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

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

**Series on the Safety of Manufactured Nanomaterials
No. 60**

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OECD Environment, Health and Safety Publications

Series on the Safety of Manufactured Nanomaterials

No. 60

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

IOMC

INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

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

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

Also published in the Series of Safety of Manufactured Nanomaterials:

- No. 1, *Report of the OECD Workshop on the Safety of Manufactured Nanomaterials: Building Co-operation, Co-ordination and Communication (2006)*
- No. 2, *Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 1st Meeting of the Working Party on Manufactured Nanomaterials (2006)*
- No. 3, *Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 2nd Meeting of the Working Party on Manufactured Nanomaterials (2007)*
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- No. 25, *Guidance Manual for the Testing of Manufactured Nanomaterials: OECD Sponsorship Programme: First Revision (2010)*
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- No.37, *Current Developments in Delegations on the Safety of Manufactured Nanomaterials - Tour de Table at the 10th Meeting of the WPMN (2012)*
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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 Airborne 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)*
- No.59, *Developments on the safety of manufactured nanomaterials: 2013 (2015)*

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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,
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or contact:

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

Fax: (33-1) 44 30 61 80

E-mail: ehscont@oecd.org

FOREWORD

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

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

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

This document is published under the responsibility of the Joint Meeting of the Chemicals Committee and Working Party on Chemicals, pesticides and Biotechnology of the OECD.

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EXECUTIVE SUMMARY

This document compiles information, provided by delegations including the European Commission (EC), 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.

Background

The purpose of the Tour de Table is to give delegations the opportunity to describe recent or planned national initiatives and/or events related to the safety of manufactured nanomaterials. This will facilitate delegations to share their experiences and preoccupations with respect to safety, and will identify opportunities for future co-operation and co-ordination.

The OECD Working Party on Manufactured Nanomaterials (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 January and July 2014**.

Headings for the Tour de Table

Delegations were invited to prepare a short written paper and to organise, 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
- Work completed, underway or planned
 - 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 risk assessment decisions;
 - Developments related to good practice documents;
 - 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 public/ stakeholder consultation;
 - Research programmes or strategies which focus on life cycle aspects of nanomaterials
 - 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.

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

AUSTRALIA

Highlight of developments

- Australian regulatory authorities continue to regulate nanomaterials using regulatory frameworks applicable to conventional chemicals.
- Food Standards Australia New Zealand (FSANZ) has completed qualitative survey of the food packaging industry, brand owners and food retailers on the use of nanomaterials as part of a review of the regulatory requirements relating to articles and materials in contact with food.
- The Commonwealth Scientific and Industrial Research Organisation (CSIRO) published several scientific papers addressing human health and/ or environmental safety aspects of nanomaterials.
- An SG report on measurement of nanomaterials in air, undertaken by Safe Work Australia, Workplace Health and Safety Queensland and Queensland University of Technology, will be presented at the 52nd Joint Meeting for declassification

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

Consistent with the OECD Council recommendation, the Australian government regulator of industrial chemicals, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), continues to regulate industrial nanomaterials using the regulatory framework applicable to conventional industrial chemicals (with some minor administrative adjustments – refer below for details).. NICNAS uses a working definition (applicable to this sector only) to identify nano-forms of industrial chemicals. 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>

Food Standards Australia New Zealand (FSANZ) develops and administers the Australia New Zealand Food Standards Code, which lists requirements for foods such as food additives, food safety, labelling and contaminants. Food substances including food additives, processing aids, novel foods and nutritive substances that involve the use of nanotechnology will require premarket approval, if potentially unsafe. This approval requires a rigorous safety assessment by FSANZ using the best available scientific evidence.

FSANZ has amended its Application Handbook requesting that appropriate information is provided to ensure that any novel characteristics introduced by nanotechnologies in food or food ingredients are taken into account as part of the risk assessment process. For example, the Handbook section on Food Additives requests ‘sufficiently detailed information to enable the technological properties of the additive in a food matrix to be characterised, such as how it may interact with different foods, as well as providing general information on the likely metabolic fate of the additive following consumption. In cases where particle size is important to achieving the technological function or may relate to a difference in toxicity, the applicant must provide information on particle size, size distribution, and morphology, as well as any size-dependent properties.’

FSANZ has published a paper ‘Regulation of Nanotechnologies in Food in Australia and New Zealand’ which is available, together with further information on nanotechnology and food (2011), on the FSANZ website:<http://www.foodstandards.gov.au/consumer/foodtech/nanotech/Pages/default.aspx>

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 5-year 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:

Carcinogenicity: Category 2

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>

In Australia, cosmetic product labels must include full ingredient disclosure in accordance with the Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991 administered by the Australian Competition and Consumer Commission (ACCC). This labelling standard does not mandate the labelling of nanomaterials. At the present time the ACCC considers that existing labelling requirements for cosmetics in Australia are adequate and that there is no current scientific justification to recommend mandatory labelling for nano-scale substances in cosmetics. Companies are free to voluntarily label their products a containing nanomaterials if they so wish.

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 the group for developing the general framework for 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

A Nanotechnology Work Health and Safety Programme has been implemented by Safe Work Australia. The programme is Australia-focused, and also contributed to global efforts on nanotechnology work health and safety. More information about the programme 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 relevant to nanotechnology. Fourteen research reports have been published to date.

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

Safe Work Australia's 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/at201008workhealthandsafetypassessmenttool>

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 in development. This document is available at: <http://www.safeworkaustralia.gov.au/sites/SWA/about/Publications/Documents/664/Safe%20Handling%20and%20Use%20of%20Carbon%20Nanotubes.pdf>

Since the 12th WPMN, the Commonwealth Scientific and Industrial Research Organisation (CSIRO) has published several scientific papers, , addressing the following human health and/ or environmental safety aspects of nanomaterials:

“Detecting free radicals in sunscreens exposed to UVA radiation using chemiluminescence.” Millington KR, Osmond MJ & McCall MJ (2014) *Journal of Photochemistry and Photobiology B: Biology*, 133, 27-38.

This paper describes a photo-induced chemiluminescence technique for detecting free radicals generated in sunscreens alone, or when applied to various substrates including skin, following exposure to UVA. The work showed that one sunscreen, believed to contain photocatalytic P25 TiO₂, had an intense photo-induced chemiluminescence emission and, under extended exposure, caused pitting into the cuticle surface of keratin fibres in wool fabric (a dry model for the stratum corneum of mammalian skin). <http://www.sciencedirect.com/science/article/pii/S1011134414000633>

“Surface coatings of ZnO nanoparticles mitigate differentially a host of transcriptional, protein and signalling responses in primary human olfactory cells.” Osmond-McLeod MJ, Osmond RIW, Oytam Y, McCall MJ, Feltis B, Mackay-Sim A, Wood SA, Cook AL (2013) *Particle and Fibre Toxicology*. 10:54. <http://www.biomedcentral.com/content/pdf/1743-8977-10-54.pdf>

The effects of commercially-available nano-ZnO products on primary human cells cultured from the olfactory mucosa were examined for modulation of cytokine levels, activation of intracellular signalling pathways, changes in gene-expression patterns across the whole genome, and compromised cellular function over a 24 h period. ZnO nanoparticle toxicity was mediated through a battery of mechanisms largely related to cell stress, inflammatory response and apoptosis, but not activation of mechanisms that repair damaged DNA. Surface coatings on the ZnO nanoparticles mitigated these cellular responses to varying degrees. The nano-ZnO products tested included those selected for study in the OECD Sponsorship program, but the batches used were different from those distributed through the Program.

“Quantification of ZnO nanoparticle uptake, distribution, and dissolution within individual human macrophages.” James SA et al (2013) *ACS Nano*, 7, 10621-10635. <http://pubs.acs.org/doi/abs/10.1021/nn403118u>

The paper describes an in vitro study to assess uptake of ZnO nanoparticles by macrophages, and the fate of these nanoparticles once inside. The study finds that ZnO nanoparticles are engulfed by the macrophages (with some macrophages taking up a greater number of nanoparticles than others). Some of the nanoparticles that are engulfed by the macrophages (partially) dissolve, releasing locally high concentrations of zinc ions. The immune system, via macrophages, is able to process ZnO nanoparticles.

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

In 2013, FSANZ undertook a small qualitative survey of the food packaging industry, brand owners and food retailers on the use of nanomaterials, as part of a review of the regulatory requirements relating to articles and materials in contact with food. Whilst no companies in Australia and New Zealand stated that they are currently using nanomaterials in packaging, many are maintaining a watching brief. Larger global companies are actively investigating potential future uses of nanomaterials in packaging. Companies identified that they are investigating barrier improvements (eg. UV blocker) delivered through nanotechnology and the potential for improving freshness/shelf life through smart technologies. In general,

Australian businesses are taking a cautious approach due to public perception concerns and potential food safety, and occupational health and safety concerns.

Development related to exposure measurement and exposure mitigation.

Australia led the SG8 project on measurement of nanomaterials in air. The work was undertaken by Safe Work Australia, Workplace Health and Safety Queensland and Queensland University of Technology. The report will be provided to the 52nd OECD Joint Meeting for declassification.

AUSTRIA

Highlight of developments

- The implementation report 2012 of the “Austrian Nanotechnology Action Plan” recommends to carry out coordinated enforcement of legislation which is relevant for nanomaterials

In cooperation with European partners, enforcement activities in the field of REACH-regulation will be launched in year 2014 including checks of safety data sheets for nanomaterial-relevant information. The project is lead-managed by the Federal Ministry of Agriculture, Forestry, Environment and Water Management. Austria participates also in the Prosafe Joint Action Nanotechnology and Cosmetics. Testing for nanomaterials content will be part of the project (cremes, liquides with TiO₂, SiO₂, AlO₂, ZnO₂ or mixtures thereof). The project is lead-managed by the Federal Ministry of Health.

- As another measure of implementation of the Austrian Nanotechnology Action plan five projects from three calls of the national **NANO Environment Health and Safety** programme (<http://www.ffg.at/nano-ehs>) are conducted (see bullet 9). 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.

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

No national laws/regulations are planned at the time being.

The Austrian Nanotechnology Action plan (adopted on 2nd March 2010 by the Austrian government, an English and German version can be downloaded), 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@bmlfuw.gv.at) and elaborated based on a broad stakeholder involvement (see also chapter 7). 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>

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 title “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: <https://www.sozialversicherung.at/portal27/portal/auvaportal/content/contentWindow?action=2&viewmode=content&contentid=10007.672853>.

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 lysosomes 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). Lanthanide-doped nanocrystals as imaging agents to improve the sensitivity and reliability of fluorescence-based technologies are evaluated for biocompatibility in the frame of the COST action **CM1403 The European Upconversion Network: From the Design of Photon-upconverting Nanomaterials to (Biomedical) Applications** (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 support tools shall enable the grouping of materials 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 Development 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 dispersabilty 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.

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), the Federal Ministry of Health, the Federal Ministry of Agriculture, Forestry, Environment and Water Management and the Federal Ministry of Labour, Social Affairs and Consumer Protection 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://epub.oeaw.ac.at/ita/nanotrust-dossiers>

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

In the FP7 project **NANOREG** Austrian partners from BioNanoNet (contact: Andreas Falk, national coordinator) and from AIT - Austrian Institute of Technology GmbH (contact: Mats-Olof Mattsson) are involved in several workpackages. Alexander Pogany from Austrian Federal Ministry for Transport,

Innovation and Technology is national advisor. The project deals with regulatory testing of nanomaterials (www.nanoreg.eu).

Information on public/ stakeholder consultation

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>

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** (www.nanodiode.eu) 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 Nanotechnologies”) 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.

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 Exposure” (**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. The final report (language German; additionally, an English summary is available) of the project is available in the website: <http://cms.bionanonet.at/>.

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 (TiO₂, CeO₂, 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).

