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

Series on the Safety of Manufactured Nanomaterials
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Series on the Safety of Manufactured Nanomaterials

No. 67

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

Environment Directorate
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT
Paris, 2016

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

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

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

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

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

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

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

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

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

This publication is available electronically, at no charge.

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

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FOREWORD

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. Since then, this programme has focused on human health and environmental safety implications of manufactured nanomaterials (limited mainly to the chemicals sector), and aimed 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 compiles information, provided by WPMN participating delegations, before and after the 15th WPMN meeting (November 2015), 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.

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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AUSTRALIA

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

Consistent with the OECD Council recommendation, all Australian government chemical regulators continue to utilise existing frameworks for regulating nanomaterials.

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) approach to regulating industrial nanomaterials uses the current regulatory framework applicable to conventional industrial chemicals, with some minor administrative adjustments. Reforms to NICNAS are currently underway that aim to streamline the assessment process for industrial chemicals to reduce the regulatory burden on the sector, while also ensuring Australia's robust safety standards are maintained (http://www.nicnas.gov.au/about-nicnas/nicnas-reforms). Consideration will be given to the regulatory approach for nanomaterials in the implementation of these reforms.

As part of the review of existing arrangements for the regulation of nanotechnologies in food and food packaging, Food Standards Australia New Zealand (FSANZ) sought expert scientific opinion on the use and safety of nanotechnologies in relatively insoluble food additives and in food packaging. Two reports were commissioned, which included:

- A review of the available literature on whether there is reasonable scientific evidence to support the potential application of nanotechnologies to existing food additives in Standard 1.3.1 of the Food Standards Code may pose a risk to public health and safety, following oral ingestion in foods.
- A study of the potential effects of nanotechnologies on the safety of food packaging due to the migration of nanomaterials into food.

The reports are currently being finalised and will help inform FSANZ's updated strategy on nanotechnologies. FSANZ is planning to develop technical guidance on the use of nanotechnology in food and food packaging. Minor amendments to the FSANZ Application Handbook are envisaged in line with publication of this guidance. The reports will be published on the FSANZ website when complete.

FSANZ has also recently updated its communication material on nanotechnology and food.

Activities initiated to implement the OECD Council Recommendation

Reforms to the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) are currently underway that aim to streamline the assessment process for industrial chemicals to reduce the regulatory burden on the sector, while also ensuring Australia's robust safety standards are maintained (http://www.nicnas.gov.au/about-nicnas/nicnas-reforms). In line with the OECD Council

Recommendation, consideration will be given to the regulatory approach for nanomaterials in the implementation of these reforms.

Information on related to good practice documents

The National Measurement Institute Australia (NMIA) actively contributes to the development of documentary standards for Nanomaterials through participation in ISO TC229 (nanotechnologies). In particular, NMIA continues to maintain active interest in the activities of ISO TC 229's working groups 1, 2 and 3, which cover Terminology and Nomenclature, Measurement and Characterization and Health, Safety and Environmental aspects of Nanotechnologies, respectively.

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

The National Measurement Institute Australia (NMIA) has been participating in a number of technical Preliminary Work Items organised by ISO TC 229 WG2 relating to the use of transmission electron microscopy (TEM) for the determination of primary particle size of nanomaterials with size distributions of varying complexity. The aim of these studies is to develop and standardise a protocol framework for the analysis of particle size distribution by TEM.

Information on research or strategies on life cycle aspects of nanomaterials

The Australian Government Department of the Environment commissioned a research project completed in September 2015 on Transformation and release behaviour of fullerence nanoparticles in soils amended with biosolids, This project investigated the degradation, transformation and partitioning of fullerenes. The background to this project is the likelihood that nanoparticles will enter the environment through waste disposal, in particular the reuse of biosolids as agricultural amendments. This laboratory study concentrated on evaluating the fate of buckminsterfullerene (C60) through the use of a radioactively labelled (14C) substrate. The results suggest that the mineralisation of C60 in biosolids is minimal. Transformation of C60 appears to be limited by retention in soil. However, some light mediated transformation of C60 in soil probably occurs with the formation of epoxides and oxides. Taken together with results obtained from previous studies funded under this programme, it now appears that C60 will undergo only limited transformation in soil and that it will be strongly retained in the soil compartment. The results of this study are to be published in the peer reviewed scientific literature.

AUSTRIA

Highlight of developments since February 2015

- The implementation report 2012 of the "Austrian Nanotechnology Action Plan" recommends to carry out coordinated enforcement of legislation which is relevant for nanomaterials (see http://nanoinformation.at/uploads/media/Umsetzungsbericht_2012_EN.PDF):

- In cooperation with European partners, **enforcement activities in the field of REACH-regulation** have been launched in year 2014 including checks of safety data sheets for nanomaterial-relevant information and products with a "nano-claim". The project is lead-managed by the Federal Ministry of Agriculture, Forestry, Environment and Water Management with support of the Environment Agency Austria and chemical inspectors. A considerable

amount of compnies have difficulties to identify nanomaterials. Even in cases, in which the nanomaterial definition according to the EU recommendation was known, it was only seldom stated that indeed nanomaterials were present, terms like "unclear", "possible", "probable" were more often used. In the safety data sheets there was rarely information whether nanomaterials are present – even when claimed that the products contains nanoparticles. Due to a lack of nanomaterial specific provisions in REACH it is difficult and time consuming for the authorities to evaluate and comprehend hazards and risks resulting from nanomaterials.

- Austria participated also together with nine further Member states in the **Prosafe Joint Action Nantechnology and Cosmetics** (supported by the Comission) to examine cosmetic products regarding their nanomaterial content and compliance with resulting labelling requirements (s. http://www.prosafe.org/index.php?option=com_content&view=article&id=57&Itemid=605). Testing for nanomaterials content was 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. The results were presented in a Workshop in Brussels in February 2015. Only few products not complying with the legal requirements were found.

- As another measure of implementation of the Austrian Nanotechnology Action plan the national **NANO Environment Health and Safety** programme (http://www.ffg.at/nano-ehs) has been established (see also bullet 10), which has been prolonged. The next call is foreseen for autumn 2015 also within the EU-Project Prosafe for international projects. This EHS programme is owned by the Federal Ministry of Agriculture, Forestry, Environment and Water Management and Federal Ministry of Federal Ministry for Transport, Innovation and Technology and is handled by the FFG - Austrian Research Promotion Agency.

