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

14-Sep-2015

English - Or. English

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

DEVELOPMENTS ON THE SAFETY OF MANUFACTURED NANOMATERIALS

2013

JT03381627

ENV/JM/MONO(2015)41
Unclassified
English - Or. English

OECD Environment, Health and Safety Publications

Series on the Safety of Manufactured Nanomaterials

No. 59

DEVELOPMENTS ON THE SAFETY OF MANUFACTURED NANOMATERIALS: 2013

Environment Directorate
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT
Paris, 2015

Also published in the Series of Safety of Manufactured Nanomaterials:

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

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

No.37, *Current Developments in Delegations on the Safety of Manufactured Nanomaterials - Tour de Table at the 10th Meeting of the WPMN (2012)*

No.38, *Co-Operation on Risk Assessment: Prioritisation of Important Issues on Risk Assessment of Manufactured Nanomaterials - Final Report (2013)*

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No.41, *Report of the OECD Expert meeting on the Physical Chemical Properties of Manufactured Nanomaterials and Test Guidelines (2014)*

No.42, *Report of the questionnaire on regulatory regimes for manufactured nanomaterials 2010-2011 (2014)*

No.43, *Genotoxicity of Manufactured Nanomaterials: Report of the OECD expert meeting (2014)*

Nos. 44-54, These items are the dossiers derived from the Testing Programme on Manufactured Nanomaterials which are located at:
http://www.oecd.org/chemicalsafety/nanosafety/testing-programme-manufactured-nanomaterials.htm

No.55, *Harmonized Tiered Approach to Measure and Assess the Potential Exposure to Airbone Emissions of Engineered Nano-objects and their Agglomerates and Aggregates at Workplaces. (2015)*

No.56, *Analysis of the Survey on Available Methods and Models for Assessing Exposure to Manufactured Nanomaterials (2015)*

No.57, *Guidance Manual towards the integration of risk assessment into life cycle assessment of nano-enabled applications (2015)*

No.58, *Preliminary guidance notes on Nanomaterials: Interspecies variability factors in human health risk assessment (2015)*

ABOUT THE OECD

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

The Environment, Health and Safety Division publishes free-of-charge documents in 11 different series: **Testing and Assessment; Good Laboratory Practice and Compliance Monitoring; Pesticides; Biocides; Risk Management; Harmonisation of Regulatory Oversight in Biotechnology; Safety of Novel Foods and Feeds; Chemical Accidents; Pollutant Release and Transfer Registers; Emission Scenario Documents; and Safety of Manufactured Nanomaterials.** More information about the Environment, Health and Safety Programme and EHS publications is available on the OECD's World Wide Web site (www.oecd.org/chemicalsafety/).

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

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

This publication is available electronically, at no charge.

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

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FOREWORD

This document compiles information, provided by delegations, together with non-member economies, on current developments on the safety of manufactured nanomaterials.

This document is to provide delegations with background information on activities related to manufactured nanomaterials, as well as other activities on nanotechnologies at the international level. The information provided in this document captures activities that occurred in OECD delegations between February and December 2013.

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

Background

The purpose of the Tour de Table is to give each OECD delegation the opportunity to describe recent or planned national initiatives and/or events related to the safety of manufactured nanomaterials. This is to facilitate the implementation of the OECD programme on the Safety of Manufactured Nanomaterials by allowing delegations to share their experiences and preoccupations with respect to safety, and to identify opportunities for future co-operation and co-ordination. The work of this Programme is implemented by the Working Party on Manufactured Nanomaterials (hereafter WPMN).

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

The information provided in this document captures activities that occurred in delegations **between February and December 2013**.

Headings for the Tour de Table

In considering the Tour de Table, each delegation is invited to prepare a short written paper. The information is organised, where possible, under the headings identified below. Nevertheless it is recognised that not all delegations would be able to supply information under each heading.

With this in mind, submissions are organised around the following topics:

- Highlight of developments since the previous meeting of the WPMN
- Work completed, underway or planned
    - 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;
    - Developments related to voluntary or stewardship schemes;
    - Information on any risk assessment decisions;
    - Information on any developments related to good practice documents;
    - Information on any developments related to Integrated Testing Strategies and/or Alternative test methods
    - Research programmes or strategies designed to address human health and/ or environmental safety aspects of nanomaterials;
    - Information on any public/ stakeholder consultation;
    - Information on research programmes or strategies which focus on life cycle aspects of nanomaterials, as well as positive and negative impacts on environment and health of certain

nano-enabled applications. Information on any development related to exposure measurement and exposure mitigation

- Additional Information (i.e. any consideration on the benefits of nanotechnologies; consideration of ethical implications; and Information on past, current or future activities on nanotechnologies that are being done in countries in co-operation on a bilateral basis with non-OECD countries.

RESPONSES FROM DELEGATIONS

AUSTRALIA

Highlights

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) continues to monitor new chemicals notifications for nanoforms.

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

The APVMA has commissioned the development of a series of 'reflection papers' on nanomaterials in agricultural and veterinary chemicals and chemical products.

The Department of the Environment has commissioned a program of work regarding the environmental fate of nanomaterials.

The Commonwealth Scientific and Industrial Research Organisation (CSIRO) has published various scientific papers in 2013 addressing human health and/ or environmental safety aspects of nanomaterials.

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

The Australian government regulator of industrial chemicals, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), is continuing to implement its strategy for the regulation of industrial nanomaterials. This approach is consistent with the OECD Council recommendation. Under this strategy, NICNAS uses a working definition for industrial nanomaterials applicable to this sector only. The full definition is available at:

http://www.nicnas.gov.au/communications/issues/nanomaterials-nanotechnology/nicnas-working-definition-for-industrial-nanomaterial

Administrative arrangements for nanoforms of new chemicals (i.e. those that are not on the national inventory) were implemented by NICNAS in 2011. NICNAS has deferred development of regulatory options for notification and assessment of nanoforms of existing chemicals while a broader review of the role and function of NICNAS is underway. More information on NICNAS's approach to regulating industrial nanomaterials is available at: http://www.nicnas.gov.au/communications/issues/nanomaterials-nanotechnology/our-approach-to-regulating-industrial-nanomaterials

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

a. Preparation of Safety Data Sheets for Hazardous Chemicals and

b. Labelling of Workplace Hazardous Chemicals,

available at:

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

Safe Work Australia published a report by NICNAS on *Health Hazard Assessment and Classification of Carbon Nanotubes*, together with an associated information sheet, in October 2012. Classification of carbon nanotubes was undertaken against all health hazard endpoints according to both the 3rd Revised Edition of the GHS and Australia's previous criteria, the *Approved criteria for classifying hazardous substances*, which is being replaced by the GHS criteria but may still be used during the regulatory transition period.

Unless product-specific information indicates otherwise, it is recommended that carbon nanotubes are classified as hazardous chemicals in the workplace, with the following GHS classifications:

a. Carcinogenicity: Category 2

b. Specific target organ toxicity - repeated exposure: Category 2

The full report and information sheet are available at:

http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/human-health-hazard-assessment-and-classification-of-carbon-nanotubes

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is comprehensively reviewing its regulatory arrangements to ensure they remain adequate to assess and manage the risks that may be associated with agricultural and veterinary (agvet) chemicals and chemical products containing engineered nanomaterials. In this regard the APVMA is committed to ongoing engagement with registrants, researchers, regulators and policy makers throughout Australia and internationally.

The APVMA has commissioned the development of a series of 'reflection papers' on agvet nanomaterials. The papers will address potential applications of nanotechnology in the agriculture and animal husbandry sectors, definitions, the characterisation of nanomaterials, nanometrology, the manufacture of agvet nanomaterials and formulated nanoproducts, and the potential impact of agvet nanomaterials on human health and the environment. The objective of the 'reflection papers' is to highlight regulatory considerations, not to stipulate data requirements, and represent a first but important step in the development of an APVMA regulatory framework for agvet nanomaterials. The 'reflection papers' will be published in 2014.

Information on any developments related to good practice documents

Australia's Committee on Nanotechnology (NT-001), established under the national standards authority, Standards Australia, continues to provide input to the International Organization for Standardization (ISO) Nanotechnology Committee (TC229) for the development of international nanotechnology standards and good practice documents. NT-001 is also represented on the ISO TC229 HSE Working Group, which coordinates the development of international HSE related nanotechnology standards, and on two project groups:

Nanotechnologies – Guidance on the voluntary labeling of consumer products containing manufactured nano-objects

General framework for the development of occupational exposure limits for nano-objects and their aggregates and agglomerates

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

The Department of the Environment has commissioned a program of work regarding the environmental fate of nanomaterials. A method to quantify levels of C_{60} in complex environmental matrices including soils and sediments was developed. Methods have also been developed for measuring the environmental partitioning of Ag, CeO_2 and carbon nanotubes. Subsequently, more detailed experiments have been conducted to examine the fate of C_{60} fullerenes in biosolids mixed with soil. Other research has investigated whether combustion of CeO_2 in diesel fuel alters physico-chemical properties which are important for partitioning and solubility. These research projects are complete and a number of published papers are available, and the reports from all projects are planned to be published during 2014.

A Nanotechnology Work Health and Safety Program has been implemented by Safe Work Australia. The program was Australia-focused, and also contributed to global efforts on nanotechnology work health and safety. More information about the program is available at:

http://www.safeworkaustralia.gov.au/sites/swa/whs-information/nanotechnology/pages/nanotechnology

Eighteen projects have been commissioned by Safe Work Australia to progress work in key areas. Fourteen research reports have been published to date, with the following reports published since the 10th WPMN:

Development of an automated high-throughput screening procedure for nanomaterials genotoxicity assessment

Evaluation of potential safety hazards associated with the use of engineered nanomaterials

Investigating the emissions of nanomaterials from composites and other solid articles during machining processes

http://www.safeworkaustralia.gov.au/sites/swa/whs-information/nanotechnology/nano-publications/pages/nanopublications

The work program is supported by two reference groups, the Nanotechnology Work Health and Safety Expert Working Group and the Nanotechnology Work Health and Safety Measurement Reference Group. Information on both of these groups is available at:

http://www.safeworkaustralia.gov.au/sites/swa/whs-information/nanotechnology/pages/nanotechnology

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

http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/at201008workhealthandsafetyassessmenttool

Focus is being placed on developing training and guidance materials and a guidance document on *Safe handling and use of carbon nanotubes* was published in March 2012. A Nanotechnology work health and safety training course is currently being developed.

The Commonwealth Scientific and Industrial Research Organisation (CSIRO) has published various scientific papers in 2013 addressing the following human health and/ or environmental safety aspects of nanomaterials:

a) **Fate and transformations of manufactured nanoparticles in waste water treatment plants and aquatic and terrestrial environments, including impact on microbial communities**:

Behavior of fullerenes (C60) in the terrestrial environment: potential release of fullerenes from biosolid-amended soils. Navarro et al (2013) Journal of Hazardous Materials, 262, 496-503. http://www.sciencedirect.com/science/article/pii/S0304389413005876

The impact of size on the fate and toxicity of nanoparticulate silver in aquatic systems. Angel et al (2013) Chemosphere, 93, 359-365.

http://www.sciencedirect.com/science/article/pii/S0045653513007212

Transformation of PVP coated silver nanoparticles in a simulated wastewater treatment process and the effect on microbial communities. Doolette et al (2013) Chemistry Central Journal, 7, 46.

http://link.springer.com/article/10.1186/1752-153X-7-46#

b) CeO2 as a diesel fuel catalyst:

Characterization and ecological risk assessment of nanoparticulate CeO2 as a diesel fuel catalyst. Batley et al. (2013) Environmental Toxicology and Chemistry, 32, 1896-1905. http://onlinelibrary.wiley.com/doi/10.1002/etc.2246/full

c) QSARs – developing computational models to predict the toxicity of nanoparticles based on the physical-chemical properties:

Applying quantitative structure–activity relationship approaches to nanotoxicology: Current status and future potential. Winkler et al. (2013) Toxicology 313, 15-23. Review. http://www.sciencedirect.com/science/article/pii/S0300483X12003976

d) Dermal absorption of Zn from sunscreens containing ZnO nanoparticles applied to humans and mice:

An inter-laboratory comparison of high precision stable isotope ratio measurements for nanoparticle tracing in biological samples. Larner et al. DOI: **10.1039/C3JA50322D** (Paper) ***J. Anal. At. Spectrom.*** (2014), Advance Article.

http://pubs.rsc.org/EN/content/articlehtml/2013/ja/c3ja50322d

Dermal absorption and short-term biological impact in hairless mice from sunscreens containing zinc oxide nano- or larger particles. Osmond-McLeod et al. Posted online on November 25, 2013. (doi:10.3109/17435390.2013.855832).
http://informahealthcare.com/doi/abs/10.3109/17435390.2013.855832

NICNAS continues to progress the technical component of its overall nanotechnology strategy. Technical activities are aligned as appropriate with national and international developments in this area, more information is available at: http://www.nicnas.gov.au/communications/issues/nanomaterials-nanotechnology/nicnas-technical-activities-in-nanomaterials

Information on public/ stakeholder consultation

NICNAS continues to hold Australia-wide stakeholder education sessions which included updates on administrative arrangements for new industrial nanomaterials.

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

Australia is leading the SG8 project on measurement of nanomaterials in air. The work is being undertaken by Safe Work Australia, Workplace Health and Safety Queensland and Queensland University of Technology and the report will be provided to the 12th WPMN to request declassification.

AUSTRIA

Highlights

- The **implementation report on the Austrian Nanotechnology Action plan** including an English translation has been finalised after a public consultation see http://nanoinformation.at/oesterreichischer-aktionsplan/umsetzungsbericht-2012.html

- As a measure of implementation of the Austrian Nanotechnology Action plan the Austrian **Nanoinformation Commission** was founded by the federal Minister of Health to provide expertise regarding nanotechnology for consumers and decision makers. This commission comprises representatives from several ministries, agencies, NGOs, research institutions, industry and other experts. This work will also include the update of the **website on nanotechnology for the public** including chances and risks of nanomaterials:
  http://www.nanoinformation.at

- As another measure of implementation of the Austrian Nanotechnology Action plan four projects from two calls of the national **NANO Environment Health and Safety** programme (http://www.ffg.at/nano-ehs) are conducted (see bullet 9). A third call was launched in June 2013. This EHS programme is owned by the Federal Ministry of Agriculture, Forestry, Environment and Water Management and Federal Ministry of Federal Ministry for Transport, Innovation and Technology and is handled by the FFG - Austrian Research Promotion Agency.

The Austrian Nanotechnology Action plan (adopted on 2nd March 2010 by the Austrian government, an English and German version can be downloaded on

http://www.lebensministerium.at/umwelt/chemikalien/nanotechnologie/nano-aktionsplan.html), includes about 50 measures which will be implemented by Austrian stakeholders on national, EU and international level. The action plan was lead-managed by the Federal Ministry of Agriculture, Forestry, Environment and Water Management (BMLFUW, contact: Renate.Paumann@lebensministerium.at) and elaborated based on a broad stakeholder involvement (see also chapter 7).

Information on any developments related to good practice documents

The central labour inspectorate (part of the Federal Ministry of Labour, Social Affairs and Consumer Protection) mandated a project investigating Austrian nano-workplaces to get a preliminary overview on different **uses and risk management applied**. Based on this report a **guidance in German language to ensure safe and healthy workplaces regarding nanomaterials** was developed and updated end of 2013: "Leitfaden für das Risikomanagement beim Umgang mit Nanomaterialien am Arbeitsplatz". An accompanying folder summarises the results. The guidance is targeting small and medium enterprises and shall support the central labour inspectorate in advising enterprises dealing with nanomaterials.

(http://www.arbeitsinspektion.gv.at/AI/Arbeitsstoffe/nano/default.htm.)

In the committee 052 „Occupational health, ergonomics, safety techniques" the working group

052.73 with the titel "Nanotechnologies and Nanomaterials" was established: The aim is the compilation, collection and distribution of international standardisation documents (CEN and ISO; lead-managed by Austrian Standards Institute).

The Workers' Compensation Board in co-operation with the central labour inspectorate developed a document in German language: Merkblatt M 310 Nanotechnologien Arbeits- und Gesundheitsschutz: http://www.auva.at/mediaDB/761748_M310.pdf.

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

At Medical University of Graz, **nanotoxicology studies** (cytotoxicity, genotoxicity, impact on macrophage function, intracellular accumulation in lysosoms and cellular effects after long-term exposure; in-vitro model for exposure to nanoparticles in aerosols generated from suspensions) regarding **CNT (SW + MW),** and polystyrene are performed (contact: Eleonore Fröhlich).=

A multi-parameter cell chip for **high-sensitive nanotoxicology assays** is currently developed by AIT (Austrian Institute of Technology GmbH.)

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

The FP7 project **NanoDefine** develops analytical tools and methods for the categorization of materials according to the recommendation for a definition of nanomaterials. The methods and decision supprt tools

shall enable the grouping of materails as being nano or not. The Department for Environmental Geosciences, University Vienna (contact: Frank von der Kammer) is involved in several workpackages. The central workpackage on confirmatory methods is lead by UNIVIE.

The project Develoment of a Decision Support Tool for the Investigation of the Environmental Behavior of Nanomaterials on the Basis of their Dispersion Stability and Solubility as a Function of Enviromental Conditions funded by the German Environmental Protection Agency and aims at developing the scientific basis and experimental methods to determine the dispersabiltiy and dispersion stability in the context of the OECD WPNM testing framework. This project is lead by the Department for Environmental Geosciences, University Vienna (contact: Frank von der Kammer).

NanoTOES (Nanotechnology: Training Of Experts in Safety), a Network of Initial Training (ITN) in the framework of FP7 coordinated by Albert Duschl from the University of Salzburg aims at development and validation of methods for examination of possible nanorisks for health and environment coupled with research for a better understanding of the involved mechanisms. Furthermore it will focus on the education of young academics in the field of nanosafety and will be a European best practice" example in this respect. University of Salzburg´s main specialist work will be research on the effects of nanomaterials on the immune system.

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

In the FP7 project **MARINA** Austrian partners from University of Salzburg (contact: Christian Huber) and from Department for Environmental Geosciences, University Vienna (contact: Frank von der Kammer) are involved in several workpackages. UNIVIE is involved in material characterization and developing analytical methods for the **quantification of ENPs in environmental samples**. University of Salzburg plans to investigate nanoparticle **effects on the proteome level**.

In the FP7 project **NanoLyse** the Department for Environmental Geosciences, University Vienna (UNIVIE, contact: Frank von der Kammer) is leading the workpackage for the **sample preparation and quantification of inorganic nanoparticles in food**. UNIVIE is responsible member of the project management board and also involved in the development of organic nanoparticle analysis (www.nanolyse.eu).

The **European Center for Nanotoxicology** (EURO-NanoTOX) is a topic-oriented platform which is co-ordinated by the BioNanoNet Forschungsgesellschaft mbH. EURO-NanoTOX develops nanosafety strategies and serves as an international node for nanotoxicology. See: http://www.euro-nanotox.eu/

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

The FP7 CSA NanoEIS (www.nanoeis.eu) is coordinated by University of Salzburg. The focus lies on enhancement of education in Europe including nanosafety.

Information on public/ stakeholder consultation

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

BioNanoNet is partner in **NanoDiode** project focussing on educational activities specialising in the knowledge transfer of relevant nanotech information on several educational levels (secondary schools, universities, research facilities, etc). BioNanoNet will organize several citizen dialogues and in-depth interviews to reach the goal of developing an innovative outreach and dialogue on responsible nanotechnologies in EU civil society.

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

The FP7 project **SUN - Sustainable Nanotechnologies** develops strategies and tools for a combined risk assessment and life cycle assessment to develop a user-friendly, versatile software-based decision support system (DSS) for practical use by industries and regulators. The Department for Environmental Geosciences, University Vienna (contact: Frank von der Kammer) is involved in the development of techniques to detect and analyse nanoparticles released from products and investigation on the life cycle induced modifications of nanoparticles and how these changes affect their environmental behaviour.

University of Vienna (contact: Thilo Hofmann) is WP leader in FP7 **NANOREM**: Taking NANOtechnological REMediation Processes from Lab Scale to End User Applications for the Restoration of a Clean Environment.

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

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

Information on development related to exposure measurement and exposure mitigation

The project **DetectNano** –aims at the development of quantification methods for nano-metal oxides (TiO2, CeO2) in surface water. The project is conducted by University of Vienna (contact: Frank von der Kammer) and sponsored by the national research program NANO Environment, Health and Safety.

"Nanoproducts - Identification and Expoure" (**NanoProdEx**) is a research project (lead: BioNanoNet Forschungsgesellschaft; partners: Environment Agency Austria, Montanuniversität Leoben, Mondi Uncoated Kraft & Fine Paper GmbH) within the national research program NANO Environment, Health and Safety: In this project, consumer goods that are produced or used in Austria have been investigated in terms of the nanomaterials they contain. A questionnaire and face-to-face-interviews have been conducted in order to prepare realistic exposure scenarios, which also take the chemical´s legislation REACH into account (see http://cms.bionanonet.at/content/view/403/22/lang,english/).

The project "**Nano-Metals in food contact materials**" (lead: Austrian Agency for Health and Food Safety (AGES), partner University of Vienna) aims at developing methods for detection and quantification of nanomaterials using food simulants (sponsored by the national research program NANO Environment, Health and Safety).