In the project **NanoMIA** conducted by the Institute für Waste Management of the University of Natural Resources and Life Sciences, Vienna, and the Institute of Technology Assessment of the Austrian Academy of Sciences an existing Austrian database for nanoproducts will be updated. Based on this database six consumer products will be chosen to develop material flow oriented disposal and release scenarios. These scenarios aim exemplarily to review the environmental fate of nanoproducts at their end-of-life and to evaluate the waste legislation as well as the surveillance mechanisms in waste management (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/>). Several documents in the area of responsible use of nanomaterials and associated risk management e.g. Safety Data Sheets for TiO₂, nanoAg and nano ZnO nanoparticles and drafted Exposure Scenarios, Guidelines on Responsible Use and Production of Nanomaterials, can be downloaded from the website www.nanoforceproject.eu

BELGIUM

Federal Public Service Health, Food Chain Safety and Environment

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 Royal Decree is waiting to be signed and published, requiring the registration of manufactured nanomaterials, which are or will be placed on the market.

The draft Decree involves nanoscale substances, mixtures that contain one or more of these substances and articles or complex objects in which nanoscale particles have been incorporated.

The registration becomes mandatory for substances, starting from 1st January 2016 and for mixtures from 1st January 2017. No date has been set yet for the articles and complex objects.

The development of the web-based registration tool is under development, and will be strongly based on the tool France is using. We also develop guidance on the royal decree and the IT tool in collaboration with industry

CANADA

Highlights of developments

The following activities have taken place since the 12th meeting of the Organization for Economic Cooperation and Development (OECD) Working Party on Manufactured Nanomaterials (WPMN) in December 2013:

- The United States and Canada continued their cooperation on nanomaterials under the Regulatory Cooperation Council (RCC), and the RCC Nanotechnology Final Results Workshop was held January 14, 2014 in Washington, DC, formally concluding the Nanotechnology Work Plan.
- Under the RCC, Canada has developed a policy document entitled *RCC Nanotechnology Policy Principles for Decision-Making Concerning Regulation and Oversight of Nanotechnology and Nanomaterials* and it is available at: <http://nanoportal.gc.ca/6AEDAEB-759A-4C21-A3C0-52CAA61783AE/RCCenglish2.pdf>.

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.

International Cooperation

Regulatory Cooperation Council (RCC) Nanotechnology Initiative

Canadian Prime Minister Stephen Harper and United States (U.S.) President Barack Obama released the Regulatory Cooperation Council (RCC) Action Plan in 2011. Since then, Canada and the U.S. have been working to better align their regulatory approaches and boosting North American trade and competitiveness in a number of areas, including nanotechnology.

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 undertook joint activities in consultation with stakeholders through workshops/webinars and through the development of a stakeholder technical team.

The RCC Nanotechnology Work Plan is now complete and the following work products have been developed:

1. *Shared policy principles to guide the regulatory oversight of nanotechnology*: Canada reviewed existing U.S. policy principles, amended them to ensure they were applicable within the Canadian landscape and, in 2014, adopted them as a Government of Canada document entitled “*RCC Nanotechnology Policy Principles for Decision-Making Concerning Regulation and Oversight of Nanotechnology and Nanomaterials*”. These policy principles promote: scientific integrity with the flexibility to take into account new knowledge, consistency in risk assessments and risk management, awareness of potential benefits and potential costs of regulations, openness and transparency in decision making, communication with stakeholders, and coordinated activities including research domestically and internationally.
2. *Classification/Priority Setting*: Canada and the U.S. shared information on how their regulatory programs are currently classifying nanomaterials for the purposes of risk assessment and management. A classification scheme was developed based on similarities in chemical composition and it is meant to: (1) identify which types of nanomaterials the programs typically assess using nano-relevant information; and (2) provide a framework upon which information from one nanomaterial can be used to assess another similar nanomaterial. These findings will be shared with the OECD (e.g. **Expert Meeting on Categorization of Manufactured Nanomaterials**).
3. *Risk Assessment/Risk Management*: Canada and the U.S. compared the two countries’ risk assessments processes and identified common best practices. A joint case-study was conducted to compare a risk assessment on multi-walled carbon nanotube that had been reviewed as a new chemical substance by both countries.
4. *Commercial Information*: An analysis was conducted on information collected from Canadian and U.S. regulatory programs, public databases, and third-party reports to increase understanding of commercial uses of industrial nanomaterials in Canada and the U.S. With active collaboration from industry and other government departments, a table was developed which identified nanomaterials

and their associated uses in Canada and the US. Through this work, paints, coatings, and composites were identified as the largest uses of nanomaterials in Canada and the US.

Final reports have been prepared for three work products (i.e. classification, risk assessment/risk management and commercial information) and will be available online in summer 2014. They have been reviewed by a stakeholder technical team and were shared at the final RCC Nanotechnology Initiative Workshop on January 14th, 2014 in Washington, D.C., United States. Canada and the US are now exploring joint activities to implement key outcomes from these work products, including (a) exploring a joint pre-notification consultation process; and (b) conducting nanomaterial case-studies. *Tri-lateral Meeting of Canada, US and ECHA*

Canada-United States-European Commission tri-lateral discussion on nanomaterial regulatory frameworks

On April 23rd 2014, the European Commission led tri-national discussions with Canada and the United States to discuss respective nanomaterial relevant regulatory frameworks. The European Chemicals Agency presented on the Registration, Evaluation, Authorisation, And Restriction of Chemicals (REACH) program, while both Canada and the United States presented on their new substances programs for industrial chemicals, including activities under the RCC. The meeting was very positive as it showcased similar challenges between the three jurisdictions and identified areas of mutual interest where joint projects could be initiated.

Information on Risk Assessment Decisions.

Industrial or commercial chemicals: In line with the 2013 OECD Council Recommendation, Canada is using its existing chemical regulatory framework to manage nanomaterials, making adaptations where necessary to take into account the specific properties of nanomaterials. As such, industrial nanomaterials are assessed and managed by the New Substances Program, under the New Substances Notification Regulations (Chemicals and Polymers) of the Canadian Environmental Protection Act, 1999 (CEPA 1999). A guidance document is being prepared to clarify when engineered nanomaterials require notification and under which circumstances the Program will request additional nano-specific information in addition to what is required under the current regulations.

In addition, Canada is looking into developing an approach to assess nanomaterials that are currently in Canadian commerce and do not require notification under the New Substances Program because their Chemical Abstract Service (CAS) number is already listed on Canada's domestic chemicals inventory (i.e. the Domestic Substances List).

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. Canadian Government, industry, research, user, and consumer interests are participating as designated experts 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 along with 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 working 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.

Developments related to Integrated Testing Strategies and/or Alternative test methods.

Environment Canada and Health Canada have supported two projects: (1) a state-of-the-science report on the use of alternative testing strategies for environment and human health endpoints for manufactured nanomaterials; and (2) a database compiling all relevant studies on a case-study substance. Outcomes of these projects will feed into the alternative testing strategy project being led by Canada and the United States within SG-AP, including a results workshop on this topic being planned for September, 2014 in Washington D.C.

1. 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. Part of this work has been accepted for publication in a peer reviewed journal.

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 was also conducted to gather information on industrial activities and market trends in Ontario and Alberta, via NanoOntario and an independent consultant, respectively. This work has contributed to a better understanding of the nanomaterials being manufactured, imported and used in Canada.

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 finalising approaches to begin lab testing in the Spring/Summer 2014.

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 was circulated for comments in March 2014 for consideration at the next WPRPW meeting in November 2014.

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

Developments 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.ilsil.org/ResearchFoundation/RSIA/Pages/FoodAdditiveMainPage.aspx>

DENMARK

Highlights of developments

- Final preparation 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. Expected to enter into force in June 2014. First year of registration ends in June 2015
- 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 ***Work completed, underway or planned***

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. At present it is expected that the register will enter into force in June 2014. The first registration

year is expected to be from June 2014 to June 2015. A guidance for importers and producers of nanoproducts in relation to the register is expected to be published in June 2014.

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

The Danish Environmental Protection Agency (DK-EPA) is responsible for implementing the initiatives under the National action plan for getting better control of nanomaterials (2012-15). Under this activity, a range of projects are currently being developed. These projects cover:

- General knowledge status and identification of knowledge gaps in relation to fate and effects of nanomaterials.
- Research oriented projects addressing important knowledge gaps
- Nanomaterials and waste
- Surveys and risk evaluations of specific uses of nanomaterials (aerosol projects, nanopigments, anatase titan-dioxide)
- Overall assessment of environment and human risk in relation to nanomaterials in Denmark

As a part of these activities 10-15 reports will be prepared over the next years.

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 Working Group 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.

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 was published 2013.

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 (as National Coordinator) and **Finnish Institute of Occupational Health** together with industry partners **UPM Kymmene** and **Stora Enso** are participating in the FP7 project NANOREG by testing and assessing nanofibril cellulose, and regulatory issues.

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. The activities of the virtual Centre ended on December 31st 2013 as agreed in the contracts at the beginning of the co-operation. The targets set for the Centre were fulfilled.

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 nanocellulose¹. 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. The EffNet programme ended in June 2013. The project results have been published in a public report². In addition, a review on the safety assessment of bio-based nanomaterials will be published in Handbook of Green Materials in June³ and a paper containing results on toxicity testing of nanocellulose has been submitted to be published in Cellulose.

VTT is or has been involved in several research projects related to nanomaterial safety:

- EffTech/EffNet as described above
- MARINA - Managing Risks of Nanomaterials (EU-FP7, 2011-2015). “Standardised” measurement strategies and characterisation methods for nanoparticles and nanomaterials to be used in risk management of nanomaterials.
- Nanosafe 2 - Safe production and use of Nanomaterials (EU FP6).
- Nanosolutions (EUFP7, 2013-)
- NanoSustain – Development of sustainable solutions for nanotechnology-based products based on hazard characterization and LCA (EU-FP7, 2010-2013).

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

² http://fibic.fi/wp-content/uploads/2012/07/EffNet_Ohjelmakirja_web.pdf

³ <http://www.worldscientific.com/worldscibooks/10.1142/8975>

- Nanoturva - Nanoparticle detection and assessment of exposure in industrial facilities, part of the FinNano 2005-2010 (Finnish national nanosafety program) program funded by the Finnish Funding Agency for Innovation (TEKES).
- SUNPAP – Scaling up nanoparticles for modern papermaking (EUFP7, 2010-2012). VTT as coordinator

In addition, VTT has submitted a proposal to Horizon2020 NMP28 call titled Re-Nano – Release and Environmental fate of nanomaterials.

Finnish Institute of Occupational Health and its Nanosafety Research Centre 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. 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 coordinating or participating several ongoing research projects on nanomaterials:

- Coordination of European Commission 7th Framework Programme project “NANOSOLUTIONS”
- European Commission 7th Framework project "QualityNano”
- European Commission 7th Framework project "Scaffold”
- European Commission 7th Framework project “MARINA”
- European Commission 7th Framework project “NANoREG”
- European Commission 7th Framework project “GUIDEnano”
- European Commission COST action “MODENA”
- European Commission Marie Curie student exchange programme “Brasinoeu”
- Academy of Finland project "Carbon nanomaterial induced inflammatory effects "
- In addition, FIOH is coordinating European NanoSafety Cluster which includes all the EU funded projects concerning nanosafety.

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 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".

GERMANY

Highlight of developments

A. Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB)

Expert dialogue on nanomaterials and the aquatic environment

Representatives of the scientific community, industry, environmental associations, government and government agencies met on 19 – 20 May on the invitation of the BMUB. At the conference the discussion focused on nanotechnology procedures for eliminating pollutants and for avoiding potential risks from nanomaterials in groundwater, surface water and drinking water. The results will be published in a thematic report on the homepage of BMUB.

The conference on nanomaterials and the aquatic environment 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.