- The 10th anniversary of the International Conference on the Environmental Effects of Nanoparticles and Nanomaterials (**ICEENN 2015**) was held in Vienna, Austria, September 6-10, 2015 (see: http://nanoenvironment2015.univie.ac.at/home/)

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 on http://www.lebensministerium.at/umwelt/chemikalien/nanotechnologie/nano-aktionsplan.html), includes about 50 measures which will be implemented by Austrian stakeholders on national, EU and international level. The action plan was lead-managed by the Federal Ministry of Agriculture, Forestry, Environment and Water Management (BMLFUW, contact: renate.paumann@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

Information 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.

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

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 Environmental Conditions is funded by the German Environmental Protection Agency and aims at developing the scientific basis and experimental methods to determine the dispersability and dispersion stability in the context of the OECD WPNM testing framework. This project is led by the Department for Environmental Geosciences, University Vienna (contact: Frank von der Kammer).

At Medical University of Graz, **nanotoxicology studies** (cytotoxicity, genotoxicity, impact on macrophage function, intracellular accumulation in lysosoms and cellular effects after long-term exposure; in-vitro model for exposure to nanoparticles in aerosols generated from suspensions) regarding **CNT (SW + MW),** and polystyrene have been performed (contact: Eleonore Fröhlich). With exception of the carboxylated SWCNT, the assessed particles showed little effect at concentrations that might occur in vivo.

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

The H2020 project NanoFase will develop a comprehensive modelling framework for nanomaterials in the environment, including release, transformation in waste streams, and behaviour in fresh waters, estuarine and marine waters, soil and sediments. Uptake routes are addressed as well. The project is coordinated by the UK NERC. The Department for Environmental Geosciences, University of Vienna (contact: Frank von der Kammer) is involved in several work packages. The central work package on surface water and sediments is led by University of Vienna.

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 work packages. The central work package on confirmatory methods is led by UNIVIE.

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 work packages. 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). Furthermore, within NANoREG-project one of the Value Chain Case Studies (VCCS) with focus on TiO2 coating (project name "GALANT") is done with Austrian industry and scientific partners.

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**.

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 **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. The 4th revised and expanded edition of the ENT-expertise-catalogue was published in July 2015. See: http://www.euro-nanotox.eu/

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 H2020 pilot-projects **Inspired**, **R2R-Biofluidics** and **Hi-Response** (start: beginning of 2015). Austrian partner BioNanoNet is responsible for the nano-related safety-tasks. BioNanoNet together with international project partners is developing an integrated safety strategy to reduce the potential risk upon worker's exposure to MNMs during production and manipulation processes (contact: Andreas Falk).

Information on public/ stakeholder consultations;

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 also includes 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.

ZSI, the centre for Social Innovation in Vienna coordinated the **NanOpinion project** which terminated in October 2014. It was a 30 month FP 7 project to investigate how opinion on nanotechnologies is shaped, and how to inform public debate, especially among hard to reach groups, and enhance education. The results inform recommendations about future discussion and regulation of NT (available at: http://results.nanopinion.eu/)

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 has organized 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. Additionally, NanoDiode has developed a workshop programme for teachers and students (secondary school) in order to inform young people about new technologies and provide a toolkit for teachers to implement those into the curriculum (Contact: Andreas Falk).

Information on research or strategies on life cycle aspects of nanomaterials

Austria (BMVIT and AIT) was partner of the **ERA-net SIINN** ("Safe implementation of innovative Nanoscience and Nanotechnolgies") and leader of WP3 ("Risk assessment and life cycle validation"). The ERA-Net coordinates European activities in the area of Nano-EHS and has published three joint calls for research projects. The ERA-Net ended in August 2015.

During the second call the project **FENOMENO - Fate and effect of wastewater-borne manufactured nanomaterials in aquatic ecosystems** was approved: http://www.fenomeno-nano.de/. The Research Institute for Limnology Mondsee of the University of Innsbruck (contact: Josef Wanzenböck) is responsible for the work package 4: Environmental partitioning of manufactured nanomaterials contamination in lakes. The goal is to compare bioconcentration studies performed in the lab with the real environmental situation in Lake Mondsee along the food chain from algae to zooplankton and fish. National funding is provided by the FFG - Austrian Research Promotion Agency.

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.

Information related to exposure measurement and exposure mitigation.

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).

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.

In the project **Nano-DESTINARA** research on sewage treatment plants regarding nanoparticles (TiO_2, CeO_2, Ag, fullerenes) was performed by Environment Agency Austria and Vienna University of Technology (sponsored by the national research program NANO Environment, Health and Safety): In acute as well as in chronic tests no inhibition of carbon respiration or nitrification were detected. More than 90% of the nanoparticles were retained in the sewage sludge. No fullerenes were measurable in the inlet or sludge of real sewage treatment plants.

University of Vienna (contact: Frank von der Kammer): WG-4- partener 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 & storm water to rivers.

BELGIUM

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

The Royal Decree concerning the placing on the BE market of substances produced in nanoparticular state has been signed, and published on 24th September 2014.

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

Existing substances have to be registered before 1st January 2016, existing mixtures before 1st January 2017. Substances, resp.mixtures placed on the market after these dates, have to be registered before they are actually placed on the market.

The web based tool for registration is available since mid September 2015 onwards.

The website www.nanoregistration.be contains the link to the registry, as well as the guidance documents concerning the Royal Decree and the registry.

Activities to implement the OECD Council Recommendation

In answer to the 'Review of the OECD Council Recommendation on the Safety Testing and Assessment of Manufactured Nanomaterials':

BE supports the proposition of the Secretariat. It is clear that the WPMN has a central role in the process of elaborating this report. However, the whole lifecycle of the nanomaterials has to be considered, including the stage 'waste'. It is important that this type of activity will also be reported to the Council.

We propose thus to add the next phrase to paragraph 6 of the document:

"In relation to article IV, the Secretariat can offer a summary of activities undertaken by WPRPW in this field and their main outcomes".

Information on developments related to good practice documents

Three BE partners are involved in the FP7 research project NANoREG (NMP.2012.1.3-3; Regulatory testing of nanomaterials). This in both characterization of nanomaterials (including SOPs development) as well as in advancement of regulatory risk assessment and testing (development of solubility testing procedures, the relevance of barriers, in vitro toxicity assays). The Federal Public Service Health, Food Chain Safety and Environment acts as a National Coordinator. In March 2015, a national mid-term meeting has been held.