In the project **Nano-DESTINARA** research on sewage treatment plants regarding nanoparticles (TiO_2, CeO_2, Ag, fullerenes) will be performed by Environment Agency Austria and Vienna University of Technology (sponsored by the national research program NANO Environment, Health and Safety).

University of Vienna (contact: Frank von der Kammer): WG-4- lead in "Engineered Nanoparticles in the Environment" of the **NORMAN Network** (Network of reference laboratories for monitoring of emerging substances) and participation in **COST Action ES1205**: The transfer of engineered nanomaterials from wastewater treatment & stormwater to rivers.

BioNanoNet Forschungsgesellschaft mbH is partner in the project **NANOFORCE** "Nanotechnology for Chemical Enterprises – how to link scientific knowledge to the business in the Central Europe"; and responsible for the WP "How to foster the responsible use of nanotech and manage associated risks" (see: http://www.nanoforceproject.eu/). The theme of responsible use of nanomaterials and associated risk management as on the topics of NANOFORCE Project is going to the final phase being able to publish Safety Data Sheets for TiO2, nanoAg and nano ZnO nanoparticles and Exposure Scenarios. Furthermore the Guideline on Responsible Use and Production of Nanomaterials as well as the White Book of Recommendations will be available soon for public download on www.nanoforceproject.eu

CANADA

Highlights

The following activities have taken place since the 11th meeting of the Organization for Economic Cooperation and Development (OECD) Working Party on Manufactured Nanomaterials (WPMN) in February 2013:

- Under the Canada-United States Regulatory Cooperation Council (RCC), Canada and the United States continue to work together to better align regulatory approaches, where possible. A joint Canada-United States RCC focused technical stakeholder workshop was held in March 2013. A final workshop to report on results of the initiative will be held in January 2014. Members of the WPMN are invited to attend. .

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.

Regulatory Cooperation Council Nanotechnology Initiative

Following the creation of the Canada-United States Regulatory Cooperation Council (RCC) to better align the two countries' regulatory approaches, the heads of the two countries released a Joint Action Plan on Regulatory Cooperation that included regulatory approaches to nanomaterials (http://actionplan.gc.ca/en/page/rcc-ccr/joint-action-plan-canada-united-states-regulatory).

The goal of the RCC Nanotechnology Work Plan is to promote the development of consistent regulatory approaches for nanomaterials. This work is considered within the current Canadian and US regulatory frameworks.

As part of the RCC Nanotechnology Work Plan (http://actionplan.gc.ca/en/page/rcc-ccr/nanotechnology-work-plan) and to better inform risk assessments and risk management of nanomaterials, Canada and the US have undertaken joint activities and successfully increased our knowledge of commercial uses of nanomaterials in the two countries; developed a classification scheme based on similarities in chemical composition to increase the utilization of read-across/analogue and increase consistency in additional information requests; and developed common risk assessment frameworks and assumptions to inform joint best practices. The final documents, which have been reviewed by a stakeholder technical team, on these topics will be shared at the final RCC Nanotechnology Initiative Workshop on January 14th, 2014 in Washington, D.C., United States. A webinar will be available for stakeholders who cannot attend the Workshop.

Information on any Risk Assessment Decisions.

Industrial or commercial chemicals: Since February 2013, an additional four notifications have been received for nano-related assessment under the New Substances Notification Regulations (Chemicals and Polymers) of the Canadian Environmental Protection Act, 1999 (CEPA 1999). The Significant New Activity (SNAc) provisions of CEPA 1999 have been applied to three submissions where additional information is required prior to manufacture and import of the substances at the nanoscale or in other nanoscale applications.

Developments Related to Good Practice Documents.

A. The Canadian Standards Association (CSA) has drafted a national standard, CSA Z5100 "Cellulosic Nanomaterials – Test Methods for Characterization". This standard is intended to build on Canada's leading role in nanocellulose production and R&D. As follow-up, Canada will be seeking approval of this standard at the international level by submitting it as a New Work Item Proposal (NWIP) within ISO/TC229.

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

C. Canada is the co-lead (together with the US) for the ISO TC 229 Task Group 1 (TG1) on Nomenclature. This Task Group includes active representation from ISO member states and includes regulators, industry, and academia, as well as observers from the International Union of Pure and Applied Chemistry (IUPAC). A liaison between ISO TC 229 and IUPAC has been secured and a subcommittee has been formed to pursue work on developing nomenclature. Joint IUPAC-ISO work groups have been created and work is starting on the development of nomenclature systems. Canada is providing expertise for the development of a nomenclature system for nanometals.

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

Scientific research

Health Canada is conducting research to investigate the effects of surface-modified silica nanoparticles. The aim of these projects is to: (1) study the importance of size and surface functionalization; and (2) to provide a genotoxic profile and to identify mechanistic relationships of particle properties to elicited toxic responses. These silica nanoparticles have been modified to most closely resemble those for which notifications for assessment have been received by the New Substances Program under CEPA 1999.

Environment Canada continues to support various academic research projects. This research has to date included studying fate and effects of nanomaterials in the aquatic, sediment, and soil compartments. Projects supported in 2012 and 2013 are aimed at studying the transformations and removal efficiencies of nanoparticles in wastewater treatment processes. This research is meant to directly feed into risk assessments of nanomaterials by: (1) informing on transformation and removal efficiencies to improve calculation of environmental concentrations; and (2) informing on the development of predictive models.

Environment Canada has also continued to foster excellence within its own department by conducting research on the fate of nanomaterials in aquatic, soil, sediment, and air compartments. This includes a research project, conducted with academic partners and Health Canada, which currently studies transformations of carbon nanotubes in the atmosphere. The objective of this study is to link observed physical and chemical changes to these nanotubes as a result of atmospheric processes, to broad changes in human and aquatic toxicity. The research is contributing to the OECD WPMN Sponsorship program in addition to risk assessments within Canada.

Market research

Canada is working with provincial nanotechnology associations and other sector contacts in order to gain a broader understanding of the nanotechnology marketplace. In 2013, NanoQuebec was engaged to provide information on research and industrial activities taking place in that province. Work is also currently underway to gather information on industrial activities and market trends in Ontario and Alberta, via NanoOntario and an independent consultant, respectively. Canada hopes to continue working with other provinces to gain a more complete understanding of the nanomaterials being manufactured, imported and used in Canada.

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

The second ***Workshop on the Human Health and Environmental Risk Assessment of Nanomaterials*** was held in Ottawa (Canada) on October 3-4, 2013. The purpose of this Workshop was to provide a small-meeting forum for evaluators and regulators to exchange their experiences on the assessment of nanomaterials (NMs).

The specific objectives of that two-day workshop were:

- To become acquainted with the state of the science of *in vitro* / high-throughput testing methodologies for nanomaterials,
- To discuss the range of applicability of these tests to different classes of nanomaterials,
- To discuss the robustness of these tests for extrapolation to *in vivo* effects, *and*
- To identify and prioritize areas of research needs and cooperation.

The event featured presentations from five experts followed by facilitated discussions centred on the specific objectives of the workshop.

A workshop report is in preparation and will be shared with participants when completed.

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

Canada, along with Government agencies in the United States, Non-Governmental Organizations and Industry, is engaged in a project led by the International Life Sciences Institute (ILSI) to look at releases of nanomaterials from industrial consumer matrices (e.g., coatings). The objectives of this project are to develop information on different test methodologies and nanomaterials used to study releases from matrices, and to develop standard methodologies (validated through interlaboratory testing) to quantify releases of nanomaterials from a matrix. At present, Technical Groups have published two of the three white papers (the third paper is planned to be submitted shortly for peer-review) to inform on the present state pertaining to multi-walled carbon nanotubes (MWCNTs) in polymer matrices. In addition, a state of the science report is being drafted to provide recommendations and direction for the laboratory testing stage. After selecting the nanomaterial system and relevant test methods, this project is now considering approaches to begin lab testing. Additional information can be found at http://www.ilsi.org/ResearchFoundation/Pages/NanoRelease1.aspx.

Under the OECD Working Party on Resource Productivity and Waste (WPRPW), the expert group on waste containing nanomaterials is currently developing four reflection papers on the fate of nanomaterials in waste treatment operations. Canada is preparing the paper on the fate of nanomaterials in landfills; Switzerland on the recycling of waste containing nanomaterials; Germany on the incineration of waste containing nanomaterials; and France on nanomaterials in wastewater treatment sludge. The purpose of these papers is to provide an overview of the existing knowledge on the behaviour of nanomaterials during disposal operations and identify the information gaps. At the fourth meeting of the WPRPW that took place on 12-14 November 2013, three of the four reflection papers were considered by members. Canada's paper

was not discussed at this meeting but will be circulated for comments in January 2014 for consideration at the next WPRPW meeting in November 2014.

Also, refer to Section 5 (wastewater treatment processes).

Information on development related to exposure measurement and exposure mitigation.

Canada has been an active contributor in the NanoLyse project, a European collaborative research project aimed at developing methods to detect different types of nanomaterials in food. The success of this project has led to a phase II follow-up project "NanoDefined" (2013), which focuses on the development of analytical methods for nanoparticles, specifically exploring screening and quantitative methods and to produce candidate reference materials.

Canada is participating in the International Life Sciences (ILSI) NanoRelease Food Additive project. This international, multi-stakeholder project aims to identify, evaluate and develop scientific methods for nanomaterial detection which can be used in risk assessment. The first phase of the project began in 2012 and involves the drafting of state-of-the-science white papers on detection methods for nanomaterials in food and in the gastrointestinal tract. Health Canada held a joint workshop on the NanoRelease and the EU NanoLyse project in Ottawa on September 25 and 26, 2013 titled "Advances in the Determination of Engineered Nano-materials in Complex Matrices and their Application to Toxicology and Regulatory Science." to discuss project updates, identify synergies between the two projects and develop priorities moving forward. More information on the ILSI project can be found at: http://www.ilsi.org/ResearchFoundation/RSIA/Pages/FoodAdditiveMainPage.aspx

Additional Information

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

DENMARK

Highlights

- Agreement of Amendment Act to the Danish Chemicals Act with the purpose of establishing the necessary legislation for a mandatory national nano product database
- Proposal and public hearing of Statutory order on a national register of mixtures and articles that contain nanomaterials as well as the requirement for manufacturers and importers to report to the register.
- Submissions of projects under the national action plan for getting better control of nanomaterials: Literature reviews of absorption of nanomaterials by dermal and oral exposure.

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 2011 the Danish Government has allocated funding (approx 3,2 mio € from 2012-15) for establishing activities aimed at gaining clarity about the consequences for consumers and the environment due to the use of nanomaterials. The activities include the establishment of a database on products with nanomaterials. In October 2012 an Amendment Act to the Danish Chemicals Act was proposed with the purpose of establishing the necessary legislation for a mandatory national nano product database. After a public hearing, this proposal was presented in the national parliament in December 2012 and the first debate took place in the parliament on 29th of January. The amendment entered into force on the 12th of March 2013.

Following this amendment a proposal for a statutory order on a national register of mixtures and articles that contain nanomaterials as well as the requirement for manufacturers and importers to report to the register was submitted for public hearing in June 2013. An updated version taking comments from the public hearing into consideration was notified to the EU-commission in accordance with Directive 98/34/EF. In this version of the order it is expected that the register will enter into force in March 2014. The first registration year is expected to be from 1st of May 2014 to 30th of april 2015. A guidance for importers and producers of nanoproducts in relation to the register is expected to be published in the spring 2014.

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

Under the national action plan for getting better control of nanomaterials The Danish Environmental Protection Agency (DK-EPA) has submitted two projects on dermal and oral exposure of nanomaterials.

http://www.mst.dk/Publikationer/Publications/2013/October/978-87-93026.htm

http://www.mst.dk/NR/exeres/45B743E3-491E-4C68-A431-241F6994E7B8.htm

Under the national action plan for getting better control of nanomaterials The Danish Environmental Protection Agency (DK-EPA) has initiated the project "Nanomaterials - Occurrence and effects in the Danish Environment". The project has a budget of 2,495,000 DKR (approx. 350,000 €) and is planned to be finished on first of May 2015. Further a project on Consumer exposure and risk assessment of nanomaterials on the Danish market (of 2,997,000. DKR; approx. 425.000 €) was initiated in August 2014. This project is expected to be finalized in March 2015. Further the following projects are expected to be finalized in January 2014:

- Supplemental survey of nanoproducts in cosmetics, pesticides, food, food contact materials, medicinal equipment and other groups not covered by the national product-database which is under preparation in Denmark.

- Occurrence and risk considerations regarding products containing nanosized anatase titanium dioxide.

The national center for nanosafety has been established at the National Research Centre for the Working Environment. The Centre will perform research and collect knowledge from the scientific literature on the potential adverse effects of exposure to engineered nanoparticles and nanomaterials. The Centre's research will cover the following areas:

- Physico-chemical characterization of nanoparticles
- Measurement and modeling of exposures to nanoparticles
- Studies of the toxicological properties of inhaled nanoparticles – including studies of the underlying mechanisms of action
- Development of methods for risk assessment and risk management
- The use of these various, specific exposure scenarios.

The Danish EPA published in June 2012 the report Assessment of nanosilver in textiles on the Danish market. The survey identified 94 textile products marketed in Denmark via retail, internet shops or other means where there could be suspicion of content of nanosilver. Since no nanosilver was found in any of the products, the results of this survey did not support the hypothesis that nanosilver treated textiles are widely used in Denmark. Further analyses of 16 selected products revealed silver content in 15 of the products. Studies of migration of silver to artificial saliva or sweat and during washing revealed a varying release of silver that could be substantial (up to 84% during washing). Based on the existing data and the survey results, there appear to be no risk for health effects or environmental effects.

http://www2.mst.dk/Udgiv/publications/2012/06/978-87-92903-31-0.pdf

Several Danish research-groups are participating in the European project NANoREG.

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

The Danish Environmental Protection Agency has submitted a project "Information Requirements for nanomaterials - IRNANO". In this project a proposal for nanomaterial information requirements under the REACH-regulation is developed. The proposal is developed based on a review of existing scientific projects/reports prepared by various expert groups, associations and authorities.

http://www.mst.dk/Publikationer/Publications/2013/March/978-87-92903-51-8.htm

FINLAND

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

Finland is a member of the EU and accordingly follows the EU regulations. Finland and Finnish Safety and Chemicals Agency (Tukes) as Competent Authority for chemicals, plant production products and biocides is actively participating in REACH competent authority (CARACAL) subgroup on nanomaterials (CASG-nano) and also ECHa wg for nanomaterials including GAARN work on already registered NMs, Tukes had been involved in the development of technical guidance how to apply the regulation on nanomaterials.. Similarly the work on novel foods and cosmetics is followed at EU level.

The Ministry of Health and Social Affairs has established an official discussion forum on nanotechnology in order to follow and participate in the national and international discussions.

Information on Developments Related to Good Practice Documents

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

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

The alternative in vitro test methods are used in the several research projects among the in vivo tests.

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

Tukes and Finnish Institute of Occupational Health are participating in the FP7 project NANoREG by testing and assessing nanofibril cellulose, and regulatory issues.

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

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

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

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

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

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

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

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

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

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

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

- European Network on the Health and Environmental Impact of Nanomaterials

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

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

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

Finnish Environment Institute (SYKE) has started Academy of Finland project ”Nanosafety on trial(s): Understanding politics and potentials of product oriented environmental policies” that analyses how environmental and safety concerns are integrated into the development and design of nanocellulose products and production. The project aims to deepen our understanding of industry - government interaction and provides means to assess new regulatory approaches in the fields of nanotechnology and -materials and potentials of product-oriented environmental policy in general.

The SYKE laboratory of the has studied on aquatic exposure concentrating especially on nanomaterial characterization, fate and effects. The research has been funded by several national foundations.

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

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

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

FRANCE

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

Le gouvernement français a rendu public le premier bilan du dispositif national de déclaration des substances à l'état nanoparticulaire fabriquées, distribuées ou importées en 2012. Au 30 juin 2013, date limite pour déclarer les données 2012, plus de 930 déclarants ont réalisé plus de 3400 déclarations, représentant 500 000 tonnes de substances mises sur le marché en France en 2012. Ce bilan, consultable sur le site internet du ministère de l'Ecologie, présente des données générales sur les déclarations et recense les noms chimiques et les usages déclarés ainsi que les bandes de tonnage correspondantes, agrégées par substance.

Cette obligation de déclaration, pionnière en Europe, a pour objectifs de mieux connaître les substances mises sur le marché national, leurs volumes et leurs usages, de disposer d'une traçabilité des filières d'utilisation, d'informer le public et les travailleurs, et de collecter auprès des déclarants les informations disponibles sur les propriétés toxicologiques et écotoxicologiques de ces substances. Ces informations permettront de guider les travaux de recherche et d'expertise sur les risques éventuels et les mesures de gestion adaptées, notamment en faveur des populations les plus sensibles.**Developments related to voluntary or stewardship schemes**

Information on developments related to good practice documents

- Standardisation (normalisation) : publication d'un document ISO « control banding » piloté par la France (CEA) sur la base de travaux de l'Anses. Développement d'un documents Iso pilotés par la France (LNE) : L'étiquetage volontaire des produits contenant des nano –objets. Developpement d'un document CEN sur la nano-responsabilité piloté par la France aussi (ministère de la santé) sur la base de travaux de l' INERIS.

- Dans le cadre du mandat (M461) de la Commission européenne invitant les organismes européens de normalisation - CEN, CENELEC et ETSI - à élaborer un ensemble de normes concernant les nanomatériaux, l'INERIS est depuis début 2013 animateur du CEN TC 352 « nanotechnologies » WG1 « detection, identification … ». L'INERIS y a également pris en charge le pilotage du projet de rédaction d'une spécification technique sur l'explosibilité et l'inflammabilité de nano-poudres.

- A la demande du CGDD et dans le cadre de la récente rencontre du groupe de travail sur la productivité des ressources et les déchets de l'OCDE, l'INERIS et le CEREGE ont contribué à la rédaction de 4 documents de synthèse sur les connaissances relatives à l'incinération de nanomatériaux, la mise en décharge de nanomatériaux, le recyclage de nanomatériaux et enfin la présence de nanomatériaux dans les unités de traitements des eaux et les boues résiduelles. Un groupe de travail s'est constitué, en charge de consolider ces documents pour une diffusion fin 2014.

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

- L'action conjointe européenne Nanogenotox a pour but d'évaluer la sécurité des nanomatériaux manufacturés en caractérisant leur génotoxicité potentielle au moyen d'une méthode rigoureuse. Cette action s'est terminée en Mars 2013 (après 3 ans) et les principales conclusions de ce projet sont les suivantes:

- Les nanomateriaux d'une même famille ne peuvent être considérés comme une mono-substance (différence en caractérisions, in vivo et in vitro)

- Pour identifier le danger de ces NMs, les lignes directrices de l'OCDE existantes sont à adapter en fonction des routes d'expositions (lignée cellulaire) et il est également nécessaire d'intégrer de la toxicocinétique pour choisir les organes cibles.

- Les NMs étudiés n'ont pas montré une génotoxicité forte *in vivo* et *in vitro*, néanmoins des effets génotoxiques ont été détectés même à faible dose.

Tous les documents rapports, protocols, presentations sont disponibles sur le site http:// www.nanogenotox.eu.

- Actions menées sur la caractérisation des dangers écotoxicologiques de deux nanoparticules de titane identifiées dans le cadre du sponsorship programme (NM 101 et NM 104) en considérant l'essai d'inhibition de la croissance des microalgues d'eau douce (OCDE 201). Les principales conclusions des ces travaux sont les suivantes :

- Mise en évidence de l'influence de la méthode d'exposition des algues sur les résultats obtenus avec cet essai (flaconnage et mode d'agitation). Il convient pour cet essai de définir un protocole d'exposition pertinent et optimal pour les nanoparticules et donc de fixer dans la ligne directrice, les conditions acceptables pour ce type de composés.

- Sensibilité différente de la souche d'algues (*Pseudokirchneriella subcapitata*) en fonction de la nanoparticule de titane testée.

- Mise en évidence de limitations concernant les méthodes de comptage de la concentration algale au cours de l'essai.

- Aux USA au moins deux consortiums qui travaillent sur l'évaluation des risques : CEINT (Center for the Environmental Implications of NanoTechnology) et UC-CEINT avec des périmètres différents : UC-CEINT, effets sur les organismes vivants ; CEINT, prise en compte tout le cycle de vie environnementale et les transformations possibles qui affecteraient les effets sur le long terme ainsi que l'exposition.

Un axe de recherche est particulièrement partagé entre certains membres de SERENADE et CEINT la fin de vie et plus particulièrement le devenir des nanomatériaux dans les boues de station d'épuration (transformations par oxydo-réduction, suivie de formation de nouvelles phases ….) jusqu'aux applications en agriculture et les transformations et transferts vers les plantes (blés, pois, tabac…).