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 Environment Agency (Umweltbundesamt, UBA)

UBA published an article presenting its considerations and recommendations on how to adequately adapt REACH to nanomaterials: Schwirn, K., et al. (2014). "Why are nanomaterials different and how can they be appropriately regulated under REACH?" Environmental Sciences Europe 26(1): 4. (<http://www.enveurope.com/content/26/1/4>)

Developments related to Integrated Testing Strategies and/or Alternative test methods

A. Federal Ministry of Education and Research (BMBF)

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

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

BfR is involved in a still ongoing EU FP7 Project QualityNano, which is an infrastructure project dedicated to enhance quality in nanosafety research. In this project BfR is leading a workpackage for development of alternatives to animal assays. The strategy applied in this project involves a careful analysis of established alternatives for their suitability in testing nanoparticle toxicity but also developing new approaches. In particular we focus on analysing bio-nano interactions (i.e. analysis of protein corona) and on high content analysis (HCA) of nanoparticle toxicity. Furthermore we develop best practice SOP's by testing protocols for suitability and robustness in round robins and interlaboratory comparisons.

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 projects are expected to begin in 2014. They will address the effects and interactions of manufactured nanomaterials on human health and the environment, the development of reliable experimental techniques and testing strategies and the creation of a framework for the safe handling of nanomaterials.

Germany is coordinating the European FP7 ERA-NET project “SIINN” (Safe Implementation of Innovative Nanoscience and Nanotechnology - www.siinn.eu) in which 20 organizations from 13 European countries/regions and Israel are participating. The SIINN ERA-NET is bringing together today's fragmented research activities on the potential risks of engineered nanomaterials for the environment, human health and safety through networking and joint transnational calls.

The first SIINN Call resulted in three transnational projects which started in June 2013:

- The project “nanoIndEx” (www.nanoindex.eu) focuses on the assessment of individual exposure to manufactured nanomaterials by means of personal monitors and samplers.
- The project “NanOxiMet” (www.nanoximet.eu) aims to assess the use of particle reactivity metrics as an indicator for pathogenic properties and as a predictor of potential toxicological hazard. A grouping of MNMs is envisaged by using a combined strategy. It is envisaged that this approach provides bridging of nanomaterial characterization and toxicity evaluation by simplifying a MNM classification e. g. for MNM producers.
- The project “Nanoheter” (<http://www.siinn.eu/en/joint-calls/2012-first-siinn-call/call-1-funded-projects/nanoheter/119>) deals with the exposure aspect of engineered nanoparticles (ENPs), focusing on their fate in surface water.

A second SIINN call was published in 2013.

B. Federal Environment Agency (Umweltbundesamt, UBA)

Finalized project:

Within the BMBF measure “NanoNature” a project called “UMSICHT (Abschätzung der Umweltgefährdung durch Silber-Nanomaterialien: Vom chemischen Partikel bis zum technischen Produkt)” (translation: “Assessment of environmental risks of silver nanomaterials: From the chemical particle to the technical product”) was initiated. Within this project a consortium of 17 partners from research institutes, as well as industry and authorities (e.g. UBA) investigated the potential environmental hazards of silver nanomaterials released from textiles. The contribution of the UBA within this project focused on the assessment of aquatic toxicology using standardised test methods, as well as on the measurement of the antibacterial effects of nanomaterial containing products and the release of nanosilver from these products upon simulated use. Based on the results of UMSICHT, UBA performed an exemplary environmental hazard and risk assessment for nanosilver used in textiles. Factors that limit the hazard and risk assessment were also included in the scope of this project.

The results of the microbicidal activity of Ag - NP allocated in textiles showed a reduction of airborne germs in the indoor air due to the presence of an Ag - NP -allocated curtain. This was especially observed in the measurements during the colder months. The results of the product-specific simulated use with wipes on various surfaces (marble, glass, wood) showed only a reduced particle release in the range between 30 and 60 nm. In the range higher than 100 nm almost no particle release was observed. The determination of the silver content in the wipes (whether the wipe was used or not), by means of ICP – OES, showed an almost constant concentration of silver which was uniformly distributed over the surface of the wipe. Thus, regarding the silver content, no difference could be observed between the various surfaces investigated. The results of the study with the real worn textiles (socks) showed an unbalanced distribution of the silver in the socks: while very little silver was incorporated in the cuffs, the concentrations in the heel and toe area were significantly higher. The initial silver concentration decreased by about 80% with increased wearing time. However it is not clear whether the release of silver takes place during wearing or washing.

Ecotoxicological investigations with silver nanoparticles (NM-300K) and silver nitrate have been conducted on a variety of aquatic organisms representing different levels of aquatic food webs. The final research objective was to increase the knowledge of effects, behaviour and toxic potential of silver nanoparticles in aquatic ecosystems. Therefore, ecotoxicological tests have been performed in accordance to international standardized test guidelines and in compliance with the strict regulations of the international quality assurance system GLP. In close cooperation with several project partners the ecotoxicological studies were complemented by different analytical investigations and sophisticated methods of nanoparticle characterization.

For the aim of an exemplary risk assessment of nanosilver released from textiles used for domestic uses environmental exposure scenarios (via WWTP with waste water supply from domestic homes) were developed from which PECs (*predicted environmental concentrations*) were deduced for wastewater treatment plants and for the environmental compartments surface water, sediment and soil after sewage sludge application. These PECs were related to PNECs (*predicted no effect concentrations*). These PNECs were deduced from effect concentrations for the selected nanosilver material NM-300K compiled in the context of the UMSICHT project. With respect to the examined environmental compartments and based on the chosen scenarios and defined conditions no environmental risk of the nanosilver NM-300K was identified. However, it has to be considered that this assessment is only valid for NM-300K and the usage of it in textiles used for domestic purposes. The inclusion of measurements of the total content of silver in

sewage sludge in the respective regulations is recommended. An increase of the silver content would be an indicator of a potential risk due to an increasing content of nanosilver, which would be part of the measured total silver.

The final report written in German is available at:

<http://edok01.tib.uni-hannover.de/edoks/e01fb14/784804850.pdf>

Publications presenting the results of UMSICHT are in preparation.

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

BfR was involved in the recently finished BMBF funded project “nanoGEM”, where in total 19 partners were assessing possible human health risks of NM including exposure and hazard assessment. The focus of this project was on the role of specific surface modifications of industrial relevant NM and how those surface modifications alter behaviour and toxicity. BfR was co-leading a work package characterizing NM *in situ* in different biological test media and analysed the protein corona of 16 different NM. In addition BfR analysed genotoxicity applying COMET assay in 3D lung models and was assessing mechanisms of toxicity, in particular mechanisms related to oxidative stress and alterations in cellular signalling pathways. Furthermore BfR was co-leading a work package for preliminary risk estimation and was analysing exposure of consumers from various types of consumer products with different NM applying various exposure modelling. Overall only few of the 16 NM had toxic effects. In general surface modification could alter toxicity, i.e. reduce toxicity. The nano-size per se does not mean that the particles are toxic or hazardous. A detailed case-by-case analysis is needed.

BfR is involved in the EU project NanoDefine, which started in November 2013. It is a four year project, which consist of a 29-partner consortium of top European RTD performers, metrology institutes, and nanomaterials and instrument manufacturers will address the still existing uncertainties surrounding environment, health and safety (EHS) issues and the questions that need to be addressed: what is or isn't a nanomaterial. One challenge consists in the development of methods that reliably identify, characterize and measure nanomaterials (NM) both as substance and in various products and matrices. In responses, the European Commission has recently recommended a definition of NM as a reference to determine this (2011/696/EU). Based on a comprehensive evaluation of existing methodologies and a rigorous intra-lab and inter-lab comparison, validated measurement methods and instruments will be developed that are robust, readily implementable, cost-effective and capable to reliably measure the size of particles in the range of 1 - 100 nm, with different shapes, coatings and for the widest possible range of materials, in various complex media and products. Practical case studies will assess their applicability for various sectors, including food/feed, cosmetics etc. One major outcome of this project will be the establishment of an integrated tiered approach including validated rapid screening methods (tier 1) and validated in depth methods (tier 2), with a user manual to guide end-users, such as manufacturers, regulatory bodies and contract laboratories, to implement the developed methodology.

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

BAuA, UBA, BfR, BAM and PTB have published an English translation of the first evaluation on the Joint Research Strategy of German Governmental Research Institutions "Nanotechnology - Risks related to Nanomaterials for Humans and the Environment" (2007 - 2011)

<http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/Nanotechnology/pdf/evaluation.pdf>

BAuA has launched a working and a research and development program for 2014 – 2017. As a part of the main topic “Ensuring safe use of chemicals and products” the following policy and R&D activities are planned for a safe use of nano and other advanced materials:

“With scientific findings on the safety of nanomaterials it became evident that European regulations on chemical safety do not yet take sufficient account of significant risks arising through the inhalation of dust particles and fibres. Even in the case of substances with no specific toxicity, biopersistent particles and fibres of low solubility can enter the lungs by inhalation and, once there, can trigger inflammation and cancers. In addition to some nanomaterials, this can also relate to other dust-forming materials. Within the framework of research and development, the focus will be expanded in the programme period beyond nanomaterials to include other newly developed materials (advanced materials), which are identified as a specific area of technology for support in the EU’s 8th framework programme for research (“Horizon 2020”). Measurement and testing methods are to be further developed and knowledge is to be generated in relation to the assessment of possible health risks. This will centre on investigations into dust generation by substances, the shape, surface and size distribution of released particles, and the biopersistence and cytotoxicity of such particles as first indications of a possible hazard. The medium-term aim of the activities is to consistently integrate protection from dusts and fibres that can enter the deep lung into the EU’s chemical safety regulations. Furthermore, model-based consultation will enable research institutions and start-up companies to recognise risks to humans and the environment as early as possible. In this way, safe design and the safe use of advanced materials are to be promoted even for production quantities that lie below the registration thresholds for REACH.”

- BAuA working program 2014 – 2017
<http://www.baua.de/en/Publications/Brochures/I31.html>
- BAuA research and development program 2014-17
<http://www.baua.de/en/Publications/Brochures/I30.html>

Information on public/ stakeholder consultation

A. Federal Ministry of Education and Research (BMBF)

The BMBF funds the web-based knowledge and data platform ‘DaNa – The Knowledge Platform on Nanomaterials’, which has been revamped and now includes new features. The new website of the DaNa^{2.0}-Project (www.nanopartikel.info/en/) provides information about nanomaterials, available from smart phones, tablets or desktops. The aim of the web presence is to illustrate research results on safety aspects of nanomaterials to a broad audience – to experts as well as to lay people – well-structured and intelligible to all. The core of this website is the data base of nanomaterials in the domain ‘nanoINFO’, which concentrates the latest knowledge in this field.

The BMBF continues its series of dialogue events “citizens meet experts” to inform the interested public on chances, risks and perspectives of nanotechnology and to provide an opportunity for the participants to discuss with experts.

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 publishes data sheets concerning nano-products. The data sheets focus on the

description of application and on ecotoxicological and health aspects. So far, three fact sheets were published which are available on the UBA website:

- <http://www.umweltbundesamt.de/publikationen/use-of-nanoscale-iron-for-the-remediation-of>
- <http://www.umweltbundesamt.de/publikationen/nanotechnology-based-lighting-systems-organic-light>
- <http://www.umweltbundesamt.de/publikationen/use-of-nanomaterials-in-textiles>

Currently, UBA published a fourth data sheet “Einsatz von Nanomaterialien in Beschichtungen” (Use of nanomaterials in coatings). At the moment it is only available in German, but will be published in English soon.

Investigation of the impacts of selected nanotechnology based products on the resource and energy demand: On behalf of Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB) and Federal Environment Agency, the Institute for Applied Ecology (Öko-Institut e.V.) has presented a study, in which the expected raw material and energy demands for particularly promising nanotechnology application fields are qualitatively and quantitatively described as far as possible. Basically, the results from two case studies – electrically dimmable windows and organic photovoltaic modules – show significant potentials for savings on raw material and energy. Against the background of this study it is particularly evident that a consideration of the entire life cycle is essential important, and that rebound effects must be included in the analysis as well. The results have been published in TEXTE 21/2014 (German) (<http://www.umweltbundesamt.de/publikationen/untersuchung-der-auswirkungen-ausgewahlter>).