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

- Exposure to nanomaterials defining the influence of nanoparticles aggregation / agglomeration on toxicity
- Nanomaterials in articles: inventory, characterization and estimation of exposure via air
- Nano Global Risk Assessment
- Nanomaterials and human health in Brussels

CANADA

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

A consultation document on a Proposed Approach to Address Nanoscale Forms of Substances on the *Domestic Substances List* was published with a public comment period ending on May 17, 2015. The proposed approach outlines the Government's plan to address nanomaterials considered in commerce in Canada (on Canada's public inventory). The proposal is a stepwise approach to acquire and evaluate information, followed by any necessary action. A follow-up stakeholder workshop is being planned to discuss next steps and possible approaches to prioritize future activities. The consultation document is available at: http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=1D804F45-1

A mandatory information gathering survey was published on July 25, 2015. The purpose of the survey is to collect information to determine the commercial status of certain nanomaterials in Canada. The survey targets 206 substances considered to be potentially in commerce at the nanoscale. The list of 206 substances was developed using outcomes from the Canada-United States Regulatory Cooperation Council (RCC) Nanotechnology Initiative to identify nanomaterial types. These nanomaterial types were cross-referenced with the *Domestic Substances List* to develop a preliminary list of substances which are potentially intentionally manufactured at the nanoscale. The focus of the survey aligns with the Proposed Approach to Address Nanoscale Forms of Substances on the *Domestic Substances List* (see above) and certain types of nanomaterials were excluded during the development of the list of substances. The information being requested by the survey includes substance identification, volumes, and uses. This information will feed into the Government's proposed approach to address nanomaterials on the *Domestic Substances List*. Available at: http://gazette.gc.ca/rp-pr/p1/2015/2015-07-25/html/notice-avis-eng.php

Information on:

a. risk assessment decisions, including the type of: (a) nanomaterials assessed ; (b) testing recommended; and (c) outcomes of the assessment;

Four substances were notified to the program since the WPMN14 – three surface modified substances and one inorganic substance. No actions, including additional data requests, were taken due to low expected exposures in accordance with the *New Substances Notifications Regulations (Chemicals and Polymers)* (NSNR) for two of the substances. Two of the substances notified were subject to a Significant New Activity Notice. A Significant New Activity notice is an information gathering tool used to require submission of additional information if it is suspected that a significant new activity may result in the substance becoming toxic under the *Canadian Environmental Protection Act, 1999*.

b. Proposals, or modifications to previous regulatory decisions

As part of the Government's Chemicals Management Plan, a review is being undertaken for all substances which have been controlled through Significant New Activity (SNAc) notices (see above). As part of this activity, the Government is reviewing past nanomaterials SNAc notices to see if new information is available to refine the scope and information requirements. As a result of this review, 9 SNAc notices previously in place for nanomaterials have been rescinded. This work is ongoing, and a complete review of all nanomaterial SNAcs is currently planned to be completed in 2016.

Information related to good practice documents

The Canada-led, ISO standards project, ISO/DTR 19716 *Nanotechnologies -- Characterization of cellulose nanocrystals,* initiated in April 2014, is now at Committee Draft (CD) 3-month ISO ballot, closing Aug 31, 2015. Ballot comments will be addressed during JWG2 *Measurement and Characterization* working group meetings at the 18th Plenary of ISO/TC229, *Nanotechnologies*, being held in Edmonton, Alberta, Sep. 28 - Oct. 2, 2015.

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

Scientific research

Environment Canada continues to support various academic and departmental research projects. This research has to date included studying fate and effects of nanomaterials in the aquatic, sediment, soil, and air compartments. Funding in fiscal 2015-16 continues to support such projects, including sub-surface transportation, determining key physical-chemical parameters to predict ecotoxicity, and impacts of nano-silver addition to a whole lake ecosystem. Environment Canada has also partnered with the National Research Council of Canada recently to initiate a project on the development of test methods to identify surfaces of nanomaterials for the purposes of regulatory identification and to support risk assessments. In addition, Environment Canada is working with academic laboratories in Canada and Germany to prepare guidance to support testing of nanoparticles using the OECD Test Guideline for soil column leaching.

Health Canada continues its research efforts to investigate the effects of surface-modified silica nanoparticles. The aims of these projects are to: (1) study the importance of size and surface functionalization; and (2) provide a genotoxic profile and to identify mechanistic relationships of particle properties to elicited toxic responses. A manuscript reporting the *in vitro* genotoxic, cytotoxic and transcriptomic responses following exposure to silica nanoparticles has recently been submitted to a peer reviewed journal and is currently undergoing review. Additional manuscripts reporting the toxicity results obtained to date are in preparation.

Information on public/ stakeholder consultations;

A consultation document on a Proposed Approach to Address Nanoscale Forms of Substances on the *Domestic Substances List* was published with a public comment period ending on May 17, 2015 (see Question 1). Comments were received from approximately 20 stakeholders representing industry and industry associations, as well as non-governmental organizations. These comments will inform decision making to address nanomaterials in commerce in Canada.

Information on research or strategies on life cycle aspects of nanomaterials

Canada, along with Government agencies in the United States, Non-Governmental Organizations and Industry, is engaged in a project to look at releases of nanomaterials from industrial consumer matrices

(e.g., coatings). The objectives of the NanoRelease Consumer Products project are to develop protocols or methods (validated through interlaboratory testing) to measure releases of nanomaterials from solid matrices as a result of expected uses along the material life cycle for consumer products that contain the nanomaterials. The project is currently in the advanced stages of Phase 3 (Interlaboratory Studies). The objectives of Phase 3 of the project are to develop robust methods for producing and collecting samples of CNT-epoxy and CNT-rubber materials under abrasion and weathering scenarios, and to detect and quantify, to the extent possible, CNT release fractions. Selected laboratories in the US, Canada, Korea and the European Community are finalising the generation and analysis of sanding and weathering samples and the results are being collected in a data hub for further interpretation and analysis.

Additional details about the project can be found at the project website: http://www.ilsi.org/ResearchFoundation/RSIA/Pages/NanoRelease1.aspx

Under the OECD Working Party on Resource Productivity and Waste (WPRPW), the expert group on waste containing nanomaterials has developed four reflection papers on the fate of nanomaterials in waste treatment operations. Canada prepared 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. 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 presented and discussed at the fifth meeting of the WPRPRW that took place on 8-10 December 2014. The four papers were declassified by EPOC in June 2015, and an introductory chapter was prepared to draw these papers together. The introductory chapter and accompanying papers will be published in Fall 2015. At the sixth meeting of the WPRPW in June-July 2015, the Secretariat presented a proposal for an information-sharing platform that would allow delegates to share research and documents related to nanomaterials. During a trial phase, delegates will be asked to use the platform and provide feedback on its use at the next meeting of the WPRPW in December 2015. This information-sharing platform will also be accessible to delegates of the WPMN.