Au sein du labex SERENADE l'exposition est un des axes de recherche important. Un travail associant l'INERIS, CALCIA et le CEREGE concerne l'altération des ciments contenant des nanoparticules de TiO2 et leur relarguage en analysant et modélisant l'hydratation et els changements texturaux dans la zone d'altération. Cela se fait grâce aussi à la plateforme ARDEVIE d'Aix-en-Provence et l'Equipex NanoID en particulier avec les tomographes X (Micro et Nano). Cette recherche devrait aboutir à une meilleure connaissance des flux de TiO2 via l'altération des bétons par l'eau de pluie et de la complexité minéralogique des phases relarguées et leur stabilité.

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

- Dans le projet européen NANoREG . L'INRS est principalement impliqué sur les aspects de toxicologie *in vivo*, les expositions professionnelles et la protection collective.

- Le projet MARINA vise à proposer des méthodes et outils de références pour l'évaluation des risques liés aux nanoparticules aux instances normatives européennes et internationales. Le consortium MARINA est composé d'acteurs industriels majeurs dans le domaine des nanotechnologies, des scientifiques de haut niveau participant à 10 projets européens majeurs et des participants de Chine et de Russie. L'INERIS est impliqué notamment sur l'étude de la dispersion de nanoparticules en champ proche dans un espace confiné mais aussi sur l'étude de l'inflammabilité & explosivité de nanoparticules. Les résultats des études vont notamment permettre de construire le projet de « spécification technique » du CEN TC 352 sur ce même sujet.

- Le projet SANOWORK vise à développer et tester des stratégies de maîtrise des risques d'exposition de procédés de fabrication, développer une méthode pour évaluer l'exposition des travailleurs (efficacité des mesures techniques et organisationnelles existantes ou proposées pour réduire le risque d'exposition, identifier les scénarios d'exposition chronique et accidentelle et enfin d'évaluer le rapport coût / efficacité des stratégies proposées sur la base des résultats d'analyse des risques, des performances des matériaux et d'assurer le transfert des connaissances aux assureurs. Plusieurs campagnes de mesures auprès de partenaire Espagnol et Italien ont été réalisées en 2013, ce afin de finaliser un guide sur la stratégie de mise en œuvre de moyens et méthodes de caractérisation des expositions.

- Dans le cadre d'un mandat (M461) de la Commission européenne invitant les organismes européens de normalisation - CEN, CENELEC et ETSI - à élaborer un ensemble de normes concernant les nanomatériaux, l'INRS participe à quatre projets en lien avec l'évaluation des expositions. Tous les projets comprennent des recherches dites prénormatives ainsi que la rédaction de documents normatifs. Ces travaux seront réalisés notamment pour répondre aux interrogations du groupe de travail CEN/TC 137 WG3 consacré à « *L'évaluation de l'exposition aux agents chimiques et biologiques sur les lieux de travail – Les aérosols* ». Ayant démarré en janvier 2013, ils se poursuivront jusqu'en 2019.Plus particulièrement, l'INRS coordonne l'ensemble des actions relatives à la caractérisation de la pulvérulence des nanomatériaux en poudre, en partenariat avec les organismes polonais (CIOP), anglais (HSL), allemand (IGF), danois (NRCWE) et néerlandais (TNO). L'INRS apporte également sa contribution sur les sujets relevant de la mesure des concentrations en nombre, masse et surface des aérosols. Par ailleurs, l'INRS participe au développement d'une stratégie harmonisée d'évaluation des expositions.

- Un projet ANR a été proposé avec SUEZ, SOLVAY, BRGM, CEREGE sur le traitement des résidus médicamenteux par des nanomatériaux réactifs (adsorption et transformation).

- Un projet ANR qui s'est terminé il y a un an a étudié l'impact environnemental de 4 produits modèles (ciments, verres, peinture et crèmes solaire) aux différentes étapes de leur cycle de vie.

Information on development related to exposure measurement and exposure mitigation

- L'INRS a inauguré le 4 octobre 2013 son pôle de recherche spécifiquement dédié aux études portant sur la prévention des risques professionnels associés aux nanomatériaux. 500 m2 consacrés

aux recherches portant sur la toxicologie in vivo, sur la caractérisation des expositions professionnelles, sur l'efficacité des dispositifs de protection collective et des équipements de protection individuelle. Il s'agit pour l'INRS d'amplifier les travaux déjà engagés, de créer un véritable pôle d'excellence ainsi que de développer des partenariats avec d'autres organismes, tant sur le plan national qu'international.

Additional Information

- Consideration on the benefits of nanotechnologies:

Le développement de nanoparticules de fer métal pour le traitement in-situ d'eaux souterraines polluées par des composés organiques chlorées, NO3, Cr(VI) etc. semblent, suite au programme NanoFrezes (ANR-Ecotech) présenter à la fois un intérêt technologique et économique. La réactivité de ces produits est importantes et de relativement longue durée. Elle est intéressante pour traiter l'eau proche de la source de contamination et nécessite des formulation de surface des nanoparticules peu couteuses et faciles à faire. La toxicité des nanoparticules de fer zéro diminue très vite au fur et à mesure qu'elles s'oxydent (cf article par exemple M Auffan et al ES and T 2009). Les nanoparticules se transforment en oxydes de fer (III).

- Other:

La plate-forme Nanosécurité du CEA à Grenoble a été inaugurée le 22 Novembre 2013. Elle propose des actions de formation et de certification des travailleurs exposés aux nanoparticules ainsi qu'une série de mesures in situ et de recherches sur l'exposition et la toxicité. Voir : http://www.cea.fr/le-cea/actualites/1ere-pierre-de-la-plateforme-nanosecurite-a-gren-74997

GERMANY

Highlights

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

From the 13th to 14th of November 2013 BMU organized a stakeholder workshop concerning nanomedicine. Around 30 representatives from science and research, individual companies, environmental organizations as well as government agencies discussed the main opportunities and risks of nanomedicine. Therefore the discussion was focused on current and future fields of applications and legal provisions. The results will be published in a thematic report on the homepage of BMU.

The conference on nanomedicine constitutes the continuation of the fourth phase of the NanoDialogue – a platform for the discussion of emerging issues with stakeholders starting in 2006. The emphasis of the dialogue workshops is based on the societal context of the respective topics. The main objective is to facilitate the exchange of views among the stakeholders.

- **Federal Ministry of Education and Research (BMBF)**

The Final Conference of the "nanoGEM" project ("nanoGEM – Nanostructured Materials – Health, Exposure and Material Characteristics") took place from the 12th – 13th June at the German Federal

Institute for Risk Assessment (BfR) in Berlin. The project, which began in 2010, was jointly supported by the BMBF and German industry with € 6.4 mio.

- **Federal Institute for Occupational Safety and Health (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, BAuA), Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR), Federal Environment Agency (Umweltbundesamt, UBA)**

BfR has completed two projects that focused on the perception of the German population and on the presentation of Nanotechnology in the German Media.

The first project, NanoView, was a representative population survey. The results show that consumers are now generally less aware of nanotechnology than in 2007. At the same time, however, concrete nanotechnological applications in the areas of dyes, textiles and cosmetics have become better known. Despite the existing knowledge gaps, the benefits of nanotechnology are seen by a clear majority to definitely outweigh any potential risks. A remarkable outcome of the study is the gender difference: Men's attitudes towards nanotechnology are clearly more positive than those of women - men are more likely to advocate nanotechnology. The pronounced differences were subsequently taken into account in the development of the communication strategy for improving consumer information. In fact the strategy was based on the outcome of the study.

Media analyses showed that the second project, NanoMedia, attracted an extensive media attention. A total of 591 articles appeared newspapers (for e.g. Frankfurter Allgemeine Zeitung, Süddeutsche Zeitung, die tageszeitung, Frankfurter Rundschau, Die Welt, Financial Times Deutschland, Die Zeit, Spiegel, Focus and Bildzeitung). Overall, the number of articles on nanotechnology has been decreasing in the period under review. At the same time, the articles appearing in the years from 2008 to 2012, were more substantial and more focused on applications. The majority of the articles appeared in the science section of the various daily newspapers and journals. Besides the representative population survey, also media reports have a clear emphasis on the benefits of nanotechnology. There is almost no article that focused on or even mentioned the potential risks. The presentation of nanotechnology in the German media since 2007 corresponds to the results of the representative population survey.

Both of these projects have been published on the BfR Website (www.bfr.bund.de).

- Physikalisch-Technische Bundesanstalt (PTB), National Metrology Institute

The PTB has participated in a European joint research project (Traceable measurement of nanoparticle size, ERA-NET Plus, Grant Agreement no 217257) in which characterization methods for traceable size measurement of nanoparticles were developed and applied. At the end of the project a comparison measurement on 7 different samples of reference particles (Au, Silica, polystyrene) in the size range from 10 nm to 200 nm was conducted with different methods (AFM, DLS, SAXS, SEM and TSEM). The combined standard uncertainties of the reference values are smaller than 1.4 nm for particles with nominal sizes up to 100 nm and below 1.5% for the larger particles. The results of the comparison were analysed and published: "Traceable size determination of nanoparticles, a comparison among European metrology institutes"; 2012 Meas. Sci. Technol. 23 125005:

http://iopscience.iop.org/0957-0233/23/12/125005

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

A) Federal Ministry for Labour and Social Affairs (BMAS)

The German Hazardous Substances Committee has published a recommendation for safe handling of nanomaterials based on the German Hazardous Substances Ordinance (Announcement on Hazardous Substances 527: http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/TRGS/Announcement-527.html).

The objective of the current publication is to give recommendations for the protection of the safety and health of employees at the workplace during activities involving substances, mixtures or articles consisting of or containing manufactured nanomaterials. The basis for this publication is the recommendation of the European Commission on the definition of the term 'nanomaterial'. Natural and incidental nanomaterials are not considered in the publication. Likewise, the paper does not address aspects of the risk assessment, when such material is used by consumers.

According to this Announcement, nanomaterials can be classified based on their toxicological properties, form and structure as well as their biopersistence into four groups:

1) soluble nanomaterials

2) biopersistent nanomaterials with specific toxicological properties

3) biopersistent nanomaterials without specific toxicological properties (GBP nanomaterial)

4) biopersistent fibrous nanomaterials

B) Federal Environment Agency (Umweltbundesamt, UBA):

New project:

The ability to describe parameters like dissolution, dispersibility and dispersion stability is essential for an adequate and valid interpretation of data regarding the environmental fate and behaviour of nanomaterials. As follow up of the OECD Expert Meeting on Environmental Fate and Ecotoxicology of Nanomaterials in Berlin (29th - 31st of January 2013) UBA took the lead on the development of a draft test guideline for dispersibility and dispersion behaviour of nanomaterials in aquatic media and a draft guidance document for dispersion and dissolution of nanomaterials in aquatic media – decision tree.

Within that framework the project "Development of a decision support tool for the investigation of environmental behaviour of nanomaterials on the basis of their dispersion stability and solubility as a function of environmental conditions" was launched and has been awarded to the University of Vienna (Austria).

Aim of the project is the development of a tiered approach for the investigation of dissolution, dispersion and dispersion behaviour of nanomaterials as a prerequisite for continuing studies on environmental behavior. The work of this project is intended to provide basis information for an OECD Guidance Document for the investigation of environmental fate of nanomaterials in aquatic media. In addition to that a draft for a new OECD Test Guideline will be developed for the examination of dispersion

stability and behaviour of nanomaterials in aquatic media. For this aim influencing factors have to be identified and valid, as well as pragmatic approaches for suitable methods and techniques have to be developed. http://www.umweltbundesamt.de/en/research-development-projects

New project:

Within the research project "Extended ecotoxicological tests with Daphnia magna and TiO2 nanoparticles" the Ecotoxicological Laboratory of UBA will investigate the toxicological potential of TiO2 nanoparticles [anatas TiO2 nanoparticles of the JRC OECD Sponsorship Program: NM100, NM 101 and NM102] to aquatic invertebrates. The ecotoxicological tests will be conducted in accordance to the OECD Guidelines for the Testing of Chemicals, No. 202: "Daphnia sp. Acute Immobilisation Test", but will be executed over a period of 96 hours instead of 48 hours.

A former study by Dabrunz et al. in 2011 gave evidence that the toxic effects of TiO2 nanoparticles on D. magna are significantly correlating with testing period. Thus, the standardised test procedure according to OECD guidelines No. 202 might be insufficient for risk assessment of TiO2 nanoparticles.

Aim of this research project is ether to prove or to disprove these results. Therefore, the German Environment Agency in cooperation with external project partners [Institute of energy and environmental technology, Technical University of Dresden] performs a variety of ecotoxicological tests, analyses and characterises TiO2 particles in the test solutions as well as on and in the test organisms.

The research project started in September 2013 and it will last until November 2014.

On behalf of UBA the project "*Impact assessment of a European register of products containing nanomaterials*" analysed the extent of nanomaterial containing products that are expected to be subject of a European register of products containing nanomaterials as well as the costs and benefits of such a register for industry and public authorities. The project is based on a concept for a European register of products containing nanomaterials developed by UBA. The analysis took special consideration of the industrial sectors that are typical of those that use nanomaterials in products. The concept drafted by UBA was examined on the basis of the results of the analysis. The final report will be published in English soon on http://www.umweltbundesamt.de/en/research-development-projects

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

In the follow up of the OECD horizontal meeting on inhalation toxicology in The Hague in Oct. 2011, BfR has taken an advisory status in the preparation of the SPSF for adapting OECD test guidelines 412 and 413 (as well as corresponding guidance documents) for nanomaterials, led by NL and US.

On the 11th of July 2013 the new EU Regulation 1223/2009 pdf-Cosmetics Regulation- came into force strengthening the safety of cosmetic products and streamlining the framework for all operators in the sector.

The Regulation includes a definition for nanomaterials as well as the following regulatory changes:

1) Industries will have to submit notification of all cosmetic products containing nanomaterials six months before market release

2) Nanomaterial ingredients will now be identified on the product label (ingredient name followed by "nano" in brackets).

The Scientific Committee on Consumer Safety (SCCS) with participation of BfR representatives was enlisted to develop guidance on the safety assessment of nanomaterials in cosmetics, which was published in June 2012

(http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_005.pdf).

This guidance document explains components of the Regulation related to the definition of a nanomaterial, and requirements for notification, labeling, and safety assessment of cosmetic products that contain nanomaterial ingredients. The SCCS guidance also provides considerations for testing nanomaterials, especially regarding the EU animal testing ban. Nanomaterials in colorants, preservatives and UV-filters must be explicitly authorized.

Developments related to voluntary or stewardship schemes;

A) Physikalisch-Technische Bundesanstalt (PTB), National Metrology Institute

The PTB participates in a running international comparison measurement on nanoparticles, registered as a supplementary comparison in length (APMP.L-S5) in the key comparison data base of the BIPM (http://kcdb.bipm.org/). This comparison is organized by the national metrology institute of Taiwan (CMS/ITRI). It targets at diameter determination of five different nanoparticles: 10 nm gold, 20 nm silver, and 30 nm, 100 nm, and 300 nm polystyrene. The measurements of the comparison are finished and the Draft B report of the comparison is currently under preparation.

Information on any developments related to good practice documents;

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

BAuA has updated in co-operation with the Association of the German Chemical Industry their common guidance for safe handling of nanomaterials at the workplace from 2007 in May 2012 (available only in German: http://www.baua.de/de/Publikationen/Fachbeitraege/Gd4.html).There´s also an 2013 update of BAuA´s overview on good practice for safe handling of nanomaterials (http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/Nanotechnologie/Links-Beispiele.html) Within the FP7 project NanoValid, BAuA is working on a case study on risk reduction strategies for occupational handling. To support industrial hygienists, other persons responsible for OSH, and universities, BauA plans to set up a training manual as a robust, updateable folder including a CD with presentations for training purposes. It is intended to distribute this manual internationally. The publication is expected in early 2015.

B) Federal Institute for Materials Research and Testing (BAM)

At BAM a Silver-Nanomaterial was certified as reference material with defined and stable size. It's proposed use is for calibration, but can also be used for biomedical purposes.

BAM-N001 is an aqueous suspension of silver particles certified for the particle size parameters d10, d50, and d90. The d10, d50, and d90 values are specific particle diameters that correspond to 10, 50, and 90 % of the total particles in the cumulative undersize distribution. These diameters were determined for both the volume- and number-weighted distribution, using small-angle X-ray scattering and other methods. The certified values for d10, d50, and d90 are number-weigthed: 6.9 nm, 12.6 nm, 19.4 nm. CRM BAM-N001 is delivered as a set of 2 brown plastic bottles containing an aqueous solution having an approximate silver concentration of 100 µg/ml. Each bottle contains approximately 5 ml of the suspension. BAM-N001

is intended to be used as a calibrant or, alternatively, a control sample for both precision and trueness estimation of particle-size determination methods, in particular of SAXS methods. The material is suitable for biomedical research purposes requiring silver particles in the corresponding range of the certified values suspended in aqueous solutions. Detailed information can be downloaded from the website of BAM:

http://www.rm-certificates.bam.de/de/rm-certificates_media/rm_cert_particle_size/bam_n001repe.pdf

C) Physikalisch-Technische Bundesanstalt (PTB), National Metrology Institute

The PTB has participated in the European joint research project 'Traceable measurement of nanoparticle size' (see section highlights). During the project a 'Good Practice Guide for the Determination of the Size and Size Distribution of Spherical Nanoparticle samples' was developed. The document can be downloaded from the website of NPL: http://www.npl.co.uk/publications/Good-practice-guide-for-the-determination-of-the-size-distributions-of-spherical-nanoparticle-samples..

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

A) Federal Ministry of Education and Research (BMBF)

Standardization efforts and OECD activities are being supported by national collaborative research projects funded under the NanoCare research priority within the WING Programme (see below).

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

A) Federal Ministry of Education and Research (BMBF)

The research priority "NanoCare - Safe Handling of Manufactured Nanomaterials – Investigating Impacts on Health and the Environment" is continued to be funded within the frame of the German funding programme "WING" (Materials Innovations for Industry and Society). The objective of this activity is to investigate the effects and interactions of manufactured nanomaterials on human health and the environment, to develop reliable experimental techniques and testing strategies as well as to create a framework for the safe handling of nanomaterials. Existing knowledge gaps about the effects of nanomaterials are addressed in order to enable the safe and responsible application of nanotechnologies as well as to strengthen the German economy. New projects are expected to start in 2014.

Germany is coordinating the European FP7 ERA-NET project "SIINN" (Safe Implementation of Innovative Nanoscience and Nanotechnology). The ERA-NET is addressing safety and risks related to the use of manufactured nanomaterials. 20 organisations from 13 European countries and Israel are participating. The main objective of SIINN is the preparation and implementation of joint transnational calls in the field of nanosafety research. Collaborative projects are funded if (1) a clear European added value can be proved and (2) the project objectives can only be achieved by a transnational European approach. Three transnational projects resulting from the first SIINN call started in June 2013.

B) Federal Environment Agency (Umweltbundesamt, UBA)

New project:

"Development of a decision support tool for the investigation of environmental behaviour of nanomaterials on the basis of their dispersion stability and solubility as a function of environmental conditions" The ability to describe parameters like dissolution, dispersibility and dispersion stability is essential for an adequate and valid interpretation of data regarding the environmental fate and behaviour of nanomaterials. As follow up of the OECD Expert Meeting on Environmental Fate and Ecotoxicology of Nanomaterials in Berlin (29th - 31st of January 2013) UBA took the lead on the development of a draft test guideline for dispersibility and dispersion behaviour of nanomaterials in aquatic media and a draft guidance document for dispersion and dissolution of nanomaterials in aquatic media – decision tree. Within that framework the project "Development of a decision support tool for the investigation of environmental behaviour of nanomaterials on the basis of their dispersion stability and solubility as a function of environmental conditions" was launched and has been awarded to the University of Vienna (Austria).

Aim of the project is the development of a tiered approach for the investigation of dissolution, dispersion and dispersion behaviour of nanomaterials as a prerequisite for continuing studies on environmental behavior. The work of this project is intended to provide basis information for an OECD Guidance Document for the investigation of environmental fate of nanomaterials in aquatic media. In addition to that a draft for a new OECD Test Guideline will be developed for the examination of dispersion stability and behaviour of nanomaterials in aquatic media. For this aim influencing factors have to be identified and valid, as well as pragmatic approaches for suitable methods and techniques have to be developed. http://www.umweltbundesamt.de/en/research-development-projects

Finalized project:

"Environmental risks of nanomaterials under consideration of relevant exposure scenarios" On behalf of UBA a research project focusing on ecotoxicological aspects of different sized nano-TiO2 was finalized. The project investigated the ecotoxicological risk of two different sized TiO_2 nanomaterials (anatase, 7-10 nm and anatase 15-25 nm, Sponsorship Programme materials) and one non-nano sized TiO_2 material (anatase, 200-220 nm, Sponsorship Programme material) to organisms inhabiting different environmental compartments. Following standardized tests (OECD) were used to investigate the influence of these materials on several test organisms:

1) *Daphnia* sp., acute immobilization test, Test No. 209 (OECD 2004b)
2) Fish embryo acute toxicity (FET) test, Test No. 236 (OECD 2013)
3) Activated sludge, respiration inhibition test, Test No. 209 (OECD 2010)
4) Earthworm, acute toxicity test , Test No. 207 (OECD 1984)
5) Earthworm, reproduction test , Test No. 222 (OECD 2004a).