ITALY

Highlight of developments

The Sustainable Nanotechnologies (SUN) project was launched on 1 October 2013; it brings together 35 partners from 12 EU countries with a total budget of about 14 million EUR. The project is coordinated by Venice University Ca’ Foscari.

SUN project is based on the idea that the current knowledge on environmental and health risks of nanomaterials, while limited, can nevertheless guide nano-manufacturing to avoid liabilities if an integrated approach addressing the complete product lifecycle is applied.

A one year national project to study health and safety issues related to silica nanoparticles, “Sviluppo di metodi validati e/o alternativi per la determinazione della dimensione, distribuzione, agglomerazione e citotossicità di nanomateriali rilevanti per applicazioni industriali” has founded by Italian Ministry of Health. The project, led by National Institute of Health (Istituto Superiore di Sanità, ISS), started in January 2014.

A webinar on “Regulatory activity on nanomaterials: state of art and future perspectives” has been organized by the Tecnic Unit of Environmental Technologies (Laboratorio Eco Innovazione dei Sistemi Produttivi) of the Agency for New Technologies, Energy and Sustainable Economic Development (ENEA) in January 2014. Aim of the webinar was to discuss on the European situation of regulatory activity on nanomaterials with particular regard on its compatibility with the industrial production.

A survey to gather opinion of European and Italian citizens on nanotechnology innovation priorities has been launched in Italy, within the activities of the EU NMP NanoDiode Project (AIRI/Nanotec IT partner). The survey will run from March to June 2014.

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 activity on the National registry on nanomaterials is still in progress. The structure of the Italian nano-database 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 from 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, chemical-physical characterization methods, terminology, online submission of huge amount of data, IUCLID compatibility.

The certification company CSQA and the high tech cluster Veneto Nanotech have published and launched (during the NanotechItaly 2013 Conference) the new standard DT n.113 “Responsible management system of nano materials in consumer products”. The standard is complementary to the UNI EN ISO 9001: 2008.

Developments related to Integrated Testing Strategies and/or Alternative test methods

In the framework of OECD WPMN Sponsorship programme - SG7 activities, ISS and 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).

ENEA and ISS experts participated to the OECD Horizontal Meeting on Nano Genotoxicity (Ottawa, November 2013) and Toxicokinetics and Mechanistic Issues (Seul, February 2014).

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

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”.

A two year national project to study health and safety issues related to silver nanoparticles, named Nanotox: Toxicology of chronic exposure to engineered silver nanoparticles has started in June 2012, led by the University of Milano.

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.

Activities related to NANoREG project (NMP.2012.1.3-3 Regulatory testing of nanomaterials) are ongoing. Under the supervision of the Italian Ministry of Health, National Coordinator, several partners are involved: ISS, Veneto Nanotech, CNR, ENEA and IIT. Besides INAIL, University of Tor Vergata and University of Turin participate to the project as third parties.

The first Italy-Brazil Joint Commission Meeting on Scientific and Technological Cooperation held in Rome in October 2013. The Commission jointly identified nanotechnology and new materials among the areas of interest for strengthening the bilateral scientific and technological cooperation. A dedicated working group jointly agreed that development of a common view on all regulatory aspects of producing and using nanomaterials, in particular with focus on methodologies and safety should be a priority in future collaborations.

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

Information on public/ stakeholder consultation

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. See point 2.

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

The NanotechItaly 2013 Conference (27-29 November, 2013) held a full session devoted to safety and societal impacts of nanotechnologies, with the participation of most relevant research, industry and policy players at national level. One of the highlights of the debate has been the safety by design approach for nanotech R&I.

Information on research programmes or strategies which focus on life cycle aspects of nanomaterials

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, held in Rome on 11-13 November 2013.

JAPAN

Highlight of developments

- Japan is positively 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 website⁴ 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 TiO₂ in nanoscale. In addition, MHLW launched development of measurement methods for airborne nanomaterials, carbon black and SW/MWCNT.

The Japanese Industrial Standards Committee (JISC), which is the national member body participating as a P-member in ISO/TC229 (Nanotechnologies), nominated the Convenor and Secretary of TC229/JWG2 (Measurement and characterisation) and currently leads 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*." In TC229/JWG2, JISC also leads a Study Group on Tiered Approach for Nano-object Identification within a Sample.

The National Institute of Advanced Industrial Science and Technology (AIST) has 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 provided, 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 projects⁵.

An expert committee, organised 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 2009⁶. From 2011 JFY MOE has been focusing their efforts on environmental risk of manufactured nanomaterials via understanding of their environmental fate and ecotoxicity. Aiming at developing methodologies for measurement of manufactured nanomaterials in the environment (i.e., ambient air and surface water), MOE has initiated their attempts through measuring nano-scale TiO₂ in a closed system and then in the open air outside of the waste shredders. MOE has also been collecting and reviewing existing literature on ecotoxicity of manufactured nanomaterials such as TiO₂, silver and CNTs to identify any harmful effects attributed to their particle size.

⁴ http://www.meti.go.jp/policy/chemical_management/other/nano_program.html

⁵ http://www.aist.go.jp/Portals/0/resource_images/aist_e/aist_today/2011_41/pdf/2011_41_p08_p17.pdf

⁶ http://www.env.go.jp/chemi/nanomaterial/eibs-conf/guideline_0903_enab.pdf

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/reti-nano/en/> to introduce this programme was released in December 2013. Some results of the R&D theme 2) above were presented at a WPMN horizontal expert workshop on toxicokinetics of nanomaterials in February 2014. 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 September 2014. Against a backdrop of the implementation of this programme, Japan 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”.

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 suitable for voluntary safety management of carbon nanotubes (CNTs) by industries. The 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, which are available for download from the AIST-RISS website⁷:

- “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”.

MHLW has promoted research on the human health aspect of several nanomaterials since 2003 through the Health and Labour Sciences Research Grants, etc. In 2014 JFY, eight research projects, including a basic research on development of methods for evaluating hazard and disposition of nanomaterials on human health, are progressing.

The Japan Bioassay Research Center launched a “Research project on the potential hazards, etc. of nanomaterials”, commissioned by MHLW, which focuses on carcinogenicity of nanomaterials used/manufactured in the workplace (six-year programme, 2009-2014 JFY). Two-year inhalation study of multi-wall carbon nanotube (MWCNT) is on-going now (2012-2014 JFY). In addition, in order to elucidate the carcinogenic mechanism, *in vitro* chromosome aberration and *in vivo* micronucleus tests have been carried out in 2014 JFY.

The National Institute of Occupational Safety and Health, Japan (JNIOSH) is currently conducting a three-year project study (2012-2014 JFY), “Toxicological Study on Ultrafine Particles of Metal Oxides”.

⁷ http://www.aist-riss.jp/main/modules/product/nano_tasc.html?ml_lang=en

This project includes investigation on 1) genotoxicity, 2) neurotoxicity, and 3) reproductive toxicity of nano-sized TiO₂ particle. Another three-year project (2013-2015 JFY), “Study on collection and analysis procedures of airborne particulate matters in nanomaterial-handling workplaces” 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, and a continuous generating method of multi-dispersed particles simulating real workplace environment.

The National Institute for Environmental Studies (NIES) completed the 1st nanotoxicology programme (2006-2010 JFY) 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 (2011-2015 JFY) which includes *in vivo* toxicological studies of MWCNT, *in vitro* and *in vivo* toxicological study of silver nanoparticles in reference to dissolution of metal nanoparticles, toxicokinetics of fluorescence-labelled dendrimers and ecotoxicological study of TiO₂ nanoparticles using embryo and sac-fry fish.

KOREA

Highlight of developments

- 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 Trade, Industry and Energy (MOTIE, previously called as 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)’, MOTIE launched the 2nd tier project called “Development of safety evaluation based technology for nano-product to promote commercialization” The project has continued from 2013-2015.
- 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.

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 any risk assessment decisions

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

Developments related to good practice documents

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

Developments related to Integrated Testing Strategies and/or Alternative test methods

KATS(Korea Agency for Technology and Standards) is developing two international standards in the ISO/TC 229 (Nanotechnologies) relevant to nanomaterial safety testing “Aerosol generation for NOAA (Nano-objects, and their aggregates and agglomerates) air exposure studies” and Electron spin resonance (ESR) as a method for measuring reactive oxygen species (ROS) generated by metal oxide nanomaterials”. These standard documents will complement the work of the OECD WPMN and other related framework documents

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, SiO₂) 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 Trade, Industry and Energy (MOTIE)

MOTIE in collaboration with MSIP has initiated the programme "Strategy on Nano Convergence Industry Development" to strengthen research on the safety and social impact of nanomaterials. The MOTIE/KATS implemented "Risk Management Platform Technology for NanoProducts (2009-2013)" which provided an infrastructure for the certification of nanoproducts based on a risk management system including characterization, efficacy quality and safety assessment along with standard development. MOTIE 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)’, MOTIE launched three Tier 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. From 2013, Tier 2 project called “Development of safety evaluation based technology for nanoproduct to promote commercialization” was launched. The project has continued from 2013-2015. The project has 3 parts; Part 1(Establishment of database for product containing nanomaterials and inventory) includes nanomaterial/product safety inventory including safety data sheets for nanomaterials, and developing algorithm for certification of nanoproduct safety. Part 2 (Nanoproduct safety assessment by case studies) includes *in vivo* and ecotoxicological safety data production for nanoproducts which have different physicochemical properties, ionization and biopersistence of antimicrobial nanomaterials and preparing recommendation of reference dose for products containing nanomaterials. Part 3 (Development of testing methods and standardization of nanomaterials and product containing nanomaterials) includes development of product chemistry methods for nanoproduct, development of exposure assessment from nanoproduct, development of testing methods for nanorelease from nanoproduct and international cooperation with ISO/TC 229, OECD WPMN, ILSI

Nano release, and EU Nano safety Cluster. KATS is developing 2 international standards in the ISO TC 229 (Nanotechnologies) relevant to nanomaterial safety testing “Aerosol generation for NOAA (Nano-objects, and their aggregates and agglomerates) air exposure studies” and Electron spin resonance (ESR) as a method for measuring reactive oxygen species (ROS) generated by metal oxide nanomaterials”. These standard documents will complement the work of the OECD WPMN and other related framework documents

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 SiO₂, 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 SiO₂, 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.

THE NETHERLANDS

Highlights of developments

- The European NANoREG project, coordinated by the Dutch Ministry of Infrastructure and the Environment, evolved from the start-up phase to the working phase.
- In oral studies on silica, Dutch research showed lower bioavailability at high concentrations, which has potential implications for the dosing in toxicity studies.
- The Dutch organisations of employers and employees joint forces in a pilot study regarding the pros and cons of exposure registration for working with synthetic 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 European NANoREG project evolved from the start-up phase to the working phase. In the start-up phase, the most important basic conditions for the research and development (R&D) activities in the Work Packages 2-6, have been fulfilled. Nanomaterials to be (mandatory) used by all partners have been selected. The web-ordering system for those selected nanomaterials became operational in January 2014. In addition, a set of dispersion protocols has been agreed upon. Furthermore, the minimum requirements for characterisation of dispersions and exposure media have been defined. The results of this preparatory work have been laid down in a ‘Guidance Document on Minimum Requirements and Data Logging’ for the NANoREG partners. The focus of the R&D work was on the reviewing, development and evaluation of standardized operating procedures and test methods to be applied in the coming period. Among others, several techniques for physicochemical characterisation, measurement of size distribution, shape analysis and volume specific surface area have been reviewed and tested. The development of the regulatory framework on “how to address the safety of NMs” and the development of the NANoREG toolbox will be a priority for the coming period. The same applies for the Value Chain Projects that will link the results of the R&D work to the conceptual work. Currently, 63 beneficiaries are involved in the NANoREG Consortium. The NANoREG Industrial Consultation Committee and an Advisory and Regulatory Board have been established during the second General Assembly. More information is available at www.nanoreg.eu. Liaisons with international organisations (South Korea, Czech Republic, Brazil and Poland) have been further expanded.