Information related to exposure measurement and exposure mitigation.

Canada and the Netherlands are co-leading a project on metal impurities in carbon nanotubes. A final version of the report is expected to be ready for WPMN16. All research has been completed (e.g. all components are published or in press and there was a presentation by Pat Rasmussen to SG-08 at the Face-to-Face Meeting in Seoul June 2015). The first draft will be submitted to the SG-08 secretariat in autumn 2015. Revisions will be based on early feedback from SG-08 participants. The next steps depend on this feedback and amount of revision required.

Information on past, current or future activities on nanotechnologies that are being done in co-operation with non-OECD countries.

A webinar between ECHA, the US EPA and Canada was hosted by Canada on April 16, 2015. These are regularly scheduled trilateral discussions to keep each other informed of activities in respective jurisdictions.

In March 2015, Health Canada hosted 3 nanotechnology knowledge transfer sessions targeting Canadian government research and regulatory communities working in nanotechnology. These sessions were an opportunity to share information and perspectives on the current state of science supporting the regulatory oversight of nanomaterials with Government. Presenters provided detailed outputs from the OECD WPMN including: updates on OECD test methods and guidance documents; overviews of physical-chemical properties, as well as their relevance to toxicological testing and risk assessment; ecotoxicity and fate test methods; human health risk assessment and alternative testing strategies; and exposure measurement and mitigation. Guest speakers included Dr Richard C. Pleus Managing Director and Director of Intertox, Inc and Dr. Vladimir Murashov Special Assistant on Nanotechnology to the Director of National Institute for Occupational Safety and Health (NIOSH).

On March 4-5, 2015, Industry Canada and NanoCanada co-sponsored "Commercializing Nanotechnology in Canada", a national workshop that brought together representatives from industry, academia and government to better align Canada's efforts in nanotechnology. This workshop was the first of its kind in Canada. It also marked the official launch of NanoCanada (http://nanocanada.com/), a national initiative that is bringing together stakeholders from across Canada to bridge the innovation gap and stimulates emerging technology solutions.

GERMANY

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

The NanoDialogue of the Federal Government was established under the German Nano Action Plan as a central national platform for dialogue in 2006, with the Federal Environment Ministry taking lead responsibility. Expert dialogues about nanomedicine, aquatic environment, waste and food industry constitutes the continuation of the fourth phase of the NanoDialogue. 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. The German NanoDialogue moves on – from 2016 with the five's phase.

The results are published in thematic reports on the homepage of BMUB:

www.bmub.bund.de/P2227-1/

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

In March 2015 the Federal Institute for Risk Assessment (BfR) organised the first joint symposium on nanotechnology together with the Fraunhofer "Food Chain Management Alliance" and the Fraunhofer "Nanotechnology Alliance". At a two-day symposium, the status quo in application, research, and regulation was presented. Besides the characterisation, the toxicology of nanomaterials was in the focus. Furthermore, the societal acceptance of nanotechnology was discussed.

Moreover the 1st BfR-Academy Training School on Nanotechnologies for Risk Assessors took place in March 2015 which was specifically dedicated to persons involved in risk assessment and regulation of nanomaterials (NM). A state of the art overview on NM characterization, NM toxicity testing, exposure assessment as well as NM risk assessment was given.

http://www.bfr.bund.de/en/event/1st_bfr_academy_training_school_on_nanotechnologies_for_risk_assessors-192848.html
http://www.bfr.bund.de/en/event/1st_joint_symposium_on_nanotechnology-192756.html

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

A Federal Ministry of Food and Agriculture (BMEL)

BMEL is involved in the renegotiations of EU Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. A specific regulation of manufactured nanomaterials is discussed within the context of the new proposal.

B Federal Ministry of Labour and Socials Affairs (BMAS)

The German Hazardous Substances Committee (AGS) has decided on an assessment criterion (reference value) for granular biopersistent particles without known significant specific toxicity (nanoscaled GBP) (respirable dust) generated from manufactured ultrafine particles. English translation of the corresponding background document:

http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/TRGS/Announcement-527.html

C Federal Environment Agency (Umweltbundesamt, UBA)

As follow up of the OECD Expert Meeting on Environmental Fate and Ecotoxicology of Nanomaterials in Berlin (29th - 31st of January 2013) UBA took the lead on the development of a draft test guideline for agglomeration behaviour of nanomaterials in different aquatic media and a draft guidance document on agglomeration and dissolution behaviour of nanomaterials in aquatic media – decision tree.

Within that framework the project "Development of a decision support tool for the investigation of environmental behaviour of nanomaterials on the basis of their dispersion stability and solubility as a function of environmental conditions" (funded by the Federal Ministry for Environment, Nature Conversation, Building and Nuclear Safety) was launched and has been awarded to the University of Vienna (Austria) in 2013.

Aim of the project is the development of an OECD Test Guideline to investigate the agglomeration behaviour of nanomaterials depending on environmental parameters and Guidance Document comprises a tiered approach for the investigation of agglomeration and dissolution behaviour of nanomaterials as a prerequisite for continuing studies on environmental behaviour. The work of this project is supposed to provide also basic information for an OECD Guidance Document for the investigation of environmental fate of nanomaterials in aquatic media. For this aim influencing factors have to be identified and valid, as well as pragmatic approaches for suitable methods and techniques have to be developed. http://www.umweltbundesamt.de/en/research-development-projects

In this context a meeting between experts that are involved in the development of the related OECD Test Guidelines and Guidance Documents met at University Vienna and UBA in January 2014 and January 2015, respectively. The first draft of the Test Guideline is available and was validated by a comprehensive round robin test this summer. In September of this year, a WNT/WPMN face-to-face meeting took place at the OECD headquarters in Paris in order to discuss the proposal for the Test Guideline on agglomeration

behaviour of nanomaterials in different aquatic media. Next to the draft of the Test Guideline, the status of the Guidance Document on agglomeration and dissolution behaviour of nanomaterials in aquatic media and the status of the draft Test Guideline on dissolution rate of nanomaterials in aquatic media was presented at the meeting and the way forward was discussed. The meeting will be followed by a WNT commenting round.