The main focus was set on the testing under potentially relevant exposure situations. Therefore, *Daphnia* sp. acute immobilization tests (OECD 2004b) and activated sludge tests (OECD 2010) were performed with solar radiation. Mixture experiments with nano-TiO_2 and an organic contaminant (triclocarban, TCC) were conducted with the acute and chronic earthworm (OECD 1984, 2004a) and activated sludge respiration tests (OECD 2010). Effects of the TiO_2 materials on embryonic development were investigated in the fish embryo acute toxicity test (OECD 2013). Where necessary, recommendations for adaptation of the applied OECD TG for the investigation of nanomaterials were made.

The results of this project directly contribute to the OECD Sponsorship Programme and will soon be published at the UBA homepage:

http://www.umweltbundesamt.de/en/research-development-projects

A research project on behalf of UBA has been finalised which was aimed at investigating the distribution, storage and excretion of MWCNTs after short-term inhalation by rats. In the first part of the experiments the exposure was performed using unlabeled MWCNTs. Investigation of lung lavage evidenced inflammatory reactions 1 day after exposure but not 28 days after exposure. Individual MWCNTs were detected in liver, kidneys and in the agarose cast of the pleural cavity using a high resolution light microscope.

In the second part of the experiments Co-60 labeled MWCNTs were used for exposure. The gamma-activity was analysed in several organs, body fluids and secretion products. The analysis of the lung lavage fluid showed, that already 1 day after exposure most MWCNTs were phagocytized by macrophages. By analysis of the agarose cast of the pleural cavity a fast translocation to the pleural cavity was detected at day 0 and 1 after exposure. Thereafter a fast decrease of MWCNT concentration in the pleural cavity was seen at day 14 and 28.

The report will be published at the UBA homepage (http://www.umweltbundesamt.de/publikationen).

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

BfR has completed an updated review on the state of understanding on human health endpoints for the TiO2 dossier within the Sponsorship Programme. The report highlights bulk vs. nano comparison in toxicity profiles, identifies data gaps and uncertainties and makes recommendations for test method modification and development. The report is currently under proof for in-house publication.

In addition, BfR has accomplished its work in the frame of the Joint Action "Nanogenotox" coordinated by France.

The EU-project NANoREG, a European approach for regulatory testing of nanomaterials, has started in March 2013. Putative carcinogenicity of nanomaterials is addressed by a 2 year study on inhalative long term toxicity/carcinogenicity (OECD TG 453). BfR is deputy leader of work package 4 "Toxicity testing and Biokinetics in vivo". The institute is involved in experimental work on quantification and distribution of ceriumdioxide nanoparticles following to inhalative uptake and in aquatic organisms.

The bilateral French-German research project "SolNanoTox" was evaluated positively by ANR (French National Agency for Research) and DFG (German Research Foundation). The aim of the project is to differentiate between modes of action of soluble and insoluble particles using the examples of aluminum and titaniumdioxide.

The EU-project "NanoDefine" has just started at the 1st of November 2013. The aim of the project is to develop robust, reliable and cost-efficient methods for the detection and quantification of nanomaterials in complex matrices. Examples of these matrices are pigment formulations, food, nanocomposites for food contact materials and cosmetic products.

D) Federal Institute of Occupational Safety and Health (BAuA)

For the assessment of health effects of a nanomaterial it seems there is no general need to separately consider each surface modification. This is the result of a study funded by BAuA and carried out by the Fraunhofer Institute for Toxicology und Experimental Medicine (ITEM). Health effects from a

nanomaterial with different surface modifications were compared. The results are published in the report „Toxic Effects of Various Modifications of a Nanoparticle Following Inhalation".

The study demonstrates that surface coating of a nanomaterial does not seem to generally have a relevant impact on its hazard potency. The scientists investigated in in-vivo experiments different common forms of coated and non-coated titanium oxide. Additionally, it was observed that only very small portions of the inhaled particles were taken up into lung tissue cells. This is contradictory to the common concern that nanoparticles can easily penetrate through membranes of a cell. It disproves the assumptions of significant health risks from translocation into the body. With the results of this project, the relevance of nanomaterial coatings for human health can now be more clearly assessed for purposes of occupational safety, health and the selection of adequate control measures at workplaces.

O. Creutzenberg: Toxic effects of various modifications of a nanoparticle following inhalation. 1. edition. Dortmund: Bundesanstalt für Arbeitsschutz und Arbeitsmedizin 2013. 404 pages, Project number: F 2246

PDF-file download: http://www.baua.de/en/Publications/Expert-Papers/F2246.html

Information on any public/ stakeholder consultation;

A) Federal Ministry of Education and Research (BMBF)

"DaNa – The Knowledge Platform on Nanomaterials".

The BMBF funds the web-based knowledge and data platform DaNa. DaNa collects high quality research data and information on the properties, toxicology and risk assessment of manufactured nanomaterials from national and international funded projects. This is presented in a clear and generally understandable way. The two websites (www.nanopartikel.info) and (www.nanoobjects.info) offer sound and unbiased information on manufactured nanomaterials and their impact on human health and the environment. The DaNa information platform is available in both English and German and contains information on 25 different nanomaterials currently being applied in typical consumer products. Short texts and more detailed articles provide information, not only about the properties of coarse-grained and nano-scale materials, but also if and how nanomaterials can be released and which consequences such releases are expected to have on human health and the environment.

BMBF organizes dialog events for an interested public on a bi-annual basis. The dialog format "Bürger treffen Experten" ("citizens meet experts") is meanwhile well established and provides the audience possibilities of discussions on nanotechnology, its chances, risks and perspectives. Four to five experts of research, industry, administration and consumer protection are available for explanations, questions and discussions on all facets of the topic. The objective is to provide the public with sound and pragmatic information on both: (1) innovation and risk research as well as (2) applications of nanotechnology. Recent events have taken place on the 5th of July 2013 in Dresden and on the 6th of December 2013 in Halle.

Furthermore the BMBF hosted a conference on the „Safe application of nanomaterials" on the 26th of November in Berlin. Aim of the conference was to communicate new results and insights from the risk research of the BMBF to stakeholders and the scientific community. In addition relevant aspects with regard to risk assessment and management were presented by leading experts and discussed with around 150 participants.

Since 2011, the BMBF initiative "nanoTruck – Meeting Place Nanoworlds" (www.nanotruck.de) has informed the German public about the basics, applications, perspectives and potential risks of

nanotechnology. As an integrated communications initiative with a focus on information and dialogue, "nanoTruck" uses a double-storey roadshow vehicle which is fully equipped with an exhibition and laboratory infrastructure. Inside the mobile exhibition, EHS aspects of nanomaterials are represented by exhibits (e.g. in vitro toxicity assays and particle analysis), interactive multimedia terminals and text panels. Furthermore, these topics are included in various "nanoTruck" dialogue events like presentations and workshops.

Additional, in-depth information is provided via flyers on special EHS topics, focusing chapters in an extensive brochure and specialized web content. The information platform "nanoTruck" is also used as a hub for further reading (e.g. BMBF publications) and for services provided by other initiatives (e.g. DaNa, www.nanoobjects.info).

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

A) Federal Environment Agency (Umweltbundesamt, UBA):

UBA has published three data sheets concerning nano-products titled *"Use of nanoscale iron for the remediation of groundwater damages*" and "*Use of nanomaterials in textiles*". The data sheets focuse on the description of application and on ecotoxicological and health aspects. They are available on the UBA website: http://www.umweltbundesamt.de/en/publikationen/use-of-nanoscale-iron-for-the-remediation-of and http://www.umweltbundesamt.de/publikationen/use-of-nanomaterials-in-textiles).

Currently, UBA published a third data sheet "*Nanobasierte Beleuchtungssysteme: Organische Licht emittierende Diode (OLED)*". At the moment it is only available in German (Link: http://www.umweltbundesamt.de/publikationen/nanobasierte-beleuchtungssysteme-organische-licht) but will be published in English soon.

ITALY

Highlights

A report on policy recommendations for Nanomaterials in the OSH area has been published by the Italian Workers' Compensation Authority (INAIL) as a follow up of the debate on the "White Paper on engineered nanomaterials and occupational health effects" published in 2011. An English version of the policy report will soon be published (http://www.ispesl.it/nanotecnologie/?pag=whitebook).

The 9th edition of Nanoforum Conference was held in Rome (18-20 September 2013). It is an important occasion in which both public and private research institutes and industries can meet and discuss each other on the relevant issues in nanotechnology applications.

National Institute of Health (Istituto Superiore di Sanità, ISS) has organized in September 2013 a National Meeting on "Nanomateriali nel settore alimentare: nuovi approcci per la valutazione della sicurezza" to make an overview on Italian activities in the field of food safety related to nanomaterials.

The Research Centre Polaris (Particulate Matter and Health Risk) hosted in Milan, University of Milano Bicocca – October 2013, a meeting on "Ambiente e salute dagli effetti di particolato atmosferico e nanoparticelle alle emissioni di gas serra" to discuss the effects of fine and ultrafine ambient particles, greenhouse emissions and nanoparticles on human health.

A one day session on Safety and Societal Impacts of nanotechnologies has been held during the Conference NanotechItaly 2013: Key Enabling Technologies for Responsible Innovation (www.nanotechitaly.it, November 2013), providing an overview of research initiatives in these areas by relevant Italian agencies (Ministry of Health, ISS, INAIL), and national and international experts. On-going activities of the NanoReg project have been also discussed.

Italy participates in the Working Groups under the International Co-operation with both CEN TC 352 and ISO TC 229 Nanotechnology.

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

In Italy we are continuing the work on National registry on nanomaterials. The structure of the Italian nanodatabase is being set in collaboration with other EU Member States in order to harmonize the approach used to gather information on nanomaterials on the EU market. Following the Eu Commission 2nd regulatory review on nanomaterials publication, Italy has been involved in discussions among MSs on possible ways to adapt existing regulations on chemicals vs proposal on ad hoc regulation with nanospecific requirements.

Developments related to voluntary or stewardship schemes;

A national Working Group on Nanomaterials under REACH Competent Authority technical committee has been established to deal with regulatory issues related to REACH and CLP application to nanomaterials. The WG sees the participation of relevant institutions involved in REACH and CLP implementation and technical bodies, workers protection Agencies and main industrial associations, plus experts form research centers and industry. Main outcome of the WG activity is the set-up of a national registry on nanomaterials on the national market and R&D. The draft project is now under public consultation among national experts and stakeholders. The following main scientific and technical challenges of the current scheme designed to gather data on nanomaterials put on the market and used, also in R&D, are under discussion: definition, tonnage threshold, chem-phys chacterization methods, terminology, online submission of huge amount of data, IUCLID compatibility.

CSQA (a private Italian certification body) and Veneto Nanotech (high tech cluster of the Veneto region) have published (November 2013) a voluntary certification scheme for Nanomaterials, named "*Responsible management system of Nanomaterials in consumer products* (D.T. 113)", that can be integrated in already existing quality management system, such as UNI EN ISO 9001.

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

In the framework of OECD WPMN Sponsorship programme - SG7 activities, ISS and the Italian National Agency for New Technologies, Energy and Sustainable Economic Development (ENEA) are involved in the Interlaboratory comparison of the Colony Forming Efficiency assay for assessing cytotoxicity of nanomaterials.

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

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

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

The two year national project Nanotox: Toxicology of chronic exposure to engineered silver nanoparticles, led by the University of Milano, is on-going. Innovative testing strategies are being designed to understand nanoparticles effects on the central nervous system (CNS). The final project workshop is expected at the end of 2014.

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

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

In the framework of NANoREG project (NMP.2012.1.3-3 Regulatory testing of nanomaterials) the Italian Ministry of Health, National coordinator in the project, organised the Italian Kick-off meeting (15 July 2013, Rome) to present Italian NANoREG Network to the stakeholders. In this project several partners are involved: ISS, Veneto Nanotech, CNR, ENEA and IIT. Besides INAIL, the University of Tor Vergata and the University of Turin will participate to the project as third parties.

The First Italy-Brazil Joint Commission Meeting on Scientific and Technological Cooperation (Rome 24/10/2013), established under the already existing Agreement of Scientific and Technological Cooperation, identified areas of interest for strengthening the bilateral cooperation, in particular nanotechnology and new materials, with focus on: *a)* development of advanced multifunctional materials; *b)* development of a Joint Virtual Lab on NT; *c)* development of a common view on all regulatory aspects of producing and using nanomaterials, in particular with focus on methodologies and safety and *d)* development of joint education programs aimed at training new generations of researchers for the acquisition of academic and entrepreneurial skills in the field.

To be directed in the R&D areas for: *a)* energy; *b)* food packaging and technologies; *c)* textile industry; *d)* health (with particular interest on nanobiotechnology, oncology, neurodegenerative diseases and skeletal tissue pathology).

Information on any public/ stakeholder consultation

The FP7 NMP project Nanodiode: *Developing innovative outreach and dialogue on responsible nanotechnologies in EU civil society* (www.nanodiode.eu), led by IVAM (NL) and including some Italian partners, started in July 2013 for 3 years. Different stakeholders consultation at national level, including a public survey, workshops and user committees, are planned in the near future.

A national Working Group on Nanomaterials under REACH Competent Authority technical committee has been established to deal with regulatory issues related to REACH and CLP application to nanomaterials.

The Ministry of Health has launched a voluntary survey on the use of nanomaterials in cosmetics, including information on safety and labelling:

http://www.salute.gov.it/cosmetici/paginaInternaCosmetici.jsp?id=3104&menu=servizi .

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

In July 2013 the European project LAMP (contract number 247928), which proposed a new approach to draw luminous patterns on OLED (Organic LED) combining new polymer/QDs interaction realized by laser patterning directly on an OLED device, was finished. In the LAMP project was forecasted a task focused on Life Cycle Assessment of the materials, techniques and products manufactured within LAMP. An LCA study on the production of QDs-LED prototype using a direct laser micro-patterning was carried out by the team belonging to ENEA (www.enea.it). A publication at a National congress has been published and an extended abstract have been published on the proceeding of 19th SETAC LCA Case Study Symposium, which will be held 11-13 November 2013 in Rome, Italy.

In May 2013 the project the NanoHex project (enhanced nano-fluid heat exchange), is aimed at developing an innovative application of nanotechnologies: the use of nanofluids (a suspension of nanoparticles in a solvent) as refrigerants for data centre and power electronics. In the NanoHex project was forecasted a Work package on Halts, Safety and Environmental was carry on by the team belonging to ENEA (www.enea.it). The ENEA Team produced carry on recommendations for the choice of nanofluids based on EHS aspects; two LCA studies on industrial applications of nanofluid one in data centere and another in traction power; qualitative risk assessment on nanofluid production; recommendations for scaling up of industrial application. The project results was presented in several International Conference.

JAPAN

Highlights

- Japan is participating in ISO/TC229 activities.
- Many of scientific research projects are still on going in Japan.

Developments related to voluntary or stewardship schemes;

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

Information on any developments related to good practice documents;

METI firstly publicised information on safety test data and management methods of manufactured nanomaterials, on METI's website in 2010 (only in Japanese). Such information was voluntarily provided and annually updated by the manufacturers. METI publicised the updated information in 2013.

Since December 2011, a committee established by METI has discussed measuring methods of nanomaterials and some case studies on risk assessment of products containing nanomaterials. In June 2013, the committee issued an interim report on its discussion.

In April 2012, a committee established by the Ministry of Health, Labour and Welfare (MHLW) began consideration of risk assessment for the prevention of impairment of workers' health caused by exposure to TIO_2 in nanoscale. In addition, MHLW launched development of measurement methods for airborne nanomaterials, carbon black and SW/MWCNT.

The Japanese Industrial Standards Committee (JISC), established within METI, is the national member body participating as a P-member in ISO/TC229 (Nanotechnologies). JISC nominated the Convenor and Secretary of TC229/JWG2 (Measurement and characterisation). Under JISC's lead, the following two TC229 documents (Technical Specifications) have been developed, which were finally published during the period from February to November 2013:

- ISO/TS 16195 "Nanotechnologies -- Guidance for developing representative test materials consisting of nano-objects in dry powder form" (published on 1 May 2013); and

- ISO/TS 17200 "Nanotechnologies -- Nanoparticles in powder form -- Characteristics and measurements" (published on 1 June 2013).

JISC currently leads a Study Group on Tiered approach for nano-object identification within a sample in TC229/JWG2.

Getting its New Work Item Proposal (NWIP) approved on 14 October 2013, JISC also started leading the development of a TC229 document (Technical Specification) in TC229/WG3 (Health, Safety and Environmental Aspects of Nanotechnologies), which is ISO/TS 19337 "Nanotechnologies -- Characterisation of nanosuspensions to verify nano-object induced toxicity assessed *in vitro*."

Two Japanese laboratories, namely, the National Institute of Advanced Industrial Science and Technology (AIST) and Teikyo Heisei University, have been participating in a WPMN interlaboratory comparison study on colony forming efficiency (CFE) assay led by the European Commission's Joint Research Centre (JRC), where Japan is providing, as one of test samples, dispersions of Super-growth single-wall carbon nanotube with a guarantee of two-month dispersion stability, which is a principal material for the WPMN Sponsorship Programme and has been developed through Japan's national R&D projects[2].

An expert committee by the Ministry of the Environment (MOE) issued the "Guidelines for preventing the environmental impact of manufactured nanomaterials" to provide manufacturers with currently available information for the environmentally sound management of manufactured nanomaterials, in March 2009[3]. Based on "Future Challenges" which were identified in the Guidelines, MOE conducted a survey the effectiveness of incineration of nanomaterials on preventing releases of nanomaterials to the environment in FY 2011 and has also surveyed researches on ecotoxicity and environmental fate of nanomaterials since FY 2011. In FY2013, MOE demonstrates the experiment on monitoring of the release of manufactured nanomaterials into the environment from waste treatment processes.

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

METI launched a five-year programme for the "Development of Innovative Methodology for Safety Assessment of Industrial Nanomaterials" in September 2011, which aims to develop fundamental hazard assessment methodology leading to a tiered risk assessment approach for industrial nanomaterials. The programme has two R&D themes: 1) establishment of equivalence criteria of nanomaterials and 2) establishment of an intratracheal administration method as low-cost and convenient method for hazard assessment to acquire basic hazard information, both of which are for regulatory purposes. A website http://www.aist-riss.jp/projects/meti-nano/en/ to introduce this programme will be released in December 2013. Preliminary results of the R&D theme 1) above, presumably a conceptual outline of the equivalence criteria of nanomaterials will be presented at a WPMN horizontal expert workshop on categorisation of nanomaterials to be held in April 2014. An outcome of kinetic studies on TiO_2 nanoparticles[4] conducted for the both R&D themes 1) and 2) above can be presented at a WPMN horizontal expert workshop on toxicokinetics to be held in February 2014, and was uploaded in JRC's NANOhub database for developing TiO_2 dossier of the Phase I of the WPMN Sponsorship Programme as well. Against a backdrop of the implementation of this programme, Japan currently leads a WPMN Risk Assessment Pilot Project "Survey on approaches to develop or use concepts of grouping, equivalence and read-across based on physical-chemical properties of nanomaterials for their human health and ecosystem hazard assessment in regulatory regimes" and actively participates in drafting a Standard Project Submission Form (SPSF) for Test Guidelines on inhalation toxicity for manufactured nanomaterials.

Also METI launched a five-year programme on the "Innovative carbon nanotubes composite materials project toward achieving a low-carbon society" in 2010, which is coordinated by the New Energy and Industrial Technology Development Organisation (NEDO, R&D management organisation). It has three R&D Themes: 1) techniques for controlling structures and properties of single-wall carbon nanotubes (SWCNTs); 2) techniques for uniform dispersion of SWCNTs in existing materials; and 3) techniques

[2] http://www.aist.go.jp/aist_e/aist_today/2011_41/feature2/feature_02.html

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

[4] Shinohara et al. (2013) Tissue distribution and clearance of intravenously administered titanium dioxide (TiO_2) nanoparticles. Nanotoxicology (doi:10.3109/17435390.2012.763001).

suitable for voluntary safety management of carbon nanotubes (CNTs) by industries. This R&D theme 3) focuses on development of toxicity testing and exposure assessment protocols for ensuring safety of CNTs and their applications, whose preliminary results were released in the end of October 2013 as the following two documents:

- "The protocols of preparation, characterisation and *in vitro* cell based assays for safety testing of carbon nanotubes"; and
- "Guide to measuring airborne carbon nanotubes in workplaces".

Both documents are available for download from the AIST-RISS website[5]. Related R&D results are also publicised in scientific papers:

- Fujita et al. (2013) Physical properties of single-wall carbon nanotubes in cell culture and their dispersal due to alveolar epithelial cell response. Toxicology Mechanisms and Methods 23, 598-609 (doi:10.3109/15376516.2013.811568).
- Horie et al. (2013) Dispersant affects the cellular influences of single-wall carbon nanotube: the role of CNT as carrier of dispersants. Toxicology Mechanisms and Methods 23, 315-322 (doi:10.3109/15376516.2012.755595).
- Hashimoto et al. (2013) Evaluating the capabilities of portable black carbon monitors and photometers for measuring airborne carbon nanotubes. Journal of Nanoparticle Research 15:2033 (doi: 10.1007/s11051-013-2033-3).