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.

Within the REACH process, the Netherlands has started a substance evaluation of silver. The focus is on the environmental fate and toxicity of the nanoforms of silver. Currently, work is underway to evaluate the available data in the REACH registration to determine if additional data may be needed, specifically in relation to the nanosized properties of silver.

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 aims 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.

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 projects 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).

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 work package that deals with the risk assessment strategy. Within the work package 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 (NVWA) organised a symposium on ‘risk assessment of nanostructured materials: the case of silica’ (Synthetic Amorphous Silica – SAS). An important aspect that was put forward was the lower bioavailability at high concentrations (Van der Zande et al., 2014). This can have implications for the dosing in toxicity studies. Furthermore, new kinetic and toxicity studies were presented which might suggest that SAS in food may pose a health risk (although the different sources of uncertainty make it difficult to draw firm conclusions). Further documentation on this risk assessment is in preparation. The low oral absorption, the dependence of the fraction absorbed on the dose, and the potential for tissue accumulation in time are considered relevant aspects for risk assessment of nanomaterials with an oral exposure route. Risk assessment based on internal exposure may be useful in such cases. It is highly recommended to include some analytical measurements on distribution to tissues (at least liver and spleen) in toxicity studies.

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

RIVM is one of the partners in the EU project FutureNanoNeeds (FNN). The project 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.

RIVM and Utrecht University are partners in the 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)”. 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.

Development related to exposure measurement and exposure mitigation

The Netherlands (TNO) and Canada (Health Canada) cooperate in the OECD-WPMN project “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. Currently, the chemical analyses have been reported and are being analysed.

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. Discussions of this group feed into projects in OECD and CEN/ISO frameworks.

The Dutch organisations of employers and employees joint forces in a pilot study regarding the pros and cons of exposure registration for working with synthetic nanomaterials. The pilot aims to get insight in the feasibility of such an exposure registration, as well as in the conditions needed to make this tool successful. Following basic principle, the exposure registration should be easy to perform by companies,

should not result in a large administrative burden, and should involve clear, comprehensible data that are easy to collect. To assess the practicality and feasibility of an exposure register in its context, also process generated nanoparticles and background concentrations of nanomaterials will be taken into consideration in the pilot. The pilot is co-financed by the Netherlands Ministry of Social Affairs and Employment and will run from April 2014 until the end of 2015.

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). A data entry module is available and all researchers are encouraged to use the templates for (future) uploading/population of the database. Currently a data analysis and comparison tool is being 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. Real workplace datasets have been collected and used to generate new data sets to extend the power of the data analysis. The first analysis has been conducted and the final results are expected by September 2014. 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 angles, i.e. the relevance of dermal exposure to nanomaterials for i) dermal uptake, ii) local skin effects, and iii) oral intake. The first phase, i.e. review of existing approaches, has been concluded and a summarizing paper is in preparation. 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).

In addition to KIR-nano, the Dutch government has initiated several other stakeholder platforms where government, science, industry and NGOs engage in discussions on nanotechnology. These platforms can function as feedback and sounding board on different topics related to nanotechnology, and include a nanomedicine platform, a platform by the Netherlands Food and Consumer Product Safety Authority (NVWA), a platform with occupational experts, a platform on environmental issues, and an advisory board on risks of nanotechnology (with representatives of industry, NGOs and government).

SOUTH AFRICA

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

The National Institute for Occupational Health (NIOH) with a sponsorship from the Department of Science and Technology (DST) in South Africa has completed a baseline study to establish the extent of production (synthesis), importation and utilization of nanomaterials in South Africa. Specific objectives include to identify institutions and/or individuals operating in South Africa involved with the production (synthesis), importation and/or utilization of nanomaterials, determine the quantity and the variety of nanomaterials produced and the utilization, both commercial and research, of nanomaterials in South Africa. Also, to determine the major methods used in the synthesis of nanomaterials in South Africa and the human resources utilized in the production, importation and/or utilization of nanomaterials in South Africa. Moreover, to determine health and safety practices in the South African nanomaterials industry and identify existing expertise at different institutions and compile information on the infrastructure and human resources that may be able to contribute to the assessment of health and safety of the synthesised or implemented nanomaterials. Finally, it was aimed to identify the funding sources for nanomaterial and nanotechnology in South Africa.

Based on the findings from this study a number of recommendations were made. Firstly, regarding policy and planning, the database established through this study should be maintained and utilized in the tracking of industry developments and possibly as a starting point for establishing an exposure registry of persons working with nanomaterials. This should ideally include a long-term medical surveillance programme. Information from these databases would play an integral role in early hazard identification and assist the government to develop appropriate regulatory frameworks. Further to this industry guidelines are needed to inform industry players how to implement appropriate occupational health and safety programmes for nanomaterials. Secondly, there is a great need for research on risk assessment and toxicology relating to nanomaterials. Lastly, capacity to conduct research in the field of nanotechnology should be augmented through the creation of partnerships and resource sharing where a need to strengthen research particularly around nanotoxicology is required. As the concept of the Nano-HSE Research Platform will be based on the Health Risk Assessment paradigm, data from a baseline study would be useful to guide future directions in research themes within focus areas identified within the boundaries of this Research Platform.

Information on public/ stakeholder consultation

To ensure that South Africa remains competitive within the international research community in this fast-developing field, the country's nanoscience and nanotechnology effort is being coordinated at national level by the Department of Science and Technology (DST) through its National Nanotechnology Strategy. The strategy aims to ensure that South Africa is ready to use nanotechnology to enhance its global competitiveness and achieve social development and economic growth targets. It is the vision of the strategy to *"draw upon existing strengths of the national system of innovation while addressing the need to enhance its research infrastructure and to create a workforce for advancing technology businesses that support the country's future competitiveness and enhanced quality of life"*.

Closely aligned to this strategy is the Nanotechnology Public Engagement Programme (NPEP) which aims at enhancing public understanding of nanotechnology and its benefits, highlighting nanotechnology applications in industry that address key societal imperatives and thereby encourage public support, and translating scientific research involving nanotechnology in such a manner that academia is able to recognise trans and interdisciplinary research opportunities, while the industry can identify from the potential innovation/entrepreneurial opportunities.

The overall objectives of this NPEP programme are therefore to disseminate information about nanotechnology research activities in South Africa, profile South African scientists in nanotechnology research, share information about events, conferences etc., both local and international, relating to nanotechnology, inform society across all sectors, including industry, policy makers, youth and civil society, of local and international research activities, create awareness around opportunities for industry and research collaborations, generate public awareness of nanotechnology and its applications, and encourage and develop scientists to be able communicate science with all level stakeholders not limited to peer communities.

SWEDEN

➤ **Swedish Official Investigation - A National Action Plan for Nanomaterials**

The Swedish Government launched in September 2012 a special investigation that in close relationship with the Swedish Chemical Agency propose a National Action Plan for Safe Use and Handling of Nanomaterials.

The overall objective of the action plan is twofold: to promote the opportunities for innovation and development of nanotechnology and to prevent adverse effects on health and the environment resulting from the handling of nanomaterials i.e. to interweave the innovation and risk processes.

The Swedish national action plan for nanomaterials proposes measures for the safe use and management of nanomaterials. These measures utilise the opportunities that nanomaterials provide while simultaneously minimising the risks to human health and the environment. Measures are proposed within the following areas.

- Measures to build knowledge about health and environmental risks
- Swedish agencies to participate actively in prioritised programmes for the development of testing and risk assessment methodology within the EU and the OECD.
- Substantially increased funding to be set aside for research and development of testing and risk assessment methodology.
- Targeted, and substantially increased, funding to be set aside for research into the health and environmental effects and safety aspects of nanomaterials and for research into the ethical and social consequences of utilising nanomaterials and nanotechnology.
- The risks in the work environment to be given particular focus.
- The risks are to be considered from a lifecycle perspective.
- Investments in research and development to set a focus on innovation and consideration of the potential health and environmental effects of nanomaterials in an early stage.
- Measures for an overview and dispersion of knowledge concerning the health and environmental risks of nanomaterials

- An inventory of the current state of knowledge to be carried out and continuously updated as regards the health and environmental effects and the ethical, legal and social aspects of nanomaterials.
- Measures to be taken to facilitate and strengthen cooperation and knowledge transfer among Swedish research groups.
- Measures to be taken to promote development in higher education nanomaterials programmes, so that knowledge about the health and environmental effects and the ethical aspects is conveyed in parallel with and tied to the technical knowledge all the way through all higher education nanotechnology programmes in Sweden.
- The relevant agency staff to receive training and continuous inservice training on nanomaterials and nanotechnology and their potential health and environmental risks.
- Measures for communication and cooperation
- Increased resources to strengthen knowledge transfer among researchers and enterprises concerning the health and environmental safety of nanomaterials and how such aspects can be integrated into the technological development of enterprises.
- Central agencies to pursue a dialogue with enterprises, organisations and other stakeholders concerning the design of guidance documents and rules regarding nanomaterials and nanotechnology.
- Greater resources to be invested in communication and dialogue with the general public, enterprises, environmental and consumer protection organisations, agencies and other stakeholders about the advantages and potential risks of nanomaterials and nanotechnology.
- A forum to be established for greater and stronger knowledge transfer, communication and dialogue between researches and enterprises, between governmental bodies and with the general public, and other stakeholders concerning health and environmental safety on nanomaterial.
- Measures for the development of the EU's regulatory framework
- The Government and relevant agencies shall work to bring about a revision of REACH, the European chemicals regulation:
 - Nanomaterials are to be registered as a separate substance.
 - The tonnage limits are reduced for nanomaterials.
 - The information to be submitted when registering nanomaterials include supplementary data on their physic-chemical properties and, when necessary, other relevant information.
 - The obligation to register products containing nanomaterials is extended.
 - The rules regarding information to downstream users are to be revised so that they also include relevant details on nanomaterials.
- The Government and relevant agencies shall work to bring about a revision of the European legislation on chemical substances and products:
 - The regulatory frameworks ensure that the data submitted and the assessments made are relevant to the substance in the form it occurs.
 - Manufacturers, importers and distributors of products containing nanomaterials should be able to declare the preceding and subsequent links in the distribution chain.
 - The proposed amendments to the regulation on novel foods, aimed at clarifying the regulations on nanomaterials, are to be adopted as soon as possible.
- Measures to increase knowledge about nanomaterials on the market
- The Swedish Chemicals Agency to be given the task of investigating how an obligation to submit information on the occurrence of nanomaterials when registering products in the product register might be worded.
- An inventory of products on the market that contain nanomaterials to be performed.
- Measures for implementation: Platform for coordination

- A Nano Council to be established and given the overarching responsibility for the further development of strategies and for prioritising measures for the safe management of nanomaterials.
- The Nano Council to be organised as an independent council under the Swedish Government.
- A Nano Centre to be established as a secretariat and operative arm of the Nano Council.

The National Action Plan has been circulated for comments to authorities and other stakeholders in Sweden. The Swedish ministry will now consider the comments and then decide on if they will implement the measures suggested in the action plan

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 Swedish Chemicals Agency (KemI) agree that nanomaterials are covered by Reach but are of the opinion that to ensure safe handling and use of nanomaterials the articles in the legislation need to be changed, and it is not enough to only change the Annexes and guidance. Therefore KemI, as a member of the group for the competent authorities of Reach, have prepared and circulated a KemI-proposal for a nanomaterials regulation for comments to the COM, ECHA, and other EU MS. A consultant will perform an impact assessment for the KemI-proposal for a nanomaterials regulation

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

MISTRA

Swedish Foundation for Strategic Environmental Research (Mistra) is now to start a nano programme focusing on safety - Mistra Environmental Nanosafety - placed on Chalmers Technical University

The Swedish Foundation for Strategic Environmental Research (Mistra) is now to start a nano programme focusing on safety. The programme, entitled 'Mistra Environmental Nanosafety' will be headed by Chalmers University of Technology, for which SEK 40 million (just over USD 6m) over four years is budgeted. The researchers will have four years to develop methods that make nanotechnology a key element in a sustainable society. The overarching aim is to create an interdisciplinary research environment for developing technology that can be used in the environmental sector. The programme will also conduct research on the environmental impact of nanotechnology to gain knowledge about the risks, safety and spread of nanomaterials.