Information on risk assessment decisions, including the type of: (a) nanomaterials assessed; (b) testing recommended; and (c) outcomes of the assessment;

Federal Environment Agency (Umweltbundesamt, UBA)

UBA published a scientific paper entitled "Nanopharmaceuticals – tiny challenges for the environmental risk assessment of pharmaceuticals. Berkner, S., Schwirn, K., Voelker, D., 2015. Environ Toxicol Chem., DOI: 10.1002/etc.3039): http://onlinelibrary.wiley.com/doi/10.1002/etc.3039/pdf

The publication examines whether the environmental risk assessment for human pharmaceuticals is prepared to properly assess the exposure, fate and effects of nanopharmaceuticals. Identified challenges are the different definitions for nanomaterials and nanopharmaceuticals, different regulatory frameworks, the diversity of nanopharmaceuticals, the scope of current regulatory guidelines, and the applicability of test protocols.

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 – Studying the effects on humans and the environment" is continued to be funded within the new frame of the German funding programme "From Material to Innovation" (2015-2024).

Four new projects started in 2015:

nanoGravur - Grouping of nanostructured materials for protection of workers, consumers, the environment and risk minimisation

CaNTser - Investigation of the toxic potency of carbon nanotubes following long time inhalation

NanoBEL - Biological Elimination of Complex Diagnostic Nanoparticles

ProCycle - Analysis and toxicological evaluation of dusts from recycling and recycling processes of nanocomposites and strategies for risk minimisation

Germany is coordinating the European FP7 ERA-NET project "SIINN" (Safe Implementation of Innovative Nanoscience and Nanotechnology - www.siinn.eu) in which 20 ministries and national/regional

funding organizations from 13 European countries/regions and Israel participate. 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.

Within the duration of the SIINN ERA-NET (8/2011 – 7/2015), several documents related to nanosafety research as accompanying work for the joint transnational calls were elaborated:

Consolidated Framework for EHS of Manufactured Nanomaterials (D2.6, 5/2015): The purpose of the consolidated framework document is to present a gateway to basic information and definitions for nanomaterials as well as the identification of best practices, synergy potentials and the elaboration of recommendations for future collaborations on the strategic and operational level addressing MNM EHS. This includes precautionary measures, pre-normative work, steps towards regulations as well as common actions and projects.

Inventory of Characterisation Methods (7/2014): The report provides an inventory of methods for characterisation of engineered nanomaterials properties, health effects and environmental impact by means of benchmarking of existing methods, evaluation and validation. It may serve as a basis for the preparation of guidelines for the risk and life cycle assessment of MNMs.

Guidelines for EHS Assessment (4/2015): Risk assessment has to take into account the entire value chain of the material, and focus the efforts on the stages where actual exposure is realistic. These guidelines provide an overview of risk assessment in general, and more specific analyses of challenges for risk assessment of MNMs.

Besides the above mentioned reports, which are available on the SIINN website (http://www.siinn.eu/en/the-project-and-results/2-publications/,173), there are several inventories of knowledge gaps, data selections and best practice.

The second SIINN Call was published in 2013 and resulted in five transnational projects (four of them with participation of Germany) which will start in 2015.

In the frame of the third SIINN call in October 2014, seven funding agencies from European countries/regions (Austria, Belgium, Germany, Portugal, Region Nord-Pas de Calais (France), Romania, Spain) and three funding agencies from the USA (NSF, CPSC, NIEHS) have agreed to launch the first joint transatlantic funding programme on nanosafety research.

Information about the SIINN funded projects is available on the SIINN website (http://www.siinn.eu).

B Federal Environment Agency (Umweltbundesamt, UBA)

UBA acts as partner in a new project launched under the research priority "NanoCare - Safe Handling of Manufactured Nanomaterials – Investigating Impacts on Health and the Environment" of the Federal Ministry of Education and Research (BMBF): **NanoGRAVUR –** „Nanostructured materials – Grouping regarding worker, consumer, and environment safety and risk mitigation". The central aim of nanoGRAVUR is to develop criteria catalogues for a grouping of nanomaterials regarding hazard and risk potentials related to different subjects of protection. UBA is involved in different work packages which inter alia address environmental aspects. Furthermore, UBA interlinks the project to current activities of the OECD WPMN and current discussions on regulation of nanomaterials. UBA is also part of the interdisciplinary research unit INTERNANO of the German Research Foundation (DFG), which starts its second project phase this year. The aim of INTERNANO is to identify processes relevant for the fate of nanoparticles at the interface between aquatic and terrestrial ecosystems. UBA contributes through the

subproject SOILMOBILE, which investigates the fate of silver nanoparticles in soils, especially their dissolution and retention.

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

BfR is involved in two new EU-funded projects:

"**NANoREGII -** Development and verification of Grouping and Safe-by-Design approaches within regulatory frameworks", funded by the EU and presumably starting in 2015. The NANoREG II project is built around the challenge of coupling Safe-by-Design to the regulatory process. Its objective is to demonstrate and establish new principles and ideas based on data from value chain implementation studies to establish Safe-by-Design as a fundamental pillar in the validation of a novel manufactured nanomaterial.

Furthermore BfR is partner of the project consortium "**SeeingNano** - Developing and Enabling Nanotechnology Awareness-Building through the Creation and Exchange of enhanced Communication and Visualisation Tools and Guidance for 'Seeing at the Nanoscale'". The project is funded by the EU (12/2014-11/2016) and will create Novel Visualisation Tools for Enhanced Nanotechnology Awareness through a coordinated collaborative approach conducted by leading experts in the relevant fields. The objective is to provide the key audiences with an ability to 'seeing at the nanoscale', and an understanding and awareness for the breadth of nanotechnologies, and the uncertainties and potential risks connected to them.

In addition BfR takes part in two recently granted projects funded by BMBF:

BfR is coordinating the project „**NanoToxClass** - Establishing nanomaterial grouping/ classification strategies according to toxicity and biological effects for supporting risk assessment". The project is going to start in 2015 and will be funded for three years by BMBF as part of the ERA-NET "SIINN - Safe lmplementation of Innovative Nanoscience and Nanotechnology". The focus of the project is on grouping strategies for nanomaterials based on toxicological effects on humans and animals. Representatives of different classes of material will be used to establish a toxicology-based grouping strategy. Some selected nanomaterials will be additionally evaluated in two representative stages of their life cycle. Emphasis is on systems biology experiments (transcriptome, proteome and metabolome analyses) will deliver data about toxicity pathways, which will allow valid categorization.