MHLW has promoted research on the human health aspect of several nanomaterials since 2003 through the Health and Labour Sciences Research Grants, etc. In FY 2013, nine research projects, including a basic research on development of methods for evaluating hazard and disposition of nanomaterials on human health, are progressing.

The Japan Bioassay Research Center launched a "Research project on the potential hazards, etc. of nanomaterials", commissioned by MHLW, which focuses on carcinogenicity of nanomaterials used/manufactured in the workplace (six-year programme, FY 2009-2014). Two-year inhalation study of multi-wall carbon nanotube (MWCNT) is on-going now (FY2012-2014). In addition, in order to elucidate of the carcinogenic mechanism, *in vitro* chromosome aberration and *in vivo* micronucleus tests have been carried out in FY 2013.

The National Institute of Occupational Safety and Health Japan (JNIOSH) is currently conducting a three-year project study (FY 2012-2014), "Toxicological Study on Ultrafine Particles of Metal Oxides". This project includes investigation on 1) genotoxicity, 2) neurotoxicity, and 3) reproductive toxicity of TiO_2 nanoparticles. Another three-year project, "Study on collection and analysis procedures of airborne particulate matters in nanomaterial-handling workplaces" has started at April 2013. This project can provide a practical procedure for exposure assessment of multi-dispersed particles by using real-time instruments and interpretation of different metrics of nanomaterials including (chemical) mass.

The National Institute for Environmental Studies (NIES) completed the 1st nanotoxicology programme (FY 2006-2010) which included the interaction of MWCNTs with cell membranes and *in vitro* transepithelial and transpulmonary migration of polystyrene or gold nanoparticles. NIES has been undertaking the 2nd nanotoxicology programme (FY 2011-2015) which includes *in vivo* toxicological

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

Please note that the English version of "The protocols of preparation, characterisation and *in vitro* cell based assays for safety testing of carbon nanotubes" will be released at around the end of 2013.

studies of MWCNT, *in vitro* and *in vivo* toxicological study of silver nanoparticles in reference to dissolution of metal nanoparticles, toxicokinetics of fluorescence-labelled dendtrimers, and ecotoxicological study of TIO_2 nanoparticles using embryo and sac-fry fish.

KOREA

Highlights (since 2011)

- The Korean government has established the 'National Nano-safety Master Plan (2012~2016)' on nanomaterials, nanotechnology, nanoproducts and occupational safety. For this plan, Ministry of Environment (MOE), Ministry of Education, Science and Technology (MEST), Ministry of Knowledge and Economy (MKE), Ministry of Employment and Labour (MOEL) and Ministry of Food and Drug Safety (MFDS) worked together.
- To carry out the 'National Nano-safety Master Plan(2012~2016)', MKE launched three projects in 2012 1) Planning for Nanoproduct Safety Center Establishment, 2) Methodology and Pilot Study on Nanoproduct Safety Evaluation, and 3) Studies on International Nanoproduct Regulation Trend and Case Studies on Self-declaration on Conformity of Nanoproduct.
- MEST developed the 3rd Korea nanotechnology Initiative (KNI) in order to promote nanotechnology development.

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

MOE has developed the guidance on exposure assessment and safe management of manufactured nanomaterials.

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

Developments related to voluntary or stewardship schemes

MOE has been conducting the project which is a voluntary survey on the production, use, import and export volumes and use patterns of manufactured nanomaterials from 2011.

Information on risk assessment decisions

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

KATS (The Korean Agency for Technology and Standards, an affiliated body of MKE) has developed a draft guideline for exposure monitoring of nanomaterials such as Carbon nano tubes (CNTs) and silver nanoparticles, and method for exposure assessment. The guideline will be published as Korean Industrial Standard in 2013.

Information on developments related to good practice documents

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

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

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

Ministry of Environment (MOE)

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

MOE and NIER (National Institute of Environmental Research, an affiliated body of MOE) have conducted the nanomaterials hazard assessment projects to review and adopt the OECD TGs on nanomaterials and cumulate the data related to physico-chemical properties, eco-toxicity, environmental fate and human-health in order to contribute to decision making since 2007. MOE and NIER launched the project for a survey on the production, use, import and export volumes, use pattern and the information on manufactured nanomaterials in order to establish inventory for nanomaterials. As a result, in December 2012, MOE conducted an inventory survey on nanomaterials and is performing a follow-up survey on four nanomaterials (CNT, ZnO, Ag, SiO_2) to investigate their states of lifecycle circulation and specific usages, etc. NIER is responsible for the Nanomaterial Risk Expert Committee that handles the nanomaterial safety issues, such as reviewing of the project planning on the nanomaterial safety assessment. Also, we are preparing a guideline on definitions of nanomaterials at an inter-ministerial level within 2014.

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

Ministry of Education, Science and Technology (MEST)

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

KRISS (Korea Research Institute of Standard Science, a subsidiary body of MEST) has been developing the National Measurement Standards of materials (including nanomaterials). In connection with this topic, the research project on "Development of Characterization Techniques for Nanomaterials Safety (2009 – 2015)" was launched. This project is composed of four parts; i) physic-chemical property characterization of nanoparticles such as silver, gold, titanium dioxide, polystyrene, silicon dioxide, CNTs and quantum dot has been conducted in order to develop their CRMs, ii) Surface structures and its compositions are studied using XPS, MALDI-ToF, ToF-SIMS etc. iii) The size measurement of nanoparticles is also executed with SMPS, DLS, PBMS, TEM, BET and AFM as a part of OECD WPMN and VAMAS (TWA34) projects. Nanoparticles trace technology using ToF-SIMS and Raman spectroscopy is under development. iv) The studies on the transport and potential transformation of nanomaterials (ADME) are underway.

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

Ministry of Knowledge and Economy (MKE)

MKE in collaboration with MEST has initiated the programme "Strategy on Nano Convergence Industry Development" to strengthen research on the safety and social impact of nanomaterials. The MKE/KATS implemented "Risk Management Platform Technology for NanoProducts (2009-2013)" which will provide an infrastructure for the certification of nanoproducts based on a risk management system including characterization, efficacy quality and safety assessment along with standard development. MKE submitted a “Plan for safety management of nanotechnology based products” to National Science and Technology Council and the plan were approved by the council in 2011. To carry out the ‘National Nano-safety Master Plan(2012~2016)’, MKE launched three projects in 2012 1) Planning for Nanoproduct Safety Center Establishment, 2) Methodology and Pilot Study on Nanoproduct Safety Evaluation, and 3) Studies on International Nanoproduct Regulation Trend and Case Studies on Self-declaration on Conformity of Nanoproduct. KATS has been developing national standards to ensure safety and support marketing of consumer products containing KATS prepared the Guidance on safe management of nanotechnology based product, which specifies appropriate compliances for nanoproducts manufacturers 1) to enhance acceptance of nanoproducts to the public, 2) to ensure sustainable development of nanotechnology, and 3) to promote safety for consumer and nanotechnology user. This guideline was published as national standard in 2011. The new national standards such as “the Generation of Nanoparticles of Inhalation Toxicity Testing Using Evaporation and Condensation Method", "the Characterization of Nano Particles in the Inhalation Chamber for Inhalation Toxicity Testing" and "the Preparation of Material Safety Data Sheet for Nanomaterials" as well as "Exposure Assessment of Manufactured Nanomaterials" will be published in 2013. The current existing standard related to the workplace safety such as “the **Error! Unknown document property name.**" will also be updated in 2013.

Ministry of Food and Drug Safety (MFDS)

MFDS and NIFDS (National Institute of Food and Drug Safety Evaluation) have conducted the safety studies for manufactured nanomaterials in order to evaluate the safety of manufactured nanomaterials and nanoproducts since 2005. NIFDS has been operating the Nanotoxicology Project since 2007. The Nanotoxicology Project mainly focuses on providing toxicity data for preparing guidelines to evaluate safety and nano risk management associated with food, drugs, medical devices and cosmetics using nanoscaled materials. Research areas in the Nanotoxicology Project encompass a wide range of safety issues related to nanoscaled nanomaterials including toxicological evaluation, risk assessment, ADME (absorption, distribution, and metabolism, excretion), kinetics, and physico-chemical characterization behavior. Test materials such as SiO_2, silver, gold, ZnO, and nano-calcium etc. have been used for the safety evaluation. Effects of size, shape and surface properties of nanomaterials on general toxicity, genotoxicity, immune response, developmental and reproductive toxicity, brain uptake mechanism, interaction with biomaterials are investigating. NIFDS has also been participating in the joint interlab study for CFE (colony forming efficiency) assay. From 2010 to 2013, NIFDS mainly conducted studies on the

selected nanomaterials, such as SiO_2, ZnO to get the information on physico-chemical properties, kinetics, and toxicity.

Ministry of Employment and Labor (MOEL)

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

KOSHA (Korea Occupational Safety and Health Agency, a subsidiary body of MOEL) has conducted the project concerning the risk assessment and management of nanomaterials in the workplace. Hazard of ultrafine dust generated from the workplace has been evaluated to study the connection between the dust and the increasing occupational disease. The inhalation exposure test of nano scaled carbon black and Indium oxide aerosols have been conducted to assess their health effects. Also, surveillance of the workplace treating nanomaterials has been carried out under the relevant guideline published in 2008, to monitor the effectiveness of safety management tool including personal protective equipment and ventilation system. Studies on the explosion and fire of nanomaterials started in 2013.

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

Information on public/ stakeholder consultation

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

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

THE NETHERLANDS

Highlights

- The European NANoREG project, coordinated by the Dutch Ministry of Infrastructure and the Environment, started on March 1, 2013.
- RIVM has facilitated a dialogue between Dutch stakeholders in order to poll views on how to address the lack of information on consumer products containing nanomaterials and under what conditions a register could actually help.
- The Netherlands are involved in several projects (with TNO leading some of them) on (worker) exposure to nanomaterials that will be fed into OECD-WPMN work as well.

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 European NANoREG project started on March 1, 2013. The project involves 60 partners from 14 EU member states and brings together regulators, toxicologists, researchers and industry. The 42-month project, with a total budget around 50 million euro, is coordinated by the Dutch Ministry of Infrastructure and the Environment. The project is aimed at answering the questions and needs of regulators regarding the environmental, health and safety (EHS) aspects of manufactured nanomaterials (MNMs). During the first eight months of the project, the work was mainly focused on generating the basic information and establishing the essential conditions for the Research and Development (R&D) part of the project. Since the (R&D) work within the NANoREG project is based upon and directed by the questions and needs of regulators in relation to EHS aspects of MNMs, these questions and needs have been updated and refined. A gap analysis has been carried out to identify the gaps in our knowledge. In order to make it possible to interlink the results of all the tests and experiments within the project as well as to previous work such as the OECD WPMN sponsorship programme, a core selection of MNMs has been established. These materials must be used by all partners. A selection of Standard Operating Procedures (SOPs) will be established in the short term. Furthermore other preparatory work for the R&D part of the project has been done; e.g. testing the applicability of protocols, developing exposure scenarios and designing experimental set-ups. A number of experiments, e.g. inhalation tests, already started. The generated information and data will be used to fill the validated NANoREG toolbox and database, in conformity with ECHAs IUCLID database structure. Tools for dissemination have been developed: the NANoREG website is operational (www.nanoreg.eu) and fact sheets, flyers and presentations for different target groups have been made available. On international level the cooperation with relevant bodies and organisations like OECD and ECHA are in an exploratory stage.

Partly based on discussions during the Policy Conference "Building Blocks for Completing EU Regulation of Nanomaterials" (hosted in The Hague by the Dutch Ministry of Infrastructure and Environment on 11-12 April 2013), RIVM published the report "Exploring building blocks for amending EU regulation of nanomaterials" that further explores the 6 building blocks that were identified to amend regulatory frameworks and improve risk assessment of nanomaterials. Furthermore, the building blocks aim at improving knowledge on nanomaterials in products. RIVM has explored these building blocks for their effectiveness and provides further interpretation for them. The six building blocks are: (1) a uniform definition of nanomaterials, (2) specific information requirements under REACH for a substance in nanoform, (3) lowering the production volume for registering a substance in nanoform or requiring certain information under REACH, (4) separate assessment of exposure and risk of nanomaterials for workers, and (5) a European register and/or (6) labelling of products that contain nanomaterials. The first building block has an overarching aim, whereas building blocks 2 and 3 are strongly related to the European REACH Regulation for chemical substances. The final three building blocks relate to other frameworks.

Information on risk assessment decisions

TNO is currently developing the next release (2.0) of their web-based risk or control banding tool Stoffenmanager-nano. Both the Hazard and the Exposure parts of the tool will be adjusted to the most recent information and agreed approaches to categorise hazard of, and exposure to nanomaterials.

Information on developments related to good practice documents

TNO coordinates LICARA, an EU funded project with special emphasis to support SMEs and SME associations with the introduction of sustainable nano-enabled products on the market by developing a risk-benefit screening tool. Within this tool life cycle assessment will be linked with human health and environmental risk assessment by developing a comparative risk assessment approach for all life cycle stages of a product.

TNO, Syntens and Nanocentre have started Nanocentre. The initiative is aimed at safe innovation with nanomaterials and includes a website, information point, newsletter and workshops with companies. Nanocentre is targeted at Dutch companies (including SMEs) and informed by an advisory board of stakeholders. All information is provided in Dutch. Nanocentre answers questions on safety of nanomaterials and assists companies in risk management of nanomaterials. In addition, Nanocentre tries to filter and translate new knowledge and channel that towards industry. Nanocentre is currently searching for ways of collaborating with innovators in nanotechnology.

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

The Dutch institutes RIVM, TNO and WUR (DLO-RIKILT) participate actively in the EU funded projects MARINA and NanoSafety Cluster, both of which will contribute to Integrated Testing Strategies and/or Alternative test methods. Recently this resulted in a publication on concern-driven integrated approaches to nanomaterial testing and assessment (Oomen et al. 2013, Nanotoxicology).

RIVM is also funding research projects investigating the use of *in vitro* studies for hazard and risk assessment of nanomaterials, possibilities to extrapolate safety data between different nanomaterials and identifying adequate dose metrics enabling the prediction of responses of different nanomaterials. Furthermore, RIVM provides two members for the management committee of an action by the European Cooperation in Science and Technology (EU COST) on Modelling of Nanomaterial Toxicity (MODENA).

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

RIVM, WUR (DLO) and TNO are actively involved in the working groups of the EU NanoSafety cluster. The EU Strategic Research Agenda (NanoVision 2020) has been released and scientists of these institutions will actively disseminate it in the EU-US Communities of Research (CoRs).

Several Dutch partners (RIVM, TNO, Utrecht University, GeoChem, and NanoThinks) are involved in the European GUIDEnano project. The project aims to develop new strategies and create a web-based guidance tool for nanotech industries to assess and mitigate nano-enabled product risks on human and environmental health in a tiered risk assessment. RIVM is leader of the WP dealing with the risk assessment strategy and within the WP Hazard Assessment RIVM is responsible for the human health hazard testing strategy.

TNO is partner in NanoInsight funded by the European Commission. NanoInsight will provide a 'nano-landscape' and give insights in industrial innovation and production activities, science and technology development, and societal needs and challenges. It also aims to provide insights in the interactions between these elements. In the societal needs and challenges, several overarching themes are discussed: the human health and environmental safety issues, regulations, drivers and barriers for nanotechnology, and societal dynamics.

Information on public/stakeholder consultation

In October 2013 the Netherlands Food and Consumer Product Safety Authority organised a symposium on 'risk assessment of nanostructured materials: the case of silica'. New, not yet published studies on the kinetics and toxicity of Synthetic Amorphous Silica (SAS) were presented and discussed in light of the potentials risks related to the presence of SAS in food (also known as additive E551).

RIVM has facilitated a dialogue between Dutch stakeholders in order to poll views on how to address the lack of information on consumer products containing nanomaterials and under what conditions a register could actually help. Representatives of various ministries, authorities, industries and non-governmental organisations were interviewed prior to establishment of a discussion panel. Three main questions were discussed: 1. Is a register/database of products containing nanomaterials desirable? 2. How can we in the Netherlands best prepare for a European register/database? 3. What information should be registered? According to Dutch stakeholders there are two main goals which an overview of products containing nanomaterials should meet, i.e. transparency for consumers and traceability in the supply chain. The database was not always seen as the only way to achieve these goals. Suggested alternatives were product labelling for transparency, while traceability can be assured if the industry itself takes action to enable timely information provision on request. Furthermore, another outcome of the dialogue was that it is important to achieve consensus with regard to the purpose of a registration system before any further action is taken. It must be clear who is to use that system (the target group) and what information they require. Only when such aspects have been finalized will it be possible to proceed to the design phase, or to establish who is to bear overall responsibility. The results of this project are available in a report (in Dutch only) and summarized in a brochure (in English).

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

RIVM is one of the partners in the EU project FutureNanoNeeds (FNN), coordinated by Prof. Kenneth Dawson of the National University of Ireland (Dublin). FutureNanoNeeds will develop a novel framework to enable naming, classification, hazard and environmental impact assessment of the next generation nanomaterials prior to their widespread industrial use. It will uniquely achieve this by integrating concepts and approaches from several well established contiguous domains, such as phylontology and crystallography to develop a robust, versatile and adaptable naming approach, coupled with a full assessment of all known biological protective responses as the basis for a decision tree for screening potential impacts of nanomaterials at all stages of their lifecycle. Together, these tools will form the basis of a "value chain" regulatory process which allows each nanomaterial to be assessed for different applications on the basis of available data and the specific exposure and life cycle concerns for that application. Exemplar materials from emerging nano-industry sectors, such as energy, construction and agriculture will be evaluated via this process as demonstrators.

RIVM and Utrecht University are partners in the recently granted EU project NCC-FOAM (Self-assembly of nanocrystalline cellulose for lightweight cellular structures). When cellulose fibrils are processed under carefully controlled conditions, it is possible to release highly crystalline nano-particles known as "nano crystalline cellulose (NCC)". Recently, NCC-FOAM partners have developed a unique technique for self-assembling NCC into highly ordered "puff-pastry-like" layered cellular structures, i.e. foams. The constituent NCC nanofibres are sustainably sourced from paper mill or forestry waste. Within NCC-FOAM, the overall objective is to develop an NCC foam/resin composite that enables the design, development and processing of sustainable structural foam materials. The use of infused resins has yet to be developed, the challenge being to produce foams that are simultaneously structural, durable and renewably-sourced.

The European project SUN will focus on data generation of case-studies by conduction LCA-analysis, toxicity testing, as well as release and exposure measurements. The project will address risk mitigation and especially safer-by-design principles to reduce potential risk of nanomaterials. Several Dutch institutes (RIVM, TNO, WUR-DLO and VU/VMC) contribute to this project.

Information on development related to exposure measurement and exposure mitigation

The Netherlands (TNO) and Canada (Health Canada) have submitted a joined OECD-WPMN SG8 project proposal: Strategy for using metal impurities as tracers to distinguish carbon nanotubes from background aerosols. The goal of the project is to identify situations where catalyst impurities in CNTs can be applied as a sensitive but qualitative indicator (yes/no) of the presence of process-related releases of CNTs, and (where feasible) distinguish CNTs released in the workplace from background aerosols, within the scope and budget of typical occupational health and safety investigations.

TNO is chairing an informal group of exposure scientists which focuses on harmonisation of measurement strategy for inhalation exposure assessment, i.e. to derive consensus on data collection, data analysis and data reporting. Its most recent meeting was in conjunction with the 6th nanoEHS symposium (October 2013, Nagoya, Japan), where 30 scientists from 30 countries (4 continents), discussed developments of the NECID database, international activities with respect to measurement/ detection methods for CNTs, reports on developments on standardisation activities with respect to measurement strategy, i.e. the OECD/BIAC project and the CEN project and the EU-CEN project harmonisation of dustiness testing.

A PEROSH (Partnership of European Research on Occupational Safety and Health) working group initiated by TNO and IFA (Germany) is currently working on the structure of a Nano Exposure and Contextual Information Database (NECID). The current status is that a data entry module is available and all researchers are encouraged to use the templates for (future) uploading/population of the database. During the next year a data analysis and comparison tool will be developed.

TNO is leading two pre-normative research projects focused on the assessment of exposure to nanomaterials and will run for 1 year. The first project has the objective to give guidance to the assessment of inhalation exposure by i) describing existing tiered-approach measurement strategies, ii) evaluation of decision criteria used in these measurement strategies and iii) propose methods for a comprehensive exposure assessment. The second project is on dermal exposure and has similar objectives. However, dermal exposure assessment to nanomaterials is in its embryonic stage and hardly any strategies have been developed so far. Therefore, the first phase of this project will be more explorative where dermal exposure mechanisms and processes will be described from different angels, i.e. the relevance of dermal exposure to nanomaterials for i) dermal uptake, ii) local skin effects, and iii) oral intake. Similar to the inhalation project some experimental work has been foreseen, however, its direction will be based on the results of the first phase of the project.

Additional Information

The Knowledge and Information centre on Risks of Nanotechnology (KIR-nano) aims at observing and monitoring the potential risks of nanotechnology, gathering relevant scientific literature, generating overviews of relevant legislation, and advising and informing governmental bodies and professionals. These activities are always performed from a risk assessment point of view. Its signalling function is put into practice by participating in national and international networks (e.g. OECD-WPMN, REACH CASG-Nano, ISO, SCENIHR, ILSI, EFSA, SETAC, WHO/FAO, ETP NanoMedicine) and bringing experts together into national expert panels on different topics (environment, food, consumer products, medical applications, and workers).