The consortium behind the winning proposal comprises Chalmers University, the University of Gothenburg, Lund University, Karolinska Institute, KTH Royal Institute of Technology and AkzoNobel.

<http://www.mistra.org/en/mistra/news/news-archive/2014-04-14-sek-40m-for-nanotechnology-with-environmental-benefits.html>

KemI Report

A KemI funded report was published 2013: Exposure assessments of nanoparticles in aquatic environments – considerations, review and recommendations. (<http://www.kemi.se/sv/Innehall/Publikationer/Rapporter/>)

The main objective of the report was to outline and discuss important considerations for the exposure assessment of nanoparticles in the aquatic environment as part of the risk assessment. This includes also to discuss environmental conditions of importance for exposure assessment of nanoparticles, to review published exposure models for nanoparticles in aquatic environment and to outline important considerations for validation of exposure models for nanoparticles.

The following recommendations to ensure good exposure assessment of nanoparticles in the future were provided by the authors:

1. Information of flows and stocks of nanoparticles in society need to be collected.
2. Emission factors would need to be developed for each product that makes use of nanoparticles.
3. Emissions should be reported both as mass and particle number until it becomes clearer which one is most relevant.
4. More research is needed in order to determine which particle properties need to be known in order to calculate the concentration of nanoparticles in the environment.
5. At least the particle size and particle size distribution, as well as the specific particle density should be reported.
6. More research is required to improve the experimental measurements of nanoparticles to be able to validate exposure models.

NANoREG

Several Swedish research-groups are participating in the European project NANoREG. The Swedish Chemical Agency has a representative in the National Reference group and also participate as an Advisor to the National Coordinator on regulatory issues within the project.

ECHA work-shop

SE participate in Scientific Committee for preparation of ECHA Topical Scientific Workshop on NM 23-24 October 2014

NanoSphere

This research program funded by The Swedish Research Council Formas started 2009 and will be finalized 2014. There will be a final conference 22 September 2014. <http://www.nanosphere.gu.se/>

The aims of the program has been to contribute to improved risk assessments for nanomaterials, by increased knowledge about:

- (i) effects of nanomaterials on human health, ecosystems, and the society

(ii) exposure pathways and nanomaterial flow

(iii) analytical method development

Nanosphere consists of twelve groups from three faculties at University of Gothenburg and from Chalmers Technical University. The research work plan consists of 8 research work packages, one societal interaction package and one education and training work package (<http://www.nanosphere.gu.se/research-focus/work-packages/>).

Information on public/ stakeholder consultation

KemI action plan

The Swedish Government has instructed the Swedish Chemicals Agency (KemI) to produce an action plan for a toxic-free everyday environment. This assignment includes reporting on measures needed in the period 2011 - 2014 to reduce the risk faced by people in their everyday lives of being exposed to hazardous chemicals and was published in March 2011. Increased knowledge in the areas of health and environmental risks of nanomaterials is an area of concern in this actionplan.

Swedish government agencies workshop

In 2013 the Swedish Medical Agency in collaboration with the Swedish Chemicals Agency invited Swedish government agencies to a third joint workshop to give an overview of their nano-related activities. The agencies were regulators, supervisors, funding agencies and/or users of nanomaterials. The main topic were the conclusions made in the Swedish National Action Plan for Safe Use and Handling of Nanomaterials and how to move forward from the different participants perspective.

SWITZERLAND

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

Depending on their use, nanomaterials are covered by existing regulations set forth in chemicals, environmental, foodstuffs and therapeutic products legislation. Existing threshold values and provisions on health protection at the workplace, on the prevention of major accidents and on waste management are also applicable.

The safety of nanomaterials is reviewed within the scope of existing procedures:

- Therapeutic products, pesticides and biocidal products are subject to an approval procedure, the approval procedure for pesticides specifically asks for nanospecific information.
- The use of different additives and ingredients in food, cosmetics and commodities is in part regulated with lists which provide information about whether a substance may or may not be used (positive and negative lists) as well as lists with quantitative restrictions. Requests are handled

analogously to those for a new, as-yet unlisted additive. The same would apply to requests for packaging materials containing nanomaterials which come into contact with foodstuffs.

- According to the Chemicals Ordinance, manufacturers of new and existing chemical substances and preparations are obligated to review the safety for consumers and the environment within the scope of their compulsory self-regulation.
- New substances are subject to a notification procedure defined by the Chemicals Ordinance (ChemO). Nanomaterials corresponding to the new substance definition set forth in ChemO are subject to registration.
- The data set necessary for the notification of new substances as well as the data set for the declaration of substances and preparations classified as dangerous has been amended with data on the identity of nanomaterials. These amendments of the Chemicals Ordinance came into force on 1st December 2012.

Link: www.infonano.ch (Legislative process and enforcement, applicable law).

Information on risk assessment decisions

Risk management: Action Plan for synthetic nanomaterials

The Swiss Federal Council launched the “Action Plan for Synthetic Nanomaterials” in April 2008. The Action Plan illustrates the work required for the safe handling of nanomaterials. On 25 April 2012 the Federal Council decided to continue the Action Plan until 2015. It is now in the final phase, where an extensive review takes place and further actions/strategies are developed for its intended continuation after 2015.

The objectives of the Action Plan include:

- development of regulatory framework conditions for the responsible handling of synthetic nanomaterials nanotechnology (examples provided above);
- creation of scientific and methodical tools aimed at identifying and preventing potential harmful effects of synthetic nanomaterials on health and the environment nanotechnology (examples provided further below);
- promotion of the public dialogue on opportunities and risks of nanotechnology (examples provided further below).

The following projects have been implemented within the scope of the Action Plan or by trade organisations:

Precautionary matrix for synthetic nanomaterials

The Federal Office of Public Health (FOPH) and the Federal Office for the Environment (FOEN) published a precautionary matrix to assist authorities, industry, trade, commerce and research laboratories in the preliminary clarification of any need for action in 2011. An updated version of the successfully launched tool has been published in 2013 and this year (2014), a downloadable version was made available. The precautionary matrix is based on a limited number of evaluation parameters, including

- size of the particles
- their reactivity and stability
- their release potential
- the amount of particles

These parameters are used to estimate the precautionary need for employees, consumers and the environment at each defined step in the life cycle. The tool considers particles up to a size of 500 nm because uptake of particles larger than 100 nm (as most of the definitions claim) has been frequently reported.

Link: <http://www.bag.admin.ch/nanotechnologie/12171/12174/index.html?lang=en>

Safety data sheet: Guideline for synthetic nanomaterials

The first version of the nano-SDS guidelines (December 2010) has been updated with new scientific developments and new international definitions. The second version (April 2012) has improved wording and is based on the nanomaterial definition recommended by the EU commission 2011/696/EU on 20.10.2011, which considers the particle size distribution. Furthermore this version has taken into consideration the latest standard and threshold values for maximal occupational workplace concentrations - the values have been integrated in the two SDS examples (SUVA standard values 2012). The two SDS examples have been separated from the main text and the accompanying leaflet summarizes the most important content of the guidelines on three pages.

Link: <http://www.bag.admin.ch/nanotechnologie/12171/12176/index.html?lang=en>

Disposal of industrial nanowaste

Industrial nanowaste containing releasable nanomaterials can arise from production, industrial and commercial processing of nanomaterials and research activities. A task force appointed by the Federal Office for the Environment (FOEN) has developed an implementation aid, describing the basic principles of the environmentally compatible and safe disposal of this type of waste. Key information and a concept paper provides the governmental statement and further information.

Link: <http://www.bafu.admin.ch/abfall/01472/12850/index.html?lang=en>.

Developments related to Integrated Testing Strategies and/or Alternative test methods

Federal Office of Public Health is a consortium member in the EU project "NanoReg", with the Federal Office for the Environment and the State Secretariat for Economic Affairs SECO being co-sponsors. We contract Swiss researchers who are contributing to three work packages, focusing on development of harmonized characterization protocols, modelling nanoparticle workplace exposure based on workplace measurements, and on establishing SOPs for (high throughput) in vitro test methods of potential future regulatory relevance.

Link: www.nanoreg.eu

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

The National Research Programme "Opportunities and Risks of Nanomaterials" (NRP 64) aims to bridge the gaps in our current knowledge on nanomaterials. The research projects (10 million Euro in total) have started in December 2010 and will come to an end in 2015. The ongoing research projects will help to solve problems and answer questions related to such particles. The research carried out under this programme will provide a scientific basis for recommendations and appropriate measures with regard to

the generation, use and disposal of engineered nanoparticles. It covers the five main areas biomedical applications, environment, food, energy, and construction materials. The insights gained from the study of engineered nanoparticles and their applications will benefit society at large and help to protect the consumer and the environment.

Link: www.NRP64.ch

Information on public/ stakeholder consultation

Expo Nano

Expo Nano is a mobile exhibition platform on nanotechnology. Focus of the exhibition are opportunities and risks of nanomaterials along their life cycle. Since summer 2013, Expo Nano stopped in different German-speaking Swiss cities, and is now being translated into French for further exhibitions in the French part of Switzerland. Expo Nano is multimedia-based, interactive, and open for free to everybody. Target audience is the broad public and focus events for specific target groups (e.g. schools, small companies) are organized specifically.

Link: <http://exponano.ch>

Website InfoNano

Since April 2012 the main information platform for nanotechnology "InfoNano" is online. InfoNano provides information in German, French, Italian and English about the opportunities and risks associated with nanotechnology and synthetic nanomaterials. It is aimed at promoting the dialogue among administrative, economic, research and societal stakeholders. It presents all relevant activities on nanotechnology made by the ministries and provide a structured entry into the world of nanotechnology, from research, to consumer products, to regulatory information and further documentation.

Link: www.infonano.ch

Information on research programmes or strategies which focus on life cycle aspects of nanomaterials

Switzerland (FOPH and Empa) is actively participating in the OECD WPMN project on the Environmentally Sustainable Use of Manufactured Nanomaterials.

UNITED KINGDOM

Developments related to good practice documents and standardisation

- The UK's National Physical Laboratory (NPL) is leading two projects under CEN TC 352 as part of the EC mandate M/461. The first is on "Guidance on measures for characterizing nano-objects and materials that contain them" giving an overview of the characteristics and measurement techniques required when characterising nano-objects. The second is on "Guidelines for aspects of Life Cycle

Assessment specific to nanomaterials", which will also contain case study examples of several common nanomaterials.

- The UK hosted a meeting of ISO TC229/WG3 (nanotechnologies – health, safety and environment) in April 2014.
- NPL is leading the development of an ISO standard on terminology for graphene and other 2D materials, which is set to be one of the first standards in this important area.
- The Health and Safety Executive has published nano guidance titled ‘Using Nanomaterials at Work’. It covers how to deal with exposure to manufactured nanomaterials.
- The Health and Safety Executive has published a report titled ‘The use of Nanomaterials in UK Universities: an overview of occupational health and safety’. It covers the occupational use and manufacture of engineered nanoparticles in the UK within universities.

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

EU Collaborative projects

NanoRem (Taking Nanotechnological Remediation Processes from Lab Scale to End User Applications for the Restoration of a Clean Environment) is now under way. Funded through the European Commission FP7, the UK partners involved are r3 environmental Technology Limited, Contaminated Land: Applications in Real Environments (CL:AIRE), University of Manchester and Land Quality Management Ltd. The project is being co-ordinated by University of Stuttgart, Germany by Professor Hans-Peter Koschitzky. See www.nanorem.eu

This research project, will focus on facilitating practical, safe, economic and exploitable nanotechnology for in situ remediation. This will be undertaken in parallel with developing a comprehensive understanding of the environmental risk-benefit for the use of nanoparticles (NPs), market demand, overall sustainability, and stakeholder perceptions.