Additionally BfR is involved in the joint project **„nanoGRAVUR** - Grouping of nanostructured materials for protection of workers, consumers, the environment and risk minimisation", which started in May 2015 and is funded by BMBF for three years. The project made it its central objective to develop different criteria catalogues for a grouping of nanomaterials according to the respective potentials for exposure, hazard and risk. It aims at defining common aspects for regulation and risk assessment for nanomaterials which are valid for protected assets, both humans and the environment.

D Federal Institute of Occupational Safety and Health (BAuA)

BAuA is involved in the nationally-funded project **"nanoGRAVUR –** Grouping of nanostructured materials for protection of workers, consumers, the environment and risk minimization**"**, which started in May 2015 for a period of three years. BAuA takes part in four different work packages dealing with grouping strategies in occupational hygiene, development of a measurement strategy to assess fibrous materials (HARN), and grouping strategies from a regulatory point of view. BAuA hosted the two-day kick-off meeting at its Dortmund site.

E Federal Research Institute of Nutrition and Food (Max Rubner-Institut, MRI)

The MRI is not directly involved in the safety of risk assessment of nanomaterials used in the food sector. However, food nanotechnology is a major research area within the MRI. The MRI performs research work for consumer health protection in the nutrition sector in the following issues:

1. Detection and characterization of nanomaterials in complex matrices such as food using different methods such as scanning electron microscopy, field flow fractionation, light scattering, single particle Inductively Coupled Plasma- Mass Spectrometry etc. Without a proper characterization of the nanomaterials in food respectively the knowledge of the nanomaterials properties conclusion about the safety of those nanomaterials will not be possible. MRI also participates in inter-laboratory studies in respect to the detection of nanomaterials in complex matrices (nano-titanium dioxide, nano-silver).

2. Research on nano-sized carrier systems for bioactive compounds - development of suitable food-grade nano-sized carrier systems, release of the bioactive compound in dependence of the food matrix, effect on the bioavailability of the bioactive compound, effect of storage and processing on the nano-sized carrier system and the release of the bioactive compound, effect of digestion on the stability and solubility of the nano-sized carrier system as well as on the release of the bioactive compound.

3. Interaction of nanomaterials with compounds of the food matrix – modulation of the nanomaterials surface by interaction with compounds of the food matrix, effect on the properties of the nanomaterials, effect of pH, temperature, ionic strength on the interaction with compounds of the food matrix.

4. Migration studies – transfer of nano-sized materials from food contact materials such as packaging to food and beverages.

Furthermore MRI is active in working groups on the potentials and risks of nanomaterials in the food sector such as the working group "Nanomaterials" of the German Association of Food Chemists (Vice-chair: Ralf Greiner), the special interest group "Bionanotechnology" of the ISEKI Food-Association and the International Society of Food Application of Nanoscale Science (ISFANS) (Chair: Ralf Greiner), a working group of the International Union of Food Science and Technology (IUFoST).

F Federal Institute for Materials Research and Testing (BAM)

BAM is involved in EU-funded (FP7) projects:

NanoDefine (FP7): The European Commission has recently recommended the definition of NM as a reference to determine whether an unknown material can be considered as a nanomaterial (2011/696/EU). The aim of NanoDefine is to support the governance challenges associated with the implementation of the nanomaterial legislation by addressing the issues on the availability of suitable measuring techniques, reference material, validated methods, acceptable for all stakeholders and delivering an integrated and interdisciplinary approach.

NanoValid (FP7): The main objective of NanoValid is the development of new reference methods and certified reference materials, including methods for characterization, detection/quantification, dispersion control and labeling, as well as hazard identification, exposure and risk assessment of ENs.

BAM is involved in an EU-funded project of the European Metrology Programme for Innovation and Research (EMPIR):

Innanopart (EMPIR): The aim of the project is to provide a metrological basis for the measurement of nanoparticle number concentration and nanoparticle surface chemistry.

http://www.nanodefine.eu
http://www.nanovalid.eu/
https://www.euramet.org/research-innovation/search-research-projects/details/?eurametCtcp_project_show[project]=1325&eurametCtcp_project[back]=450&cHash=3532c6e1abb2b2435103dcadfaf510df

Information on public/ stakeholder consultations

Federal Ministry of Education and Research (BMBF)

The web-based knowledge and data platform 'DaNa – The Knowledge Platform on Nanomaterials' is continued to be funded by BMBF (www.nanoobject.info or www.nanopartikel.info). 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.

With its information campaign "nanoTruck" the German Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung, BMBF) had presented an interesting "journey to the nanocosmos" throughout Germany. The campaign ended in March 2015 after more than ten successful years of vivid discussions, interesting workshops and exciting presentations.

Information on research or strategies on life cycle aspects of nanomaterials

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, five fact sheets were published which are available on the UBA website:

Use of nanoscale iron for the remediation of groundwater damages (http://www.umweltbundesamt.de/publikationen/use-of-nanoscale-iron-for-the-remediation-of)

Nanotechnology-based lighting systems: organic light-emitting diode (OLED) (http://www.umweltbundesamt.de/publikationen/nanotechnology-based-lighting-systems-organic-light)

Use of nanomaterials in textiles (http://www.umweltbundesamt.de/publikationen/use-of-nanomaterials-in-textiles)

Use of nanomaterials in coatings (http://www.umweltbundesamt.de/en/publikationen/use-of-nanomaterials-in-coatings)

Use of nanomaterials in energy storage devices (currently only available in German language: http://www.umweltbundesamt.de/publikationen/einsatz-von-nanomaterialien-in-der. A translation to English is planned.)

A further datasheet on use of nanomaterials in waste water remediation is underway.

Information related to exposure measurement and exposure mitigation.

Federal Institute of Occupational Safety and Health (BAuA)

BAuA is involved in the SIINN ERA-NET project "nanoIndEx – Assessment of Individual Exposure to manufactured nanomaterials by means of personal monitors and samplers". In the scope of the project, BAuA develops standard operation procedures for personal nanoparticle monitors, samplers and data evaluation. It performs laboratory tests of nanoparticle monitors and samplers and studies their applicability for (personal) exposure assessment at workplaces.

In the scope of NanoIndEx, BAuA has set up a nanofibre exposure facility in Berlin, Germany. The facility comprises a fully monitored exposure chamber of 400 liters volume. The chamber is connected to a highly-effective generator capable of providing controlled concentrations of nanofibre aerosols of constant particle morphology distribution for several hours. The facility enables studying instrument responses to nanofibre-containing aerosols. BAuA offers cooperation with external partners interesting in using this new infrastructure, e.g., for exposure testing and determination of collection efficiencies.