POLAND

Highlights

In Poland, since the 10th meeting of the Organization for Economic Cooperation and Development (OECD) Working Party on Manufactured Nanomaterials (WPMN) in June 2012, The National Platform for Nanosafety has been established which will constitute a reference centre in this field.

Information on Risk Assessment Decisions

The National Platform for Nanosafety has been established with Nofer Institute of Occupational Medicine in Lodz as the leading institution (wojciech@imp.lodz.pl). Partners of the Platform include: Textile Research Institute (Lodz), University of Lodz, and West Pomeranian University of Technology, Szczecin.

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

Researchers of the National Platform for Nanosafety participated in the following projects on nanosafety:

- EU MARINA (Managing Risks of Nanomaterials)
- EU NANOGENOTOX (Facilitating the safety evaluation of manufactured nanomaterials by characterising their potential genotoxic hazard)
- EU QualityNano: the European Union-funded infrastructure for Quality in nanomaterials safety testing
- OECD WPMN - SG7 (Colony Forming Efficiency (CFE) assay - interlaboratory study for assessing cytotoxicity of nanomaterials).
- Development of nano-structured textile composites with barrier and photocatalytic properties (EUREKA project number: E!3776 NANOTEX)
- Project funded by The Polish National Science Centre: In vitro assessment of selected protumorigenic effects favoring breast cancer development after exposure to silver nanoparticles in combination with common cosmetic constituents: aluminium salts, parabens, and phthalates (2013-2016)
- Functional nano- and micro textile materials. Project No. POIG.01.03.01-00-004/08 co-financed by the European Union with the financial resources of the European Regional Development Fund and the National Centre for Research and Development within the framework of the Innovative Economy Operational Programme, 2007-2013.
- Projects funded by The Polish Committee for Scientific Research:
- Modified TiO_2/Ag PP fibres with the limited susceptibility to accumulation of nicotine (#N N 508 4407 36)
- Multi-functional textile materials with photocatalytic properties (#N507 4460 34)
- Fiber-polymeric multilayer composite materials of new generation, protecting against electromagnetic radiation (#3 T08E 051 30)
- Cellulose nanofibers useful in medical applications (#N N507 3791 35)
- The use of nano-iron compounds in the processes of industrial wastewater purification by Fenton method (#N N523 7512 40)

- Functionalization of textile materials with metal oxide nanoparticles (#3 T08A 045 30).

Information on public/ stakeholder consultations

- Help desk (in Polish) operates on the website of Bureau for Chemical Substances (http://www.chemikalia.gov.pl/informacje_ogolne2.php) dedicated to current issues of nanosafety regulations.

UNITED STATES

Highlights

In April 2013, NIOSH released the document *Current Intelligence Bulletin 65:* ***Occupational Exposure to Carbon Nanotubes and Nanofibers*****.** This NIOSH document proposes a recommended exposure limit (REL) of 1 μg/m^3 elemental carbon as a respirable mass 8-hour time-weighted average (TWA) concentration

On June 26, 2013 EPA issued final significant new use rules (SNURs) for 7 carbon nanotubes and 7 fullerenes.

On February 25, 2013 EPA issued a proposed SNUR for 14 carbon nanomaterials including carbon nanotubes and nanofibers.

The United States and Canada continued their cooperation on nanomaterials under the Regulatory Cooperation Council (RCC). Under the RCC process, technical teams developed, disseminated and discussed with stakeholders products in the following areas: Classification/Priority Setting, Risk Assessment/Risk Management, and Commercial Information.

The 2013 National Nanotechnology Initiative Workshop on the Perception, Assessment, and Management of the Potential Risks of Nanotechnology took place on September 10-11, 2013 in Washington, DC. It gathered stakeholders from industry, labor, academia, government, and non-governmental organizations, to discuss the assessment, management, and communication of potential risks associated with the use of nanomaterials. The RCC Nanotechnology Final Results Workshop will be held January 14, 2014 in Washington, DC.

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 April 2013, NIOSH released *Current Intelligence Bulletin 65:* ***Occupational Exposure to Carbon Nanotubes and Nanofibers*****.** This NIOSH document (1) reviews the animal and other toxicological data relevant to assessing the potential non-malignant adverse respiratory effects of carbon nanotubes and carbon nanofibers, (2) provides a quantitative risk assessment based on animal dose-response data, (3) proposes a recommended exposure limit (REL) of 1 μg/m^3 elemental carbon as a respirable mass 8-hour

time-weighted average (TWA) concentration, and (4) describes strategies for controlling workplace exposures and implementing a medical surveillance program. The NIOSH REL is expected to reduce the risk for pulmonary inflammation and fibrosis.

Regulatory Actions. Since January 2005 EPA has received and reviewed more than 160 new chemical notices for potential nanoscale materials under the Toxic Substance Control Act (TSCA) including fullerenes and carbon nanotubes. EPA has issued consent orders and significant new use rules (SNURs) regulating new chemical submissions of these nanoscale materials permitting manufacture under limited conditions. A sanitized version of such a consent order is available. Because of confidential business information claims by submitters, EPA is unable to identify the chemical substance as a nanoscale material in every new chemical SNUR it issues for nanoscale materials. EPA will continue to issue SNURs and consent orders for new chemical nanoscale materials in the coming year.

On June 26, 2013 EPA issued final SNURs for 7 carbon nanotubes and 7 fullerenes. See https://www.federalregister.gov/articles/2013/06/26/2013-15032/significant-new-use-rules-on-certain-chemical-substances.

On February 25, 2013 EPA issued a proposed SNUR for 14 carbon nanomaterials including carbon nanotubes and nanofibers. See http://www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04298.pdf.

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

After responding to public comments regarding the proposed decision to conditionally register a pesticide product containing nanosilver as a new active ingredient, EPA conditionally registered the antimicrobial pesticide product, HeiQ AGS-20, for use as a preservative for textiles on December 1, 2011. In NRDC v. EPA, No. 12-70268 (Nov. 7, 2013), the Ninth Circuit Court of Appeals expressed a concern regarding the aggregate exposure calculations used to support the registration. To address the concerns of the court, EPA approved a surface coating method of application for AGS-20 with a reduced maximum application rate (at no more than 19 ppm of silver) and a more limited set of textiles and fibers as compared to parameters approved by the agency on December 1, 2011. EPA has received and is currently reviewing Tier I data required through the conditional registration and expects to make determinations on any updates to Tier II data requirements in early 2014.

On August 27, 2013, EPA announced a proposed decision to register a nanosilver-containing antimicrobial pesticide product named "Nanosilva." This silver-based product is used as a non-food-contact preservative to protect plastics and textiles (e.g., in household items, electronics, sports gear, hospital equipment, bathroom fixtures and accessories) from odor and stain causing bacteria, fungi, mold and mildew. Based on an evaluation of scientific literature and data submitted by the applicant, EPA determined that Nanosilva will not cause unreasonable adverse effects to humans (including children) or the environment. As a condition of registration, EPA is requiring the company to generate additional data to be used to refine EPA's understanding of the nanosilver particles in the product. EPA is currently reviewing and responding to comments received from the public and expects to issue a final decision in early 2014.

UC CEIN – Carbonaceous Working Group. **University of California's Center for Environmental Implications of Nanotechnology (CEIN) is f**unded by a cooperative agreement

from the National Science Foundation and EPA-ORD Agency, and is housed within the California NanoSystems Institute (CNSI) at **University of California**, Los Angeles (UCLA).

The Carbonaceous Working Group (CWG) was created to ensure that CEIN research addresses those aspects of carbonaceous nanomaterials that are important to EPA's regulation of nanomaterials. To that end, regular teleconferences with EPA and members of the working group have been held to gain common understanding of EPA's needs for carbon nanomaterials and of the CWG's initial consideration of research directions. Discussion has focused on past or ongoing testing by EPA or CEIN of various carbon nanomaterials, potential synergies between the CWG and EPA's range of work on carbonaceous materials, and identifying key areas for collaboration moving forward.

NNI Workshop on Risks of Nanotechnology. The 2013 National Nanotechnology Initiative Workshop on the Perception, Assessment, and Management of the Potential Risks of Nanotechnology took place on September 10-11, 2013 in Washington, DC. It gathered stakeholders from industry, labor, academia, government, and non-governmental organizations, to discuss the assessment, management, and communication of potential risks associated with the use of nanomaterials.

Plenary sessions featured perspectives from various communities on their approach to risk-based decisions. Representatives from the *Research, Regulatory, Nanomanufacturing, Small Business, Financial Risk, NGO and Other Public* communities participated in b*reakout sessions* on both days. The breakout sessions on day 1 focused on the "Types of Decisions" from the perspective of various communities in their approach to *Occupational Risk Analysis, Commercial Product Life Cycle, and Environmental Life Cycle*. The breakout sessions on day 2 centered on the "Decision Makers" by gathering inputs from each community. Roundtable discussions with representation from *Emerging Businesses*, the *Pharmaceutical Industry*, and *Public Risk Perception and Communication* groups also took place on day 2 of the workshop.

RCC nanotechnology joint work plan. Following Prime Minister Harper and President Obama's announcement of the Canada-United States Regulatory Cooperation Council (RCC) in February 2011, Canada and the United States have been working to better align their regulatory approaches in a number of areas, including nanotechnology.

In March 2013 the United States and Canada jointly conducted a RCC workshop to obtain stakeholder input on the topics of Classification/Priority Setting, Risk Assessment/Risk Management, and Commercial Information. Under the RCC process the following work products have been developed by technical teams, and disseminated and discussed with stakeholders over monthly conference calls and/or webinars.

Classification/Priority Setting – Participants shared information on how programs are currently classifying nanomaterials *ad-hoc* for the purposes of risk assessment and management, and developed potential classes based on current regulatory frameworks and identified important parameters within classes. RCC intends to contribute these findings to the OECD Expert Meeting on Categorization of Manufactured Nanomaterials that took place in September 2014.

Risk Assessment/Risk Management – Participants conducted a comparative analysis of risk assessment methodologies used by the two countries. This was facilitated by sharing risk assessment reports and peer-review of each country's assessments for a multi-walled carbon nanotube that was selected for the case study because it had previously been reviewed as a new chemical substance by both countries.

Commercial Information – Participants conducted analysis of information from Canadian and US regulatory programs, public databases, and third-party reports to improve understanding of commercial

uses of nanomaterials in North America. Outreach with other government departments/agencies (e.g., US Food and Drug Administration and US Consumer Product Safety Commission) and external stakeholders (e.g., Industry Coordination Group in Canada and American Chemistry Council) was used to engage, obtain and validate information, leading to development of a use matrix that correlates uses with specific types of nanomaterials. The use categories in the matrix may not correspond to specific legal categories under similar statutes and regulations in both countries, e.g., "TSCA," "FDA," or "FIFRA" uses. Accordingly, the workgroup decided to collect information on all industrial uses, which included pesticides, medical devices, and cosmetics, to provide some comparative context between both countries.

The RCC Nanotechnology Final Results Workshop will be held January 14, 2014 from 9:00 am to 4:30 pm at US EPA Headquarters, William Jefferson Clinton East Building room 1153, 1201 Constitution Ave., NW, Washington, DC 20004. At this final workshop, key findings will be presented and next steps discussed.

National Science Foundation (NSF). NSF supports nanoscale science and engineering in for about 5,000 active awards for fundamental research, centers and education in 2013. About 10,000 students and teachers have been educated and trained. The NanoEHS portfolio contains single investigator, group and center grants mostly in areas of analytical methods/instrumentation, environmental interactions, and biological effects. Three large nanoEHS centers have the main nodes at UCLA (CEIN), Duke University (CEINT) and University of West Virginia (EPSCoR – nanoEHS). While work on health effects of nanomaterials' continues in areas such as high-throughput screening and nanomaterials exposure, the current research is trending toward holistic ecosystem approaches, effects of nanocomposites, nanodevices and heterogeneous systems. This research includes studies on the fate and transport of nanomaterials in natural aquatic and marine environments, and quantification of nanomaterials in more natural matrices without extensive pre-sample preparation. While basic nanomaterials (such as Ag, Au, metal oxides, and carbon nanotubes) are still emphasized, more complex emerging nanomaterials and coating variants are increasingly examined. Due to the importance of material characterization for both fate and effects' research, there are increased collaborations that involve partnering between material scientists and EHS researchers.

Developments related to voluntary or stewardship schemes

NIST representatives as part of the committees of the US Technical Advisory Group to ISO TC229 (Nanotechnologies) have facilitated cooperation and coordination between OECD WPMN and ISO TC229. The WPMN has a formal liaison with the ISO TC229 and the two organizations share work results prior to public release. ISO TC229 is assisting the WPMN in determining for physical-chemical parameters such as particle size and the relevant measurands and measurement methods for each parameter. Initial consultation was done at the OECD Expert Meeting on Physical Chemical Properties of Manufactured Nanomaterials.

Information on risk assessment decisions

In April 2013, NIOSH released Current Intelligence Bulletin 65: **Occupational Exposure to Carbon Nanotubes and Nanofibers.** The document puts forward a Recommended Exposure Limit (REL) for carbon nanotubes and nanofibers of 1 $\mu g/m^3$ elemental carbon as a respirable mass 8-hour time-weighted average (TWA) concentration.

Since January 2005 EPA has received and reviewed more than 160 new chemical notices for potential nanoscale materials under TSCA including fullerenes and carbon nanotubes. EPA must determine whether manufacturing, processing, use and disposal of any of these materials may present an unreasonable risk.

EPA conditionally registered the antimicrobial pesticide product, HeiQ AGS-20, for use as a preservative for textiles on December 1, 2011.

On August 27, 2013, EPA announced a proposed decision to register a nanosilver-containing antimicrobial pesticide product named "Nanosilva," which is used as a non-food-contact preservative to protect plastics and textiles from odor and stain causing bacteria, fungi, mold and mildew. Based on an evaluation of scientific literature and data submitted by the applicant, EPA determined that Nanosilva will not cause unreasonable adverse effects to humans or the environment.

Information on developments related to good practice documents

In May 2012, NIOSH released the document *General Safe Practices for Working with Engineered Nanomaterials in Research Laboratories*. The document, which was initiated as a joint effort between NIOSH and National Science Foundation Center for High-rate Nanomanufacturing is intended to raise awareness of the occupational safety and health practices that should be followed during the synthesis, characterization, and experimentation with engineered nanomaterials in a laboratory setting. The document contains recommendations on engineering controls and safe practices for handling engineered nanomaterials in laboratories and some pilot scale operations.

In November 2013, NIOSH issued the document *Current Strategies for Engineering Controls in Nanomaterial Production and Downstream Handling Processes.* The focus of this document is to identify and describe strategies for the engineering control of worker exposure during the production or use of engineered nanomaterials.

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

On March 11, 2013, NIOSH reported at the annual meeting of the Society of Toxicology preliminary findings from a new laboratory study in which mice were exposed by inhalation to multi-walled carbon nanotubes (MWCNT) [see http:// blogs.cdc.gov/niosh-science-blog/2013/03/mwcnt/]. The study was designed to investigate whether MWCNT have the potential to initiate or promote cancer. Mice receiving both an initiator chemical plus inhalation exposure to MWCNT were significantly more likely to develop tumors (90% incidence) and have more tumors than mice receiving the initiator chemical alone. These results indicate that MWCNT can increase the risk of cancer in mice exposed to a known carcinogen. The study did not indicate that MWCNTs alone cause cancer in mice. This research is an important step in our understanding of the hazards associated with MWCNT.

Information on public/ stakeholder consultation.

From January 18, 2013 to March 19, 2013, NIOSH requested comment on the types of hazard identification and risk management research that should be considered for updating the NIOSH FY2013-FY2016 nanotechnology strategic plan *Protecting the Nanotechnology Workforce: NIOSH Nanotechnology Research and Guidance Strategic Plan 2013-2016* which can be found in Docket CDC-2013-0001 at http://www.regulations.gov.

In March 2013 the United States and Canada jointly conducted a Regulatory Cooperation Council (RCC) workshop to obtain stakeholder input on the topics of Classification/Priority Setting, Risk Assessment/Risk Management, and Commercial Information. Under the RCC process, work products have been developed by technical teams, and disseminated and discussed with stakeholders over monthly conference calls and/or webinars.

UNITED KINGDOM

- Completion of intelligence gathering exercise
- The EU is considering how best to ensure that existing chemicals regulation, REACH, should address nanotechnologies.
- As well as national research, the UK is active in a number of pan-European projects funded through the European research funding Framework Programme 7, and which are geared to provide answers to how existing European regulation can be made "fit for nano". These include, in particular:
    - NanoReg, which aims to provide a toolbox for regulators for testing, risk assessment and decision making on nanomaterials;
    - NanoFATE, focussing on products containing particular engineered nanoparticles (ENP) groups that are likely to reach the environment as "free" particles due to their pattern of use and disposal;
    - NanoMILE, set up to deliver new approaches for the classification of nanomaterials and the prediction of their fate & behaviour in the environment and for human health;
    - TINE, looking at land application of sewage-derived sludge.

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 EU is currently considering how the existing chemicals regulation, REACH, should address nanotechnologies. This follows a consultation over the summer by the European Commission.

The European NANoREG project, instigated under the EU Framework Programme (FP7) Regulatory Testing of Nanomaterials (NanoReg) call, was launched in March 2013. The UK Government has made a substantial commitment to the Project and is funding a consortium of UK partners to contribute to a range of activities. Early UK activities in this 42 month international collaborative initiative include (a) an industry survey of nanomaterial exposure scenarios, which is due to be launched in late 2013, and (b) initial validation and trialling of computational modelling techniques and tools at Leeds University, using data outputs from previous peer-reviewed studies. Further details on UK progress will be made available via a NANoREG website, which is expected to be launched in early 2014.

Developments related to voluntary or stewardship schemes;

The UK Government has been working in partnership with UK nanotechnologies industries and research communities to gather data on which nanomaterials are being manufactured and used in the UK. This has enabled the compilation of a database which provides details of manufacturers and users of nanomaterials, along with details of substances and anticipated uses. This dataset is to be held and periodically updated by the Government and will be used to inform governance and risk management decisions.

Information on developments related to good practice documents;

- The UK's Health and Safety Laboratory are leading a project under CEN TC 352, to develop a "Guide to the management of waste and the disposal of nanomaterials". This will provide guidelines for the management of waste and disposal of nanomaterials.

- The UK NanoSafety Partnership Group, in collaboration with the Health and Safety Executive, has produced a guidance document "*Working Safely with Nanomaterials in Research and Development*". It provides help to research establishments and academia on how to comply with their occupational health and safety legal obligations and to improve working practices.

- An output from the EU FP7 project NanoReTox on protocols for stable-isotope labelling of nanomaterials is currently being developed as a standard within CEN TC 352 following analysis of core documentation via the NanoSTAIR project.

- The Health and Safety Laboratory provides a one day course on Nanotechnology Health & Safety: A Practical Approach to industry. This training is focused on exposure assessment and control measures.

- NanoFATE has developed ecotoxicology testing methods adapted from standard operating procedures, available in Deliverable 3.1, and a tiered approach to tracking ENPs in tissues.

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

The Health and Safety Laboratory has developed human in-vitro screening toxicity tests for nanomaterials that are based on whole blood coagulation assays. Additional tests employ human respiratory and skin cells as well as human peripheral mononuclear cells. Under the EU NanoDevices project, results from HSL in-vitro tests resembled those found in animal inhalation model experiments.

The recently completed FP7 project NanoReTox utilised a series of non-OECD-standard *in vivo* models including mussels and worms. High-risk populations such as filter feeders or bethnic species may be exposed to higher than usual concentrations of nanomaterials so assessment of model species may provide important insights regarding at-risk populations. Long-term and short-term exposures were performed, and multiple publications have resulted.

Intelligent / integrated testing strategies was a key recommendation of the EU NanoSafety Cluster Research Roadmap 2020, and has resulted in inclusion of a call for a project on this in the European Horizon2020 research funding for 2015. Thus, considerable investment in this area is expected in the near term.

A multi-disciplinary working group is considering how the diagnostic tools developed at the University of Birmingham, which provide qualitative and quantitative measures of the impact of multiple stressors as subtle early warning systems, can be translated into routine environmental risk assessments for regulatory purposes. A key outcome will be the development of a template for influencing future environmental legislation.

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

EU Collaborative projects

NanoFATE has investigated the spatio-temporal variability of nano silver (nano Ag) and nano zinc oxide (nano ZnO) concentrations in surface waters and soil across Europe, modelled using the GIS-based model GWAVA and a gridded population dataset. The effect of processes such as dilution, transport, and water abstraction has been considered. This model will be further parameterised to account for transformation processes within surface waters and soils. Furthermore the role of environment characteristics, such as pH and organic matter content, in affecting bioavailability, and subsequent toxicity, of ENPs has been investigated. Correction factors for models to address these effects on bioavailability will be produced. The predicted environmental concentrations generated by this model have been combined with the results from the hazard assessment to produce pan-European risk maps. The mechanistic toxicity of non-nano and ENP forms of the metals/metal oxides studied is being compared through the generation of DEBTox (Dynamic Energy Budget) parameters, datasets on cellular- and enzyme- based biomarker assessment focussing on the role of ROS (Reactive Oxygen Species) mediated toxicity, MIAMI compliant data-sets of ENP effects measured using micro-array and/or pyrosequencing approaches.