The project is designed to unlock the potential of nanoremediation processes from laboratory scale to end user applications and so support both the appropriate use of nanotechnology in restoring land and water resources and the development of the knowledge-based economy at a world leading level for the benefit of a wide range of users in the EU environmental sector.

UK National initiatives

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

NERC grant assessing whether oxidative stress is the primary mode of toxicity for metal oxide NPs, with Kevin Chipman and Jamie Lead as co-investigators.

<http://gtr.rcuk.ac.uk/project/3493BF88-20D2-4EE6-8ABC-72DCA3C95C08>

This is an ecotoxicology study, focused on the potential effects of two metal oxide NPs (cerium oxide NPs and zinc oxide NPs) to sentinel species in freshwater ecology. This work is recent, and none of it is published yet. The following is from an abstract of a paper recently submitted to a high profile journal:

Our aim was to achieve a definitive assessment of the molecular and phenotypic effects of ceria NPs, using well-defined nanoparticles and unbiased molecular analyses. An integrated 'omics approach incorporating transcriptomics and metabolomics was used to investigate the potential toxicity of tightly constrained and physico-chemically characterised 4-5nm mono-dispersed ceria NPs to the unicellular green alga, *Chlamydomonas reinhardtii*, a sentinel freshwater species. We report evidence for the internalisation of ceria NPs into intracellular vesicles within *C. reinhardtii*, yet no significant effect on algal growth rate at any exposure concentration. Furthermore, molecular perturbations were only detected at supra-environmental ceria NP-concentrations. We conclude that for acute exposures to small mono-dispersed particles, there should be little concern regarding their dispersal into the environment for this specific trophic level.

The second study, focusing on the effects of ZnO NPs on *Daphnia magna* (water flea) has generated quite different results and conclusions:

We have identified a truly novel perturbation, that spans two trophic levels. The NPs alter the metabolism of the *Daphnia magna*, modulating their ability to generate chemical signalling molecules that are normally excreted into the water and sensed by freshwater algae. The NPs suppress these signalling molecules, and consequently the algae lose their ability to sense (or 'smell') the *Daphnia*, their primary predator. The ecological implications of this effect remain unknown. One of the primary take home messages from these investigations is that 'omics approaches (transcriptomics to measure gene expression, metabolomics to measure metabolism) are extremely powerful at discovering the underlying molecular perturbations and hence mechanisms of toxicity of nanomaterials.

Swansea University Nano(geno)toxicology Research

Research at Swansea has focussed on assessing the capacity of nanomaterials to induce DNA damage (genotoxicity) and the associated underlying mechanisms; the physical or chemical features of the nanomaterials that are responsible for any damage observed; and the modification of current test systems to ensure compatibility for nanomaterial evaluation.

Assay Testing / Modification

Several test systems are being used to quantify different forms of DNA damage (gross chromosomal damage, point mutations) in parallel with cytotoxicity induced following exposure to nanomaterials. With all of these test systems, careful methodological evaluation has been performed and the methods adapted appropriately to suit assessment of nanomaterials – this was necessary as nanomaterials are inherently reactive and therefore interact with a range of assay components.

Swansea University is currently the only academic institution in the UK to have an automated micronucleus scoring system, which has been validated to increase dramatically the through-put of the micronucleus assay – an OECD recognised test system for quantification of gross chromosomal abnormalities that is very laborious to score manually. Swansea University is also developing the application of 3D culture models for genotoxicity and biological barrier penetration assessment of nanomaterials. It is also considering the genotoxic potential of panels of nanomaterials with subtle differences in their physico-chemical characteristics:

1. Ultrafine superparamagnetic iron oxide nanoparticles with variations in oxidation state and surface chemistry.

2. A range of single-walled carbon nanotube samples that have varying length to determine if they induce similar responses to asbestos (the genotoxicity of which is also dependent upon the length of the fibres).
3. Quantum dots with different sizes, surface charges and compositions.

The over-arching aim in all these studies is to characterise the nanomaterial features that govern adverse biological responses. This data will not only inform the nanotechnology industry of those physico-chemical parameters that promote biocompatibility, but will also promote the development of predictive toxicity models for nanomaterials in the future.

Development related to exposure measurement and exposure mitigation

As part of the UK's contribution to the EU NANoREG (Regulatory Testing of Nanomaterials) project, UK project partners are embarking on a workstream which aims to understand risks arising from exposure to nanomaterials during end of life waste stream processes. A particular focus for this work will be nanomaterial exposure from waste electronics and electrical equipment. Further information about this work is available from the UK's NANoREG National Coordinator, Steve.Morgan@Defra.gsi.gov.uk.

Additional Information

Government departments and agencies will continue discussions with UK nano-researchers on longer term research aims and strategies for nanomaterials (focussing on environmental exposure/hazards/risks in this case).

UNITED STATES

Highlight of developments

On February 12, 2014 the U.S Environmental Protection Agency (EPA) issued final Toxic Substances Control Act (TSCA) significant new use rules (SNURs) for 4 carbon nanotubes and 1 infused carbon nanostructure. EPA's determination in a SNUR that a use of a chemical substance is a significant new use is made after consideration of all relevant factors, including production volume; changes to the type or form of exposure; increases in the magnitude and duration of exposure; and the manner and methods of manufacturing, processing, distribution in commerce, and disposal. A manufacturer or processor wishing to engage in a designated significant new use must submit a Significant New Use Notice (SNUN) to EPA at least 90 days before engaging in the new use. The SNUN provides USEPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs.

The United States and Canada continued their cooperation on nanomaterials under the Regulatory Cooperation Council (RCC), and the RCC Nanotechnology Final Results Workshop was held January 14, 2014 in Washington, DC, formally concluding the Nanotechnology Work Plan. 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. Pragmatic changes stakeholders can expect from the two countries include (a) a consistent policy approach

for nanomaterials based on the shared policy principles; (b) consistent use of a classification scheme to identify data needs (short-term) and how information from one substance can be used for another substance (medium to long-term); (c) consistent use of data submitted to support risk assessments based on the framework for human health information and common assumptions for ecological fate and effects; and (d) using commercial use information to better qualify exposures in risk assessments and focus information requests in control measures. Moving forward, both governments will be looking at the best approaches to communicate the results of the RCC Nanotechnology Initiative.

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 Actions. Since January 2005 EPA has received and reviewed more than 160 new chemical notices for 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 manufacturer or processor wishing to engage in a designated significant new use identified in a SNUR must submit a Significant New Use Notice (SNUN) to EPA at least 90 days before engaging in the new use. A sanitized version (i.e., without confidential business information) of such a consent order is available. Because of confidential business information claims by submitters, EPA may not be allowed to reveal to the public 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 February 12, 2014 EPA issued final significant new use rules (SNURs) for 4 carbon nanotubes and 1 infused carbon nanostructure. See <http://www.gpo.gov/fdsys/pkg/FR-2014-02-12/pdf/2014-03079.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 2014.

On August 27, 2013, EPA announced a proposed decision to register a nanosilver-containing antimicrobial pesticide product named “Nanosilva” (<http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2012-0594-0002>). 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 would require 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 2014.

UC CEIN. University of California's Center for Environmental Implications of Nanotechnology (CEIN) is funded by a cooperative agreement from the National Science Foundation and EPA's Office of Research and Development, 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.

CEIN Workshop on Categorization Strategies for Engineered Nanomaterials in a Regulatory Context. May 19/20 2014. Discussion on engineered nanomaterial (ENM) categorization, grouping, ranking and read across strategies for testing, evaluation, decision analysis, risk guidance and regulation. The focus of this discussion will be on recent advancements in the field and ongoing research. For the purpose of definition, grouping refers to the arrangement of nanomaterials into groups based on common attributes. Carbon nanotubes, where possible, will serve as a material category for the discussion, with additional categories of ENMs for which there is sufficient information (e.g. metals and metal oxides) as examples of how to further modularize across the nanotechnology landscape.

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 Workshop on Categorization of Manufactured Nanomaterials that will take 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 was held January 14, 2014 at US EPA Headquarters in Washington, DC. At this final workshop, key findings were presented and next steps discussed. Collaboration and discussion continues, between governments and with technical teams comprised of outside stakeholders. Moving forward, both governments will be looking at the best approaches to communicate the results of the RCC Nanotechnology Initiative.

Developments related to voluntary or stewardship schemes

National Institute of Standards and Technology (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. A joint ISO TC229/OECD WPMN Workshop on physical-chemical properties was held on February 28 – March 1, 2013 in Mexico.

Information on risk assessment decisions

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. As a condition of registration, EPA would require the company to generate additional data to be used to refine EPA’s understanding of the nanosilver particles in the product.

Developments related to good practice documents

NIST has developed five protocols for the measurement and dispersion of nanoparticles that are publicly available at <http://www.nist.gov/mml/np-measurement-protocols.cfm>. Three of these protocols concern the preparation of nanoscale TiO₂ dispersions in various media.

Developments related to Integrated Testing Strategies and/or Alternative test methods

At the *CEIN Workshop on Categorization Strategies for Engineered Nanomaterials in a Regulatory Context*. (May 19/20, 2014), EPA will participate in a panel discussion on Challenges in Alternative

Testing Strategies (ATS) of Nanomaterials and EPA's Strategic Research Path, and on the use of ATS data and categorization in decision analysis or regulation.

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

National Nanotechnology Initiative. On February 28, 2014, the National Nanotechnology Initiative (NNI) Strategic Plan was published. The NNI Strategic Plan is the framework that underpins the nanotechnology work of participating U.S. Federal agencies. It aims to ensure that advancements in and applications of nanotechnology continue in this vital area of R&D, while addressing potential human health and environmental safety concerns about future and existing applications. This document updates and replaces the 2011 NNI Strategic Plan. See, <http://nano.gov/node/1113>.

On March 4, 2014, the NNI Supplement to the President's 2015 Budget was published. This document provides supplemental information to the President's 2015 Budget and serve as the Annual Report on the NNI. In particular, the report summarizes NNI programmatic activities for 2013 and 2014, as well as those currently planned for 2015. EHS research investments have been sustained at approximately \$110 million per year, reflecting their continued high priority for the NNI. See, <http://www.nano.gov/node/1128>

NIOSH Nanotechnology Research and Guidance Strategic Plan. In December 2013, the National Institute for Occupational Safety and Health (NIOSH) published "Protecting the Nanotechnology Workforce: NIOSH Nanotechnology Research and Guidance Strategic Plan, 2013-2016." This plan updates the November 2009 strategic plan with knowledge gained from results of ongoing research, as described in the 2012 report *Filling the Knowledge Gaps for Safe Nanotechnology in the Workplace: A Progress Report from the NIOSH Nanotechnology Research Center, 2004-2011*. The NIOSH Nanotechnology Research Program follows a comprehensive plan that is managed as a matrix structure across NIOSH and supports multiple sectors in the National Occupational Research Agenda (NORA). This *NIOSH Nanotechnology Research and Guidance Strategic Plan* is the roadmap being used to advance basic understanding of the toxicology and workplace exposures involved so that appropriate risk management practices can be implemented during discovery, development, and commercialization of engineered nanomaterials.

EPA Office of Research and Development. The EPA Office of Research and Development Program on Chemical Safety and Sustainability maintains a coordinated research program on the public health and environmental implications of emerging chemicals including engineered nanomaterials. The program includes extramural funding through grants and cooperative agreements and an intramural program involving research in three EPA National Laboratories and two National Centers. Primary research goals are to: define procedures for characterization of the physical and chemical properties of nanomaterials as manufactured and following interactions with environmental media through their product life cycle; link the physical and chemical properties of nanomaterials to potential releases along the life cycle; understand and model nanomaterial fate, transport and transformation in the environment; and identify potential adverse effects to humans and sensitive environmental species. Key research objectives include: the development of validated and qualified toxicity testing methods with known predictive potential for adverse effects on human health and the environment; the provision of informational tools to inform nanomaterial risk assessments; and the generation of safer nanomaterials by informing their design and use. Current efforts are underway to formulate strategic research plans for 2015-2017. More information about this research program including reports and publications is available at: <http://www.epa.gov/nanoscience/>.