JAPAN

- Japan is positively participating in ISO/TC229 activities. In August 2015, a Japan-led Technical Specification ISO/TS 19337 "Characteristics of working suspensions of nano-objects for *in vitro* assays to evaluate inherent nano-object toxicity" was approved for publication. 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.

Information related to good practice documents

METI firstly publicised information on safety test data and management methods of manufactured nanomaterials, on METI's website[1] in 2010 (only in Japanese). Such information was voluntarily provided and annually updated by the manufacturers. METI publicised the updated information in 2015.

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

[1] http://www.meti.go.jp/policy/chemical_management/other/nano_program.html

exposure to TiO_2 in nanoscale. In addition, MHLW launched development of measurement methods for airborne nanomaterials, carbon black and SW/MWCNT.

The Japanese Industrial Standards Committee (JISC), 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 has led the development of a TC229 document (Technical Specification) in TC229/WG3 (Health, Safety and Environmental Aspects of Nanotechnologies) that is ISO/TS 19337 "Nanotechnologies -- Characteristics of working suspensions of nano-objects for in vitro assays to evaluate inherent nano-object toxicity" and was approved in August 2015 for publication. In TC229/JWG2, JISC leads revision of ISO/TS 10868 "Nanotechnologies -- Characterization of single-wall carbon nanotubes using ultraviolet-visible-near infrared (UV-Vis-NIR) absorption spectroscopy" and jointly (with ANSI, the American National Standards Institute) leads the Study Group on Particle Size Distribution by Transmission Electron Microscopy, and also jointly (with ANSI) leads a Preliminary Work Item "Determination of size and size distribution of nano-objects by scanning electron microscopy" (PWI 19749), and leads a Preliminary Work Item "Application of field flow fractionation for characterization of nanomaterial contents."

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 2009[2]. 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 TiO_2 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 TiO_2, silver and CNTs to identify any harmful effects attributed to their particle size.

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

The National Institute of Advanced Industrial Science and Technology (AIST), as a member of the Technology Research Association for SWCNT (TASC), released the English edition of "The protocols of preparation, characterisation and *in vitro* cell-based assays for safety testing of carbon nanotubes" in May 2014 that is available on the AIST-RISS website[3].

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 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

[2] http://www.env.go.jp/chemi/nanomaterial/eibs-conf/guideline_0903_enab.pdf
[3] http://en.aist-riss.jp/assessment/2571/

basic hazard information, both of which are for regulatory purposes. In the Summer of 2015, the Programme's website was fully updated with the new URL http://metinanoen.aist-riss.jp/ to present its results as of June 2015. Some results of the R&D theme 2) above were presented at a WPMN horizontal expert workshop on toxicokinetics of nanomaterials in February 2014 and also at a WPMN information sharing seminar on *in vivo* inhalation toxicity screening methods for manufactured nanomaterials held at US EPA, Washington DC, on 21 September 2015. Preliminary results of the R&D theme 1) above were presented at a WPMN horizontal expert workshop on categorisation of nanomaterials 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", whose draft report will be presented at the 15th meeting of WPMN.

METI also launched a five-year programme "Development of Innovation Carbon Nanotube Composite Materials for a Low Carbon Emission Society" in 2010. One of various R&D themes of the programme was "techniques suitable for voluntary safety management of CNTs by industries"[4], which focused on the development of toxicity testing and exposure assessment protocols for ensuring safety of CNTs and their applications, and whose results were released as the two documents described in 6. above and 10. below by AIST, as a member of TASC, in October 2013. The programme was converted into a three-year programme "Commercialising Carbon Nanomaterials for a Low Carbon Emission Society" starting in mid-2014. One of R&D themes of this successive programme is "to establish techniques for assessing release and exposure of carbon nanomaterials from their application products". Under this R&D theme, the following two documents (only in Japanese) regarding two types of SWCNTs[5] were released by AIST, as a member of TASC:

- "Safety data and introduction of a voluntary safety management regarding Super-growth single-wall carbon nanotubes" released in November 2014 and
- "Safety data and introduction of a voluntary safety management regarding eDIPS single-wall carbon nanotubes" released in December 2014.

MHLW has promoted research on the human health aspect of several nanomaterials since 2003 through the Health and Labour Sciences Research Grants, etc. In 2015 JFY, seven 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 Centre 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, 2009-2015). Two-year inhalation study of MWCNT was completed in 2015. In addition, in order to elucidate the carcinogenic mechanism, *in vitro* chromosome aberration and *in vivo* micronucleus tests were completed in 2015. The Japan Bioassay Research Centre launched inhalation study of TiO2.

The National Institute of Occupational Safety and Health, Japan (JNIOSH) has conducted a three-year project study (2012-2014 JFY), "Toxicological Study on Ultrafine Particles of Metal Oxides". This project included 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

[4] http://tia-nano.jp/en/core/area/nano-material.html

[5] http://tia-nano.jp/en/core/area/carbon-nano.html

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 dendtrimers and ecotoxicological study of TiO_2 nanoparticles using embryo and sac-fry fish.

Information related to exposure measurement and exposure mitigation.

AIST, as a member of TASC, released the English edition of "Guide to measuring airborne carbon nanotubes in workplaces" in October 2013 that is available on the AIST-RISS website[6]. Researchers of AIST are currently engaged in on-site measurement of airborne nanoparticles released from processing of nanocarbon composite materials.

KOREA

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

The Ministry of Environment (MOE), Republic of Korea has added nanomaterials to the list for hazard evaluation prescribed in 'Act on Registration and Evaluation, etc of Chemical Substances'.

Activities been initiated to implement the OECD Council Recommendation?

The Ministry of Environment (MOE), Republic of Korea has prepared the legal ground for survey of circulation status of nano materials in the regulation on statistical research of chemical substances.

Information onrisk assessment decisions, including the type of: (a) nanomaterials assessed ; (b) testing recommended; and (c) outcomes of the assessment;

Korea MOE plans to conduct risk assessment of silver nanomaterials in domestic market, and publish the relevant report.

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

KATS(Korea Agency for Technology and Standards)is developing 4 international standards in the ISO/TC 229 (Nanotechnologies) relevant to nanomaterial safety testing "Aerosol generation for NOAA

[6] http://en.aist-riss.jp/assessment/2571/

(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", "Aquatic Toxicity Assessment of Nanomaterials using *Artemia* sp." and "Materials specification - Antibacterial silver nanoparticles" These standard documents will complement the work of the OECDWPMN and other related framework documents.

