IEC TC 113 - "Nanotechnology standardization for electrical and electronic products and systems". It is in liaison with 10 other ISO TC's, with OECD, with the EU JRC (IRMM and Institute for Health and Consumer Protection at Ispra) and with VAMAS.

United Nations Educational, Scientific and Cultural Organization (UNESCO)

Overview of UNESCO Activities on Nanotechnology and Ethics (October 2006)

First phase: Exploring and analysing the ethical issues

Through the EST Research Programme, UNESCO has been carrying out anticipatory studies regarding ethical and social impacts of nanotechnology and its applications. The first result of this analysis has been the publication of the brochure *The ethics and politics of nanotechnology* (2006). The text explains what nanotechnology is and which ethical issues are raised by its development and applications. The text is currently available in English; translations in the other languages are in preparation.

In 2005, an ad-hoc group of experts has been set up to study and analyse the ethical aspects of nanotechnology. The following experts have been participating: Mr. Jun Fudano (member of COMEST and Director of the Applied Ethics Center for Engineering and Science at Kanazawa Institute of Technology (KIT), Japan), Mr Bert Gordijn (Professor of ethics, Department of Ethics, Philosophy and History of Medicine, Radboud University Medical Center in Nijmegen, The Netherlands), Mr Peter A. Singer (Professor of the Department of Medicine, University of Toronto, Canada and Director of the Joint Center for Bioethics of the University), Mr Abdallah S. Daar (Professor of Public Health Sciences and of Surgery at the University of Toronto, Director of the Program in Applied Ethics and Biotechnology), Mr Joachim Schummer (Heisenberg-Fellow at the Technical University of Darmstadt, Germany), Mrs Margareth Spangler Andrade (Professor of metallurgical engineering, the Federal University of Minas Gerais, Brazil, Director of technological development at the Fundação Centro Tecnológico de Minas Gerais), Mrs Michele Jean (former Chair of the International Bioethics Committee and Chair of Canadian National Commission for UNESCO), Mr Donald Evans (Director of the Bioethics Centre, Dunedin School of Medicine, University of Otago, New Zealand), Mrs. Kyunghee Choi (Professor in the Department of Science Education, Ewha Womans University of Seoul, Korea), Mr Jixing Liu (researcher at the Institute of Theoretical Physics, Chinese Academy of Sciences, Beijing, Peoples Republic of China).

The expert group has followed a twofold working strategy. The first phase involved the preparation of a "state-of-the-art" study on ethics and nanotechnology. The second phase consisted in producing materials and proposals for a UNESCO Policy Document indicating what kind of international actions could be undertaken. The outcomes of this phase are:

- The publication of a book "Nanotechnologies: science, ethics and policy issues", in the "Ethics of science and technology" series of UNESCO; the manuscript is now completed and will go into production soon. The English texts will be translated so that it will be available in the six official languages (English, French, Spanish, Arabic, Russian and Chinese).
- The elaboration of an "Outline of a Policy Advice on Nanotechnologies and Ethics". This draft document is suggesting four types of actions: awareness raising, education, research and policy. This document is now under analysis by COMEST and will be object of further consultation and deliberation during the 5th Ordinary Session of COMEST to be held in Dakar, Senegal, from 5 to 8 December 2006.

The expert group has met in UNESCO, Paris, on 5-6 July and 6-7 December 2005, and reports of both meetings can be found in the Ethics of Science and Technology webpage: www.unesco.org/shs/est, under the item "Research". The draft "Outline of a Policy Advice on Nanotechnologies and Ethics" is also accessible on the website.

Second phase: testing the relevancy of potential international actions

During the Extraordinary Session of COMEST in Paris in June 2006 it has been pointed out that the considerations of the experts, as well as the draft policy document that will be developed by COMEST, should reflect the moral concerns of the scientific community, governments and civil society. It is therefore important that the draft Outline should be subjected to extensive consultations so that COMEST will have adequate materials and proposals to transform the draft Outline into a COMEST Policy Advice. Representatives of the various sciences, policy makers and NGOs involved in the development, application and use of nanotechnologies are therefore invited to examine the strategies and options proposed. A consultation meeting with these experts will take place on 16-17 November 2006 in UNESCO Headquarters in Paris. The aim of the meeting is to discuss and review the Outline of a Policy Advice on Nanotechnologies and Ethics, in order to provide feedback and advice to the forthcoming COMEST meeting

On the basis of this consultation process, COMEST in its Ordinary Session (7-9 December 2006, in Dakar, Senegal) will prepare a Policy Advice that will be submitted to the Director-General of UNESCO. This Policy Advice will identify the possible actions of UNESCO in the field of nanotechnology and ethics.