National Science Foundation (NSF). NSF supports nanoscale science and engineering with 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.

Information on public/ stakeholder consultation

RCC Final Results Workshop. In January 2014 the United States and Canada jointly conducted a Regulatory Cooperation Council (RCC) final results workshop to present key findings and discuss next steps, on the topics of Classification/Priority Setting, Risk Assessment/Risk Management, and Commercial Information. Under the RCC process, work products were developed by technical teams, and disseminated and discussed with stakeholders over monthly conference calls and/or webinars.

CEIN Workshop on Categorization Strategies for Engineered Nanomaterials in a Regulatory Context. May 19/20 2014. Discussion on engineered nanomaterial (ENM) categorization, grouping, ranking and read across strategies for testing, evaluation, decision analysis, risk guidance and regulation. The focus of this discussion will be on recent advancements in the field and ongoing research. For the purpose of definition, grouping refers to the arrangement of nanomaterials into groups based on common attributes. Carbon nanotubes, where possible, will serve as a material category for the discussion, with additional categories of ENMs for which there is sufficient information (e.g. metals and metal oxides) as examples of how to further modularize across the nanotechnology landscape.

OECD Aquatic Toxicity Decision Tree Work Group Meeting. A work group meeting for the OECD "Guidance Document on Aquatic (and Sediment) Toxicology Testing of Nanomaterials" is scheduled for 1-2 July 2014 in Washington, D.C., USA at the Environmental Protection Agency. The need for this guidance document (GD) was identified at the OECD Expert workshop meeting held in Berlin (January 2013). The goals of the GD are to produce a testing framework to generate uniform and consistent nanomaterials ecotoxicology data to inform future risk decisions while adapting current water and sediment ecotoxicology guidelines, where appropriate.

Development related to exposure measurement and exposure mitigation

Since January 2005 EPA has received and reviewed more than 160 new chemical notices for 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. Such

conditions include limits on uses, requiring use of personal protective equipment (such as respirators and gloves), and limiting environmental releases, pending the development of necessary testing.

See also NIOSH item under Question 6, above.

THE EUROPEAN COMMISSION (EC)

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

Nanomaterial definition – review initiated

The European Commission (EC) will have to review the recommendation concerning a definition for nanomaterials in 2014. The definition is available via this link:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF>

The review process has started in earnest and the scientific evidence for the review is being gathered and analysed by DG Joint Research Centre (JRC) who have already collected information from companies and organisations via an online survey that ended on 29 September 2013.

The scientific evidence gathering and analysis will deliver in a step-wise process during 2014. The first report covering the gathered information was published on 2 May 2014, see <http://publications.jrc.ec.europa.eu/repository/bitstream/111111111/31515/1/lbna26567enn.pdf>

A draft of the report was used for a technical stakeholder meeting held in Brussels on 19 March 2014. Minutes and the presentation from this will soon be made publicly available. Later in 2014 will follow an analytical report and finally a report with scientific recommendations. Based on this work the Commission policy services will consider the options and on that basis also conduct a broader interest stakeholder consultation before concluding on the need to revise the current definition.

Impact assessment on transparency measures for nanomaterials

The Commission has launched an impact assessment on transparency measures for nanomaterials on the market. Policy options under assessment include an EU nanomaterial registry, a recommendation for the harmonisation of national registries and a nanomaterial observatory (collecting & presenting data from existing databases and/or new market studies). The impact assessment report is expected to be finalised by Q4 2014.

In support of this impact assessment, the Commission has launched a **public consultation** in order to obtain stakeholder views on the currently available information on nanomaterials on the market, the problem definition that forms the basis of the impact assessment, as well as the potential positive and/or negative impacts of the aforementioned policy options. It is open to all interested stakeholders and will be online until 5 August 2014.

In addition to the public consultation, a **validation workshop** will be organised on Monday, 30 June 2014, in Brussels. At this technical workshop, the preliminary results of the study supporting the impact assessment will be presented and discussed, including the evaluation of existing notification systems for

nanomaterials and the data in support of the assessment of different policy options. Stakeholders will be invited to provide their input on the study and the related impact assessment.

You can find the announcement of the public consultation and the validation workshop (registration will be launched by the end of May) on this page:

http://ec.europa.eu/enterprise/sectors/chemicals/reach/nanomaterials/index_en.htm

More detailed information on the consultation and a direct link to the questionnaires can be found on the contractor's website: <http://www.rpaltd.co.uk>

Follow-up on the Commission Communication on Regulatory Aspects on Nanomaterials

The EC announced in the conclusions of the General Report on the Review of REACH its intention to make an impact assessment of relevant regulatory options, in particular possible amendments of Annexes to REACH to ensure further clarity on how nanomaterials are addressed and safety demonstrated in registration dossiers. To support the proposal the EC is currently finalising an impact assessment that considers a number of different measures that may be introduced into the Annexes in a so-called 'Committee procedure' i.e. an administratively 'light' and relatively fast decision process that allows for technical changes of the Annexes.

During the consultation the EC received 142 replies from academia, companies, business confederations, government experts, NGOs and private citizens.

The EC expects the impact assessment to be finished in autumn 2014 paving the way for a proposal on technical changes to the Annexes to REACH before the end of 2014.

Group Assessing Already Registered Nanomaterials (GAARN)

GAARN was initiated to build consensus in an informal setting providing an opportunity to form best practices in assessing and managing the safety of nanomaterials under the REACH Regulation. Additional objectives with GAARN were to increase the confidence and mutual understanding among stakeholders such as industry sectors as well as policy makers namely EU Member States, ECHA and the European Commission. The work of GAARN took place in three meetings, each dedicated to a specific area of safety assessment; physico-chemical properties, hazard characterisation and the exposure and risk characterisation.

The last GAARN meeting took place on 30 September 2013 and subsequent best practices for the three areas was finalised and disseminated via ECHA's website (http://echa.europa.eu/documents/10162/5399565/best_practices_human_health_environment_nano_3rd_en.pdf).

ECHA Nanomaterials Working Group is continuing its activity with the purpose to discuss scientific and technical questions relevant to REACH, CLP and Biocides. Two meetings are foreseen per year. The next meetings are organised at ECHA on 24-25 June and 21-22 October 2014.

More detailed information on ECHA nanomaterial activities can be found at: <http://echa.europa.eu/chemicals-in-our-life/nanomaterials>.

Publications

The JRC has published a number of reports, one on the physico-chemical characterisation of Titanium Dioxide: *Titanium Dioxide, NM-100, NM-101, NM-102, NM-103, NM-104, NM-105: Characterisation and Physico-Chemical Properties*, by Rasmussen et al. It is EUR Report 26637 EN, published in 2014.

A similar report on cerium dioxide, by Singh et al. has been approved for publication and is in the final stages of editing. The title is *Cerium Dioxide, NM-211, NM-212, NM-213. Characterisation and test item preparation*, and it is expected to be public the week 2-6 June.

In addition, Aschberger et al. published a report on Considerations for Information Needs for Nanomaterials in Consumer Products; Discussion of a labelling and reporting scheme for Nanomaterials in Consumer Products in the EU. EUR 26560. ISBN 978-92-79-36378-8 (PDF). 2014, and available from <http://publications.jrc.ec.europa.eu/repository/handle/111111111/31575> .

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

a. *New projects selected under the sixth and seventh call for proposals of the seventh framework programme (FP7) have started or will start in the coming month, by topic:*

i) NMP.2012.1.3-3 Regulatory testing of nanomaterials

➤ NANOREG: "A common European approach to the regulatory testing of nanomaterials"

ii) NMP.2012.1.3-1 Systematic investigations of the mechanisms and effects of engineered nanomaterial interactions with living systems and/or the environment

➤ NANOMILE: "Engineered nanomaterial mechanisms of interactions with living systems and the environment: a universal framework for safe nanotechnology"

➤ NANOSOLUTIONS: "Biological Foundation for the Safety Classification of Engineered Nanomaterials (ENM): Systems Biology Approaches to Understand Interactions of ENM with Living Organisms and the Environment"

iii) NMP.2012.1.3-2 Modelling toxicity behaviour of engineered nanoparticles

➤ MODERN: "MODelling the EnviRonmental and human health effects of Nanomaterial"

➤ MOD-ENP-TOX: "Modelling Assays Platform "MAP" for hazard ranking of engineered nanoparticles"

➤ PRENANOTOX: "Predictive toxicology of engineered nanoparticles"

➤ MEMBRANENANOPART: "Modelling the mechanisms of nanoparticle-lipid interactions and nanoparticle effects on cell membrane structure and function"

➤ NANOPUZZLES: "Modelling properties, interactions, toxicity and environmental behaviour of engineered nanoparticles"

iv) NMP.2012.4.0-2 Support for standardisation needs – supporting actions

- NANOSTAIRS: "Establishing a process and a platform to support standardization for nanotechnologies implementing the STAIR approach" (completed)

v) NMP.2013.1.3-1 Safety in nanoscale production and products

- GUIDENANO: "Assessment and mitigation of nano-enabled product risks on human and environmental health"
- SUN: "Sustainable Nanotechnologies"

v) NMP.2013.1.3-3 Development of a systematic framework for naming and assessing safety of the next generations of nanomaterials being developed for industrial applications

- FUTURENANONEEDS: " Framework to respond to regulatory needs of future"

vi) NMP.2013.1.3-2 Nanomaterials safety assessment: Ontology, database(s) for modelling and risk assessment

- ENANOMAPPER: "A Database and Ontology Framework for Nanomaterials Design and Safety Assessment"

vii) NMP.2013.1.4-3 Development of methods and standards supporting the implementation of the Commission recommendation for a definition of nanomaterial

- 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"

b. *New Research Framework Programme 2014-2020: Horizon 2020*

The new Research Framework Programme, Horizon 2020, has been approved by the European Parliament on November 21. The specific work programmes will be published on December 5 and cover 2 years. The topics in the field "*Safety of nanotechnology-based applications and support for the development of regulation*" are:

- NMP 26 – 2014: A joint EU&MS activity on the next phase of research in support of regulation – NANOREG II.
- NMP 27 – 2014: Coordination of EU and international efforts in safety of nanotechnology.
- NMP 28 – 2014: Assessment of environmental fate of nanomaterials..
- NMP 29 – 2015: Increasing the capacity to perform nanosafety assessment.
- NMP 30 – 2015: Next generation tools for risk governance of nanomaterials

More on: <http://ec.europa.eu/research/horizon2020>

c. *Other:*

- DG RTD NMP initiative EU Nanosafety cluster also continues their activities. More details at:

www.nanosafetycluster.eu. The 2013 edition of the "Compendium of Projects in the European NanoSafety Cluster" is available: <http://www.nanosafetycluster.eu/home/european-nanosafety-cluster-compendium.html>

- The nanosafety cluster has published a "nano-EHS research strategy for 2015-2020":
<http://www.nanosafetycluster.eu/news/83/66/Nanosafety-in-Europe-2015---2025.html>
- The US-NNCO and European Commission DG RTD-Directorate G are fostering research cooperation on EHS issues of nanomaterials through joint workshops and the establishment of Communities of Research. More on <http://us-eu.org/>. The third workshop is held in Washington on 2-3 December 2013.
- The ITS-NANO project has published a report entitled: "RESEARCH PRIORITISATION TO DELIVER AN INTELLIGENT TESTING STRATEGY FOR THE HUMAN AND ENVIRONMENTAL SAFETY OF NANOMATERIALS" available for download at <http://www.its-nano.eu/>. A webinar presentation is available at http://www.youtube.com/watch?v=pXb1w3L_3Hc.