TINE is investigating the potential environmental risks of metal and metal oxide ENP use. A consideration of the potential routes of ENP transport and exposure in the environment suggested the land application of sewage-derived sludge as a key terrestrial exposure route. Therefore, TINE has focused upon tracking ENPs from wastewater through sewage works and sludge production, to sludge processing and final mixing with soil, aiming to generate contaminated sludge in as realistic a manner as possible. Sludge has been generated by spiking ENP forms of Ag, Zn (ZnO) and Ti (TiO_2) into the process feed of a pilot scale WWTP to generate a final NP-contaminated sludge. Sludge samples have been mixed with samples of a field soil and ENP bioavailability and toxicity are being assessed using a battery of tests including wheat uptake and impacts on earthworm reproduction.

Under the EU NanoImpactNet Project, the Health and Safety Laboratory have collaborated with other EU partners to draft A Road Map Toward a Globally Harmonized Approach for Occupational Health Surveillance and Epidemiology in Nanomaterial Workers.

NanoMILE, led by the University of Birmingham, is addressing engineered nanomaterial mechanisms of interactions with living systems and the environment in order to develop a universal framework for safe nanotechnology. NanoMILE includes a large systems biology / high throughput screening component.

UK partners are also active in a range of other European FP7 projects relevant to nano safety.

UK National initiatives

FABLE: From Airborne exposure to Biological Effects: Pathways for health impacts of nanoparticles - an inter-disciplinary approach to increase understanding of the human health impact of three metal nanoparticles, Cerium, Vanadium and Zinc.

NanoBEE: UK-US Consortium for Manufactured Nanomaterial Bioavailability & Environmental Exposure. The nano-BEE consortia is developing and refining, using empirical data, a critical subset of models focused on exposure to nanomaterials (NMs) and their bioavailability in the environment. UoB are one of the 3 UK partners.

NERC ENI: The Environmental Nanosciences Initiative was set up by the UK's Natural Environment Research Council to address questions of fate and behaviour, ecotoxicology and ecological effectsthrough pump priming to researchers. The second phase is undertaken in collaboration with the US and will report during 2014. As part of the ENI, the UK national Facility for Environmental Nanoscience Analysis and Characterisation (FENAC) was set up in order to produce reliable data analysing nanoparticles under realistic conditions for the better understanding of biological and environmental impacts of MNPs.

Information on public/ stakeholder consultation

The UK government held the third meeting of the UK Nanotechnologies Strategy Forum (NSF) in June 2013. This was established with a two-year mandate to facilitate discussion and engagement between Government and key stakeholders on strategic issues for the responsible advancement of the UK's nanotechnologies industries. The NSF is an ad hoc expert advisory body with a membership drawn from industry, regulators, academia and NGOs and reflecting a wide range of stakeholder perspectives. The final meeting of the current mandate will be held in early 2014 and the UK government is currently considering how stakeholder engagement will be taken forward.

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

ModNanoTox is an EU-US modelling project assessing the environmental impacts of nanomaterials, which ended in October 2013. ModNanoTox has developed a number of well-documented and technically advanced models describing the behaviour of engineered nanoparticles in an environmental or biological context, utilising as model systems silver nanoparticles and aquatic environments, with species assessed including daphnia magna, algae and bacteria. ModNanoTox also produced a fully described methodology for assessing data quality of data from the literature entered into the database, and the database is now being formatted to be ISATab compatible, and will form the training dataset for the EU ontologies and database project, eNanoMapper.

Information on development related to exposure measurement and exposure mitigation.

- HSL is developing a pragmatic strategy to assess the potential exposure of workers and assess the effectiveness of the controls, based on simple to use hand held instruments and occupational hygiene assessment of workplace.
- HSL is also involved in projects led by Germany and the Netherlands on: a **Nano Exposure & Contextual Information Database (NECID) project, on occupational exposure to NMPs, and;** CEN137 WG3, underpinning of decision criteria in a tiered approach process to develop a standard for the assessment of exposure to inhaled manufactured to nanoparticles.
- Dustiness enables the practical assessment of the propensity of nanopowders to become airborne during handling. Under the FP7 project NanoDevices, the UK Health and Safety Laboratory has completed work where 20 nanopowders have been tested in the rotating drum for mass related biological fractions, number concentration and size distribution. HSL is planning to work with PEROSH institutes to harmonise and standardise dustiness testing for nanopowders.
- HSL has just participated in an inter-laboratory comparison of condensation particle counters which will inform the development of a CEN/TC137 workplace standard for charatcterising ultrafine aerosols.
- Within NanoFATE, single particle ICP-MS technique has been applied to quantify engineered nanoparticles size distributions within environmentally realistic aquatic media, such as wastewaters and effluents. Results can inform predictive models of environmental fate and effects of ENPs.

Additional Information

HSL has developed and modified equipment to test for fire and explosion properties of nanopowders: including development of a 2 litre explosion test apparatus for measuring the maximum rate of pressure rise and maximum explosion pressure, and; development of a minimum ignition energy test apparatus using a modified Kuhner MIKE3 test apparatus.

Bilateral collaborations between research institutes are underway with partners in countries including Brazil, India and the Philippines.

SOUTH AFRICA

1. Recent developments on nanotechnology in South Africa include:

- *The Framework for the Establishment of the Nanotechnology-HSE Research Platform in South Africa:*

The Department of Science and Technology (DST) in South Africa being the custodian of the National Nanotechnology Strategy approved by Cabinet in 2005, endeavors to ensure that nanotechnology-driven benefits to the South Africans – both sociological (e.g. in water, health and energy), and economical (e.g. advanced industrial manufacturing) are exploited safely, responsibly, and sustainably. Further, the department being aware of the increasing concerns on the effects of nanomaterials to humans and other biological life forms has recently embarked in a proactive approach by establishing the Nanotechnology Health, Safety, and Environment (HSE) Research Platform. To assist the process, a base line study has been initiated to compile the required information on the extent of development of nanotechnologies and on the variety of nanomaterials synthesized and implemented in these technologies in South Africa. The latter will help identify applications that may result in significant human and environmental exposures. A similar base line study has also been initiated to compile information on the infrastructure and human recourses that may be available at different institutions to contribute to the assessment of health and safety of the synthesized or implemented nanomaterials. As the concept of the Nano-HSE Research Platform will be based on the Health Risk Assessment paradigm, these baseline studies would then be used to guide future directions in research themes within focus areas identified within the boundaries of this Research Platform.

- *Workshop on Exposure Assessment to Nanoparticles:*

The National Institute for Occupational Health (NIOH), in collaboration with the World Health Organization (WHO), recently hosted a workshop on “Exposure Assessment to Nanoparticles”. This was the first workshop of its kind to be held in South Africa. International leaders in the field presented talks that encompassed important factors for occupational health and safety. The collaborative effort represented by this workshop has focused on current global concerns and regulations surrounding nanomaterial exposure assessments. Themes discussed have included:

- An update on technologies and methodologies in exposure assessment to nanoparticles in work and research environments
- Case studies in exposure assessment to nanoparticles in developing and developed countries performed in different industries
- Global efforts on Standards for nanomaterials
- Risk assessment, risk analysis and risk management
- The 3rd South African Nanoscience and nanotechnology Summer School 24-29 November 2013:

The South African DST has initiated these summer schools with the aim of creating a pool of nanoscientists sufficiently trained to conduct nanoscience and nanotechnology research, development and innovation activities. The topic of this year's Nanoschool was nanotechnologies impact on water treatment and the environment. Around fifty students from different universities have attended the school where they were trained by national and international speakers.

THAILAND

Highlights of Developments in public agencies and institutes

The National Nanotechnology Center (NANOTEC)

NANOTEC, the most recent Technology Centres under the National Science and Technology Development Agency (NSTDA) has set strategic goals with respect to the safety of manufactured nanomaterials as follow:!

1. Conduct research on measuring nanomaterials in the workplace, including developing new measurement methods and validating measurement methods. Also, the nanotoxicity in human health,and environment is being investigated.
2. Strengthen the capability of nanosafety and risk assessment program.
3. Standardize and validate nano-scale measurement and testing methods.
4. Integrate nanosafety roadmap into the National Chemical Safety Strategic Plan.
5. Evaluate the role of nanoparticle properties in exposure-dose-response relationships, develop and validate models for nanoparticle risk assessment, and determine risk estimates of occupational exposures

1. National Nanosafety Strategic Plan which had already been approved by the Cabinet and in the process of implementation
2. Nanotechnology Information Center of Thailand (NICT) at Chulalongkorn University which has started the 2nd year of operation
3. "Nano Q" as a nanomark for selected Thai nano-products to certify the presence of nanoparticles and nano-properties e.g. anti-bacterial and water repellent

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

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

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

7. Nanotoxicity and ecotoxicity research program of nanosilver, TiO_2, fly ash particles

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

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

10. Collaboration with the Ministry of Public Health and the Ministry of Labor for nanoparticle screening in manufacturing plants

Thai Industrial Standard Institute (TISI)

Thai Industrial Standard Institute (TISI) and NANOTEC have participated in ISO TC229 and set up a steering committee for the National Terminology of Nanomaterials. Dr. Nattapan Supaka of NANOTEC accompanied the Thai Delegation to most of the recent meetings of ISO TC229.

Chulalongkorn University

NANOTEC has established the Nanotechnology Information Center of Thailand (NICT) in collaboration with Chulalongkorn University for two years. NICT has served as the focal point in monitoring movements in issues related to nanomaterials and nanotechnology. It also serves as a focal point in disseminating such knowledge to the Thai public. Over time, NICT is expected to become an independent agency in order to boost its credibility as an impartial organization. In addition to the scientific and technological components, the Center for Innovative Nanotechnology (CIN) of Chulalongkorn University has two built-in programs or units that cover the topics of nanosafety and nanoethics, respectively. A few months ago, Princess Maha Chakri Sirindhorn initiated a collaboration between Peking University and a few Thai institutions including Chulalongkorn University in various aspects of nanotechnology. Early in 2013, representatives of CIN (mostly members of the Executive Board) flew to Korea to initiate collaborative projects with faculty members and researchers of Sungkyunkwan University.

Asia Nano Forum Network Organization

In 2012, NANOTEC initiated “Bangkok Declaration” in the Asia Nano Forum Summit, which determined the collaboration and exchange information in Nanosafety and related topics among 15 economies. The ANF network is coordinated by government organization, leading R & D organization or a national nanotechnology coordination office in each participating economy:

1. Australia : Australia Research Council Nanotechnology Network & Australian Nano Business Forum Limited
2. China : Suzhou Nanotech
3. Hongkong: Nanotechnology and Advanced Materials Institute (NAMI)
4. India: Advanced Research Centre International (ARCI)
5. Indonesian : Indonesian Institute of Sciences
6. Iran: Iran Nanotechnology Initiative Council (INIC)
7. Japan: National Institute of Advanced Industrial Science and Technology (AIST)
8. Korea: Korea Institute of Science &Technology Information(KIST) and Korean Nanotechnology Researchers Society (KoNTRS)
9. Malaysia : Academy of Sciences Malaysia
10. New Zealand : Victoria University of Wellington & The MacDiarmid Institute
11. Singapore : Institute of Materials Research & Engineering (IMRE)
12. Taiwan : Institute of Physics, Academia Sinica
13. Thailand : National Nanotechnology Centre
14. Vietnam : Institute of Materials Science -Academy of Science and Technology (VAST)
15. UAE : Khalifa University of Science, Technology and Research

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

At the beginning of 2013, three nanosafety guidelines have been developed for the public, researchers, and industries. The nano-label, so called Nano-Q, have been initiated and already approved some nanoproducts in the mid of 2012 by Nanotechnology Association of Thailand. Nanosafety roadmap was initiated as the direction and implementation of the National Nanosafety Strategic Plan. Nanosafety Roadmap Workshop was co-organized by NANOTEC and UNITAR.

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

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

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

Developments related to voluntary or stewardship schemes

Stewardship schemes, i.e. NanoQ Project (certified mark of nano-products) are being implemented in parallel with the nanosafety guideline development. NanoQ has already established and started to approve nano-products for textiles, colour-paint, plastic and ceramics in order to certify nano properties e.g. anti-microbial and water-repellent.

Information on risk assessment decisions

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

Information on developments related to good practice documents

The guideline mentioned in Item 2.1 will refer to all domestic and foreign good practice documents that are found during the literature review stage.

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

Currently, NANOTEC has planned to study alternative methods how to separate and differentiate mixed nanoparticles from emulsion, lotion cream, and composite materials. Research projects on detection, characterization and interpretation of manufactured nanomaterials in heath products" are proposed**.**

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

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

Information on public/ stakeholder consultation

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

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

At present, a group of researchers at Naresuan University, a nanosafety consortium of NANOTEC, has been conducting a research focusing on the impacts of nanomaterials in the environment especially, in soils and water in order to find the exposure limit of nanomaterials. Also, the impact of manufactured nanomaterials on health of workers has been studied and monitored by Nanosafety and Risk Assessment Laboratory of NANOTEC.

Information on development related to exposure measurement and exposure mitigation

Nanosafety guidelines, related to exposure mitigation, prevention, and waste eradication, for researcher and manufactures, were established and distributed to manufactures.

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

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

BUSINESS AND INDUSTRY ADVISORY COMMITTEE (BIAC)

ACC, CEFIC, JCIA, NIA, VCI

American Chemistry Council (ACC) Nanotechnology Panel

Regulatory Engagement. Panel representatives have played an active role in the stakeholder consultations associated with the nanotechnology work plan under the U.S.-Canada Regulatory Cooperation Council (RCC).[6] The nanotechnology work plan focuses on sharing information about nanomaterials in commerce and joint approaches to regulatory aspects of nanomaterials, including terminology, nomenclature, risk assessment, and risk management. A final stakeholder workshop to discuss the outputs under the RCC nanotechnology work plan is scheduled for January 10 in the Washington, DC area.

Regulatory Definition of Nanomaterials. The Nanotechnology Panel presented a poster at the March 2013 meeting of the Society for Toxicology entitled *"Comparative assessment of nanomaterial definitions and considerations for implementation."* In the poster, the panel shows the inconsistencies among the key material properties used in existing regulatory definitions and proposes core elements of any definition developed to identify nanomaterials of potential regulatory interest. Applying the core elements is just a first step. Further evaluation would involve consideration of hazard, use patterns, and potential human and environmental exposures on a case-by-case basis. The panel is developing a more detailed manuscript on the subject and will submit it to a peer-review journal in early 2014. The SOT poster is available at http://nanotechnology.americanchemistry.com/ under "Panel Activities."

Workshop on Strategies for Setting Occupational Exposure Limits for Engineered Nanomaterials. On September 10-11, 2012, the Panel co-sponsored a workshop that brought together occupational health thought leaders from academia, government, industry, and non-governmental organizations to discuss new information and strategies for establishing and implementing occupational exposure limits (OELs) for engineered nanomaterials. Workshop presentations are available at http://nanotechnology.americanchemistry.com/OELWorkshop. The workshop steering committee is preparing a workshop summary to be published in a peer-reviewed journal, and there will be a symposium on the workshop's findings at the 2014 meeting of the American Industrial Hygiene Conference & Exposition (AIHce).

NanoRelease Consumer Products. The Panel continues to co-sponsor the NanoRelease Consumer Products project managed by the International Life Sciences Institute's Research Foundation (ILSI-RF).[7] The purpose of the project is to identify available methods for evaluating the release of nanomaterials from matrices, to identify new methods, and to test and evaluate selected methods. Multi-walled carbon

[6] See http://www.trade.gov/rcc/documents/Nanotechnology.pdf for the RCC's nanotechnology work plan and http://www.trade.gov/rcc/for more general information about the RCC and its multiple areas of activity.

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

nanotubes (MWCNTs) in polymer matrices are the first experimental system. The project is moving into inter-laboratory testing, and multiple government and industry facilities will participate. To date, the project has produced the following papers:

1. *Potential release scenarios for carbon nanotubes used in composites.* Bernd Nowack, Raymond M. David, Heinz Fissan, Howard Morris, Jo Anne Shatkin, Michael Stintz, Richard Zepp, Derk Brouwer. *Environment International. 59:1-11 (2013)*

2. *Release Characteristics of Selected Carbon Nanotube Polymer Composites.* Christopher Kingston, Richard Zepp, Anthony Andrady, Darrell Boverhof, Richard Fehir, Douglas Hawkins, Justin Roberts, Philip Sayre, Betsy Shelton, Yasir Sultan, Viktor Vejins, and Wendel Wohlleben. *Carbon.* (Accepted for publication)[8]

3. *A review and perspective of existing research on the release of nanomaterials from solid composites.* Stephan J. Froggett, Shaun F. Clancy, Darrell R. Boverhof and Richard A. Canady. Particle & Fibre Toxicol. (Submitted and responding to peer review)

4. *Measuring nanomaterial release from carbon nanotube composites: review of the state of the science.* Stacey Harper, Wendel Wohlleben, Maria Doa, Bernd Nowack, Shaun Clancy, Richard Canady, and Andrew Maynard. Nanotechnology Today (Submitted)

5. *"Phase 2.5" Comparison of existing studies of release measurement for MWCNT-polymer composites.* Richard Canady, Thomas Kuhlbusch, Elyse Lee, Mareile Renker, Libby Tsytsikova. http://www.ilsi.org/ResearchFoundation/RSIA/Pages/NanoRelease1.aspx (To be re-drafted as case study in a book on life cycle assessment)

6. *Methods for the release of MWCNTs from MWCNT-polymer composites.* Debra Kaiser, Aleksandr Stefaniak, et al. *Environ Sci Technol.* (In preparation)

European Chemical Industry Council (CEFIC)

Highlight

- Active contribution of industry to national and international regulatory initiatives to effectively manage nanomaterials and nanotechnologies.
- Cefic was an active participant in the REACH Implementation Project aimed to evaluate the current guidance to the regulation with regard to nanomaterials. Cefic continues to collaborate with the preparation of good practices and exchange of experience on technical aspects of risk evaluation with ECHA (GAARN and ECHA NMWG)
- In January 2012, Cefic revised its Guidance describing how companies can apply the principles underpinning Responsible Care to their production and handling of nanomaterials.
- Through its Long-range Research Initiative (LRI), Cefic sponsors safety research on nanomaterials, identification of the key drivers of effective policy in the area of emerging

[8] Pre-publication manuscript available at http://www.sciencedirect.com/science/article/pii/S0008622313011068.

technologies (e.g. nanotechnology) through different projects and contributes to the FP7 projects (NanoREG).

- External stakeholder events and projects on nanomaterials and nanotechnologies.

Background

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

Work underway or planned

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

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

At the end of 2009 the first out of three REACH Implementation Projects started, aiming to evaluate the applicability of existing guidance with regards to nanomaterials. This first project addresses how to conclude on Substance ID and sameness with the purpose of forming SIEFs (substance information exchange forum) ahead of registration. The other two projects, which concern guidance on information requirement and how to conduct a chemical safety report, started in January 2010. All projects are now finalised and available on http://ec.europa.eu/environment/chemicals/nanotech/index.htm#ripon. Cefic welcomes the reports as the final outcome of an extensive evaluation of not only existing REACH guidance but also several hundred scientific reports to ensure nanomaterials are appropriately addressed. In the end, the reports confirm Cefic's views that in general the REACH guidance is applicable to nanomaterials with only few amendments needed. ECHA has already incorporated the conclusions from the RIP-oN2 and 3 in the existing guidance to REACH (http://echa.europa.eu). Further technical discussions on characterization of nanomaterials and how read across applies to them are also progressed and Industry contribution (including Cefic members) has been crucial in sharing experience and expertise on these issues which are debated at ECHA Nanomaterial Working Group (ECHA NMWG). Some concrete examples are also shared in a Group Assessing Already Registered Nanomaterials (GAARN) which has issued best practices documents (http://echa.europa.eu/chemicals-in-our-life/nanomaterials).

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

With this regard, Cefic is actively contributing to the Commission impact assessment in order to set out an efficient and balanced approach for a potential adaptation of REACH Annexes.

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

On October 18, 2011, the European Commission adopted its long-awaited recommendation for a definition of the term "nanomaterial". Cefic welcomes these efforts to develop a regulatory definition for nanomaterials to help provide legal certainty and consistency, but is concerned that the Commission's recommendation is too broad in scope and therefore difficult to integrate into existing legislation in a meaningful way. Cefic fears implementing the proposed definition will add unnecessary burden for companies, leading to added costs and less efficient use of resources. In addition, its current form would define as nanomaterials some decades-old substances such as pigments used in paints and other everyday products. The chemical industry is also concerned by the lack of standardised measurement techniques, which are important for legal certainty.

Cefic is involved and supportive of JRC in the work for a pragmatic implementation of the definition through a valuable contribution in the establishment of suitable analytical methods (Eurocolour-JRC project, reply to the JRC survey on the definition implementation). A report will be available early-2014.

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

Cefic will actively contribute as a member into the ECHA NMWG by providing input in order to discuss scientific and technical questions relevant to REACH and CLP processes and to provide recommendations on strategic issues.

Moreover, Cefic considers that transparency of information on nanomaterials is of paramount importance, being involved in developing of European databases, such as REACH and CLP and JRC web portal. Cefic disagreed with the individual national reporting schemes which are generating confusion and discriminating nanomaterials.

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

Through its Long-range Research Initiative (LRI), Cefic sponsors health and environment safety research on nanomaterials (www.cefic-lri.org). As a first example, one project (N1, http://www.cefic-lri.org/projects/1268401437/172/N1-FRAU-Tiered-Approach-to-Testing-and-Assessment-of-Nanomaterial-Safety-to-Human-Health/) led by Dr Otto Creuzenberg at the Fraunhofer Institute will test the suitability of OECD testing guidelines for (agglomerated) nano zinc oxide and nano synthetic amorphous silica particles and define a tiered testing strategy for these nanoparticles. This project has started in 2010 – after a delay due to agreements needed on the reference material- and is now in the experimental phase. The ZnO part is already been completed in 2011 and the finalization of the SiO2 part was recently completed in end 2012. This project concluded on little or no toxicological concern for these materials in an inhalation testing context.

In order to address regulatory and public concerns, industry has evaluated, in a second Cefic-LRI research project (N2, http://www.cefic-lri.org/projects/1268402031/172/N2-YORK-Detection-Fate-and-Uptake-of-Engineered-Nanoparticles-in-Aquatic-Systems/), the ecological risks that may be associated with nanoparticles (coated Au particles with a starting size 10-50nm before aggregation). Currently accepted testing strategies will be evaluated, supplemented and improved, where needed, to address potential nano-specific effects focusing on ecologically relevant exposures. Through the LRI, the European chemical industry is sponsoring a project on the "assessment of nanoparticles specific effects in environmental toxicity testing". The research is being led by the group of Dr Alistair Boxall, at the University of York. The outcomes of the project have helped determine the environmental impact of nanomaterials in aquatic systems. The project is now completed. Both projects are contributions of Cefic (via BIAC) to the Sponsorship Program of the OECD Working Party of Manufactured Nanomaterials.

Finally, a third Cefic-LRI project (N3, http://www.cefic-lri.org/projects/1268402709/172/N3-TNO-Testing-and-Assessment-of-Reproductive-Toxicity-of-Nanomaterials/) has been launched on testing and assessment of the reproductive toxicity of Nanomaterials. The overall objective of this proposal is to analyze the suitability of current OECD guidelines to assess the reproductive toxicity of (aggregated) nanomaterials. Using two reference materials present on the OECD list of 'representative manufactured nanomaterials for testing' (1), synthetic amorphous silica and nano zinc oxide, the ability of current reproductive toxicity OECD guidelines to identify hazard associated with nanomaterials has been tested in this project. The research is being led by Dr J. van de Sandt at TNO, in a consortium with BASF. The results of this project should address the following questions: do the existing OECD reproductive toxicity test guidelines adequately assess a potential hazard posed by nanoparticles, can the existing guidelines benefit from some revisions to better understand health risks posed by nanoparticles, and are there endpoints used to assess the potential hazard of industrial chemicals which may be inappropriate for testing nanoparticles? The project passed the suspension and aerosol characterization initial stage and the 2nd-generation study stage. Project experimental completion took place at the end of 2012, and reporting is underway.

Stakeholder Engagement

To draw on the strength of speaking on behalf of the entire industry, Cefic initiated last year an Industry Platform with participants from the supply chain. It has been proven a success and has achieved a better coherency between different sectors but also allowed for a better alerting system on sector specific regulatory activities.

Cefic has also identified a need to improve our way of communication to ensure more balanced messages which also include nanomaterials' environmental and societal benefits. This work will be carried out with the help of case studies, and illustrated by a number of workshops. The objective of the work is to serve as basic information set for further discussions with policy makers and stakeholders (http://www.cefic.org/Policy-Centre/Environment-health/Nanomaterials/).

Cefic will also continue to progress with development of industry specific guidance on best practices where the Responsible Care Guidance will form an important part. In addition, Cefic will also actively participate to some projects related to nanomaterials within the 7th Framework Program under the ownership of DG RTD, European Commission.

Japan Chemical Industry Association (JCIA)

Based on the action plan in the Nanomaterial Opinion Statement formulated in July 2008, the Japan Chemical Industry Association (Working Group on New Issues) has been working to support the sound development of nanotechnology.

JCIA's current activities on nanomaterials are:

1) The chemical industries in Japan, the United States and Europe have jointly promoted the LRI program as per the initiative of the International Council of Chemical Associations in order to provide long-term support for research on the effects of chemical substances on human health and the environment. In November 2013, we started the second year of new LRI program. It includes 18 research themes. In these themes, two are related to nanomaterials. The first theme is "Combined evaluation for physical properties/ADME/safety of nanomaterials" focusing the dynamism of nanomaterials in living bodies and studying assessments related to physical properties, product quality, pharmacokinetics and safety that contribute to nanomaterial safety predictions. It continues from first year of new LRI. The second theme is "Study on the cellular and enivironmental effect related with solubility of industrial nanomaterials". The aims of this theme are clarifying the relationship of solubilities and toxicities of nanomaterials and establishing a evaluation systems.

2) We attended the meetings of the Risk Assessment Working Group and the Measurement Technology Working Group as an industry representative. These working groups were organized by the Japanese Ministry of Economy, Trade and Industry (METI) in November 2011 as part of the national government's nanomaterial safety review program. At the Risk Assessment Working Group, four case studies (nanoparticle in tyres, nanoparticle used in photocopy toner, nanoparticle generated from paint or coating agent, silver nanoparticle used in antimicrobial/deodorizing spray) were made. At the Measurement Technology Working Group, suitable measurement methods for classified nanomaterials (inorganic oxides, metals, carbon black, resin nanoparticles, carbon nanotubes) were reviewed. It also discussed tiered approach to classify whether a nanomaterial will meet EC nano-difinition or not. METI will continue its activities such as information gathering on usage/management of nanomaterials, development of methods for identification of nanomaterials, development of practical method for inhalation toxicity testing.

3) We are continuously attending the working group meeting to gather the latest industry informationand present our opinion, as an industry representative, regarding the chemical material risk research project of Osaka University School of Pharmaceutical Sciences, a center for nanomaterial safety research. This project is supported by funds from Ministry of Health, Labor and Welfare (MHLW). The aim of the chemical material risk research project is to establish a foundation for the analysis of exposure to nanomaterials, assess their toxicity, and gather information regarding the effects on human health. We expect that the new research will focus not only on the hazards of nanomaterials but also on risk assessments including the exposure. We are also interested in the relationship between this research and the new LRI research.

We also attended the meeting of Medical Apparatus Development Project supported by MHLW. The aim of this project is to evaluate applications of nanomaterials as medicines or drug delivery system.

4) We attended the Environmental Behavior and Ecological Effects Working Group and Methods for Demonstrative Survey Working Group as a representative of industry. These working groups are organized by the Ministry of Environment (MOE). The Environmental Behavior and Ecological Effects Working Group gathers information on ecotoxicity and environmental behavior of nanomaterials, and selects the nanomaterials of which properties above is to be clarified preferentially. It also reviews methods to evaluate ecotoxicity and environmental behavior of nanomaterials. The Demonstrative Survey Working Group reviews methods for measurement of particulate materials in the environment and make demonstrative surveys to establish methodology for measurement/analysis of particulate materials.

5) In 2008, we joined the Japanese National Committee for ISO/TC229, an OECD follow-up group, in order to proactively present our opinions. In FY2013, we focused our efforts on the ISO/TC229/WG3 nano-labeling initiatives that are being promoted by CEN and made some comment as a representative of industry.

Nanotechnology Industries Association (NIA)

Highlights

- NIA provided the BIAC co-lead representative to the 11th WPN meeting, 22 – 24 May 2013.
    - NIA provided industry input (in part through surveys run within the nanotechnology industries) to questionnaires on the 'commercialisation of nanotechnology research' and on 'skills and education for nanotechnology in an increasingly multidisciplinary environment".
- NIA participated in the OECD Tyre Industry Project Meeting, 22 – 23 May 2013.
- The NIA collated and provided dossiers for nano-Clay, nano-CeO2, and nano-ZnO to the 12th WPMN meeting.

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

NIA is continuing the coordination of the **Global-NanoMaPPP**, an international Public-Private-Partnership (PPP) for the **Integrated Measurement and Testing of Representative NanoMaterials in Support of the OECD Sponsorship Programme**. Global-NanoMaPPP provides continuing Sponsorship and Contribution of the following OECD WPMN nanomaterials: nano-ZnO, nano-CeO_2, nano-Silver, as well as nano-$BaSO_4$.

NIA is a participating partner in the following projects:

Project Title	**Project Source**	**Start Date**
Netzwerk NanoSilber (i.e. NanoSilver Network)	German BMWi	01/06/2011
MARINA - Managing Risks of Nanoparticles	EC FP7	01/11/2011
NanoRelease - Food Additive: Development of methods necessary to characterize the engineered nanomaterials "released" from foods to which they have been added	US ILSI	01/01/2012
NanoMICEX - Mitigation of risk and control of exposure in nanotechnology based inks and pigments	EC FP7	01/04/2012
LICARA - Life cycle approach and human risk impact assessment, product stewardship and stakeholder risk/benefit communication of nanomaterials	EC FP7 (SME)	01/10/2012
REACH-nanoHelpDesk - Development of a web based REACH Toolkit to support the chemical safety assessment of nanomaterials	EC LIFE+	01/10/2012
NANOReg - A common European Approach to the regulatory Testing of Nanomaterials	EC FP7	01/03/2013

Other projects (i.e. not focussed on EHS of nanomaterials):

- NIA has recently published a report on '*Closing the Gap – The Impact of Nanotechnologies on the global Divide'.*

- NIA is a participating partner in the following projects:

Project Title	**Project Source**	**Start Date**
NanoEIS - Nanotechnology Education for Industry and Society	EC FP7	01/11/2012
NanoDIODE - Developing Innovative Outreach and Dialogue on responsible nanotechnologies in EU Civil Society	EC FP7	01/07/2013
NanoInsight (AKA **NanoDATA**) - Data providing services in support of research and policy in the field of nanosciences and nanotechnologies	DG RTD	22/04/2013
NanoDEFINE - Development of an integrated approach based on validated and standardized methods to support the implementation of the EC recommendation for a definition of nanomaterial	EC FP7	01/11/2013

- NIA is full liaison partner to CEN/TC 352 and to ISO/TC 229, and expert participant in BSI NTI/1; NIA participates in meetings and contributes to drafting and balloting processes of these standardisation committees.

Information on any public/ stakeholder consultation

- On 26 November 2013, NIA organised a symposium on 'Grouping and read-across for nanomaterials'.
- Since the 11th WPMN (19th – 21st February 2013), NIA provided the following Briefings, Consultation Evidences, Comments & Opinions, and Reports.

NIA Briefings

Publ. Date	Title	Sector/Service
31/01/2013	NIA Briefing on the EC Response to the French Nanomaterial Reporting Scheme	Databases and Reporting Schemes
25/04/2013	NIA Briefing on Nanomaterials and Biocides	Agriculture, Pesticides and Biocides
02/05/2013	NIA Briefing: US Safe Chemicals Act of 2013	Chemicals and Raw Materials
02/05/2013	NIA Briefing: EU proposed Regulation on Food intended for Infants and Young Children Briefing	Food and Feed
13/05/2013	NIA Briefing: Nanoscale Materials in the Australian Regulation of Sunscreen Products	Cosmetics and Personal Care
17/05/2013	NIA Public Briefing: Nanotechnology and the Council of Europe	Medical Devices and Pharmaceuticals
27/11/2013	NIA Briefing: Horizon 2020	Innovation & Economics

NIA Reports

Publ. Date	Title	Sector
20/02/2013	NIA Document: STOA Workshop on Risk in Innovation	Chemicals and Raw Materials
01/03/2013	Materials from NIA Symposium on Mandatory Reporting Schemes and Databases	Databases and Reporting Schemes
09/04/2013	Non-NIA Attendees - Materials from NIA Symposium on Mandatory Reporting Schemes and Databases	Databases and Reporting Schemes
24/04/2013	NIA Meeting Report from the 10th CASG-nano Meeting, held 15 April 2013	Chemicals and Raw Materials
22/05/2013	NIA Meeting Report - Scientific Support to Key Enabling Technologies for Innovative SMEs	SME Services
30/08/2013	NIA EXCLUSIVE: Meeting Report on the OECD Expert Meeting on Eco-toxicity and Environmental Fate	Global Nanomaterials Safety

19/09/2013	NIA Meeting Report: The Dialogue between Science, Technology and Society around Energy and Climate Change	Global Nanomaterials Safety
01/10/2013	NIA - NanoKTN Joint Meeting Report: Current Developments in Standards and Regulation for Nanotechnologies	Standards & Norms
27/11/2013	Closing the Gap: The Impact of Nanotechnologies on the global Divide	Innovation & Economics
02/12/2013	NIA Meeting Report from the 11th CASG-nano Meeting, held 24 October 2013	Chemicals and Raw Materials

NIA Comments & Opinions (based on closed Consultations)

Publ. Date	Title	Sector
11/03/2013	NIA Comments on a Belgian National Registry of Nanomaterials (as presented on the 19 December 2012) - Deadline: 22 March 2013	Databases and Reporting Schemes
23/04/2013	NIA supports Proposal of Endorsement Effect for Registered Nano Products	Databases and Reporting Schemes
01/05/2013	NIA comments on Options for Modifying REACH Annexes presented at latest EC CASG Nano Meeting	Chemicals and Raw Materials
10/05/2013	NIA Comments on the 'Study for the Review of the List of Restricted Substances under RoHS2 (1st Draft Report)'	Electrical & Electronic Equipment
15/05/2013	NIA voices Concerns over European Nano Reporting Schemes	Databases and Reporting Schemes
10/06/2013	NIA comments on the 3rd Consultation on the Study for the Review of the List of Restricted Substances under RoHS2	Chemicals and Raw Materials
10/06/2013	NIA Comments on EC Consultation on Green Paper on Plastic Waste	Recycling and Waste
20/08/2013	NIA Comments on the Inventory of Substances present in EEE for the Review of RoHS2 Annex II	Chemicals and Raw Materials
02/12/2013	NIA input on issues regarding modification on REACH Annexes	Chemicals and Raw Materials

NIA Consultations (currently open)

Publ. Date	Title	Sector
23/10/2013	OECD WPN Survey on Nanotechnology Commercialisation Policy - Deadline: 29 November 2013	Innovation & Economics
26/11/2013	NIA Consultation: Danish Nano Product Register draft Order - Deadline: 16 December 2013	Databases and Reporting Schemes

Additional Information

More information at www.nanotechia.org.

The German Chemical Industry Association (VCI)

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

Key documents:

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

Regulatory documents:

- Requirements of the REACH Regulation on Substances which are Manufactured or Imported also as Nanomaterials
- Guidance for a Tiered Gathering of Hazard Information for the Risk Assessment of Nanomaterials
- Guidance for Handling and Use of Nanomaterials at the Workplace (updated in 2012)
- Guidance for the Passing on of Information along the Supply Chain in the Handling of Nanomaterials via Safety Data Sheets
- Guidance for Safe Recovery and Disposal of Waste containing nanomaterials (updated in 2012)

Documents on safety research:

- Roadmap for Safety Research on Nanomaterials (updated in 2012)
- Environmental Aspects of Nanoparticles
- 10 Years of Research: Risk Assessment, Human and Environmental Toxicology of Nanomaterials

These documents have been discussed with the public as well as with national and European authorities, and were also communicated to the OECD Working Party on Manufactured Nanomaterials (WPMN). The guidances for Handling and Use of Nanomaterials at the Workplace, and for Safe Recovery and Disposal of Waste have recently been updated. A "Tiered measurement strategy for the implementation of the recommendation for a nanomaterial definition of the European Commission" has been prepared and is the basis of the joint report from the Joint Research Centre (JRC) of the European Commission and the European Association of pigment producers (Eurocolour) that will be published soon.

Information on developments related to exposure measurement and exposure mitigation

In 2011, a special focus was put on workplace safety – also as VCI contribution to SG 8 of the WPMN via BIAC. The "Tiered Approach to an Exposure Measurement and Assessment of Nanoscale Aerosols Released from Engineered Nanomaterials in Workplace Operations" is now basis for a publication of the Committee from VCI, the German Federal Institute of Occupational safety and health (BAuA), the German Social Accident Insurance Institution for the Raw Materials and Chemical Industry (BG RCI), and the Federal Institute for Occupational Safety and Health (IFA) of the German Social Accident Insurance (DGUV) is now basis for a guidance of the Committee on Hazardous Substances (AGS) at BAuA aiming at deriving best practices for exposition measurement and is currently communicated at scientific and political level.

In 2006, VCI and the German Federal Institute of Occupational safety and health (BAuA) had conducted a first survey on how industry is handling nanomaterials at the workplace. This survey is currently, with VCI's support and with an extended scope, repeated by BAuA. First results are planned to be communicated in summer 2013.

Further activities within OECD to nanomaterials

VCI is engaged within the OECD Working Party of Resource Productivity and Waste (WPRPW) to discuss the know-how of the chemical industry on waste containing nanomaterials and to contribute to coordinate the efforts of the WPRPW and WPMN.

Further VCI activities

VCI was engaged in the political discussion on the EU definition of nanomaterials and is in close co-operation with its sector groups currently supportive in the establishment of suitable analytical methods for this definition.

The German chemical industry has been deeply engaged in the second phase of the German *"Nano-Dialog"* initiated by the German government. The Nano-Dialogue is continued by intensive discussions in focus workshops to accompany the implementation of future innovation policy of the German federal ministries.

Furthermore the German chemical industry is engaged in the process of implementation REACH, e.g. in the RIPoNs, in sector specific legislation addressing nanomaterials, in dialogues on safe handling nanomaterials throughout the value chain, and in updating and prioritizing the agenda on safety research on nanomaterials together with the federal government.

More information is available at www.vci.de

UNITAR

UNITAR has focused in two areas:

1. national nano pilot projects; and

2. information on SAICM-related activities.

UNITAR has the mandate to work alongside OECD in this specific area of international awareness raising comes from resolution II/4 of the second session of the International Conference on Chemicals Management in 2009, as well as a 2009 OECD Joint Meeting request to undertake awareness raising and other related activities in developing countries regarding the potential benefits and risks of nanomaterials. More recently, resolution III/2E of International Conference on Chemicals Management, ICCM-3 in September 2012, reaffirmed this work and invited "relevant international organizations, including the participating organizations of the IOMC, such as the OECD and UNITAR, to continue to support efforts to facilitate capacity-building information exchange, develop guidance and training materials and support public dialogue regarding nanotechnologies and manufactured nanomaterials".

1. National Pilot projects

At the February 2013 meeting, UNITAR updated the WPMN on the completion of the UNITAR-supported phase 1 pilot projects (undertaken with the financial support of Switzerland) that initiated in 2011 in Thailand, Uruguay and Nigeria. The purpose of these pilot projects was to assist non-OECD countries to assess and develop programmatic capacities to address nanotechnology issues at the national level. We also informed that, due to the success of the phase 1 pilot projects, and to respond to the ICCM-3 request to continue similar work, UNITAR has embarked on a second phase of pilot projects with the continued financial support of the Government of Switzerland. The three countries are Armenia, Jordan, and Vietnam and they will follow a similar approach to the phase 1 projects by considering issues related to nano and nano safety. In addition, again with the financial support of the Government of Switzerland, UNITAR plans to hold subregional events with the participation of the pilot countries commencing in second half of 2014.

2. SAICM-related activities

Nano has been considered as an ''emerging issue'' in the SAICM process. OECD and UNITAR have made progress reports to the Open Ended Working Group and ICCM.

UNITAR in conjunction with OECD have been asked by the SAICM Secretariat to hold information sharing sessions on nano at its regional meetings in a lead up to OEWG and ICCM-4. The sessions have taken place for the LAC region (Mexico) in August 2013, CEE region (Macedonia) in September 2013, and Africa (South Africa) in November 2013, with the Asia Pacific regional meeting anticipated in March 2014. It is expected that overall progress will once again be presented to the second session of SAICM's OEWG in 2014 and to ICCM-4 in 2015.

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

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

The International Organisation for Standardization Technical Committee (ISO/TC) 229 - Nanotechnologies - was established in June 2005 with a UK secretariat and chair. It has held twelve meetings to date, with the most recent being in Stresa, Italy, in June 2012. The next meeting will be in

March 2013 in Querétaro, Mexico. The committee currently has 44 members - 34 "P" and 10 "O". Twenty four documents have been published to date –see http://www.iso.org/iso/standards_development/technical_committees/list_of_iso_technical_committees/iso_technical_committee.htm?commid=381983 . The publication most relevant to the WPMN since its last meeting, in December 2011, is *ISO/TR 13014:2012 - Nanotechnologies - Guidance on physicochemical characterization of engineered nanoscale materials for toxicologic assessment*.

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

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

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

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

Acceptance requires

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

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