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

Based on the policy and research infrastructures developed from the 1st National Nano-safety Master Plan('12-16) at inter-ministerial levels(including Korea MOE, Ministry of Trade, Industry and Energy, and Ministry of Food and Drug Safety), the Korean government will establish the goal, vision, and implementation plan of the 2nd Master Plan(2017-2021), and will also develop the detail implementation projects by December, 2015.

Ministry of Trade, Industry and Energy (MOTIE), Republic of Korea in collaboration with the Ministry of Science, ICT and Future Planning (MSIP) has initiated the programme "Strategy on Nano Convergence Industry Development" to strengthen research on the safety and social impact of nanomaterials. After completion of "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 and to carry out the 'National Nano-safety Master Plan(2012-2016)',

MOTIE launched Tier 2 project called "Development of safety evaluation based technology for nanoproduct to promote commercialization" has been ongoing. The project lasts 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 algorism 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, and EU NanoReg,

In addition, MOTIE has participated EU NanoReg project from Feb, 2015. The participating tasks are "data platform and data management", NanoReg instruments toolbox for regulators and legislators", "developing technologies for nanomaterial inhalation toxicology", and "developing methodologies on exposure assessment for products containing manufactured nanomaterials". Tier 3 project lasting 2015-2017 called "Development of safety evaluation based technology for nanoproduct to promote commercialization" is formulation stage. In addition, MOTIE is actively participating "Nanotechnology Development Masterplan (2016-2026) which include safety aspects of nanotechnololgy.

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 participated 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. Recently, our results for SiO2 and ZnO have been published in Internation Journal of Nanomedicine(Special Issue on Safety assessment of silica and zinc oxide nanoparticles, vol 9(suppl 2) 2014). NIFDS has been conducting research project on the effect of ionization on the toxicity of nanoparticles since 2015. MFDS and NIFDS (National Institute of Food and Drug Safety Evaluation) have conducted the planning research for nanomedicines in order to prepare the approval and review since 2015. This planning research mainly focuses on establishing the foundation and evaluation system of nanomedicines for preparing approval and reviews. Research areas incorporate the current viewpoint of other regulatory agency for nanomedicines, research trend of industry-university-institute in domestic, digging out candidates for commercial and their evaluation methods, and working out a road-map. According to this road-map, we are preparing specific guidelines of nanomedicines for approval and reviews and we look forward to promoting nanomedicine development for the pharmaceutical industries. In fields of nanofood safety, we have conducted the validation study on internal absorption assessment methods of organic nanofoods. Also, In fields of food packaging materials, we are going to examine the possibility of nanomaterial leaching from food packaging materials if there is a safety concern related to these packaging materials.

Information related to exposure measurement and exposure mitigation.

Ministry of Trade, Industry and Energy (MOTIE) in collaboration with several research organizations has started to study exposure assessment of graphene in R&D facilities.

NETHERLANDS

- **Highlights of developments**

- RIVM, in collaboration with consultant Arcadis, has published a report on grouping of nanomaterials.
- RIVM recently published the report “Assessing health & environmental risks of nanoparticles: Current state of affairs in policy, science and areas of application”.
- A new software model ConsExpo nano (www.consexponano.nl) was developed to investigate the exposure of the consumer to nanomaterials in spray products.

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

After setting the basic conditions for its R&D work, the NANoREG project (www.nanoreg.eu) now focuses on the generation of reliable and comparable experimental data on the environment, health and safety aspects of selected NANoREG nanomaterials. These data will form the basis for the main “end products” of the NANoREG project: the Regulatory Framework and the NANoREG Toolbox. A first outline of this regulatory Framework has recently been discussed with NANoREG partners.

Activities initiated to implement the OECD Council Recommendation[7]

RIVM recently published the report "Assessing health & environmental risks of nanoparticles: Current state of affairs in policy, science and areas of application" (www.rivm.nl/bibliotheek/rapporten/2014-0157.html). The report provides an overview of the scientific knowledge of risk assessments of nanoparticles and nanomaterials and their applications. RIVM concludes that the existing models and techniques used to assess the risks of nanomaterials are not yet sufficiently tuned to determine how harmful nanomaterials are to humans and the environment. The report includes a description of the current European regulatory regime. General insights have been amplified for some distinct fields such as consumer products, food, medical applications, workplace applications and the environment.

Information on:

c. risk assessment decisions, including the type of: (a) nanomaterials assessed ; (b) testing recommended; and (c) outcomes of the assessment;

In 2014, the Netherlands has started a substance evaluation of silver within the REACH process. The focus in this evaluation is on the environmental fate and toxicity of the nanoforms of silver in relation to ionic silver. In March 2015 a first draft decision was sent to the Registrant(s) for comments. Currently, the Netherlands are evaluating the comments from the Registrant(s). It is expected that the Member State Committee will reach a final decision on this substance evaluation in 2016.

d. risk management approaches; and

For the Netherlands Food and Consumer Products Safety Agency RIVM started to evaluate the possibilities to make a web-based tool for the risk assessment of nanomaterials used as cosmetic ingredient. A first report is being prepared (expected publication date: autumn 2015) that describes the content of the so-called NanoCosmetics Tool. The tool needs to cover all aspects of the risk assessment, i.e. the physicochemical characterisation of the nanomaterials, the estimation of the consumer exposure, the possible hazards (toxicity) induced by the nanomaterials, and finally the risk assessment itself. Where only limited information is available, the tool will use default values that generally result in a conservative outcome. The overall outcome will be an estimation of potential risk indicating whether specific measures for risk mitigation and/or reduction need to be implemented. The NanoCosmetics Tool will be developed in close cooperation with the EU project GUIDEnano (www.guidenano.eu) in which a similar tool is developed for nanomaterials in products in general, but GUIDEnano specifically excludes uses in cosmetics and nanomedicine.

Developments related to good practice documents

In collaboration with consultant Arcadis, RIVM drafted a strategy for the grouping of nanomaterials and the use of read-across. First a literature review provided the definition of a minimal set of key parameters for the risk assessment of nanomaterials. This base set formed the foundation of the strategy that was built for grouping and read-across. Finally, the strategy was tested with a few case studies. The final report was published in June 2015 (www.rivm.nl/bibliotheek/rapporten/2015-0061.html).

This report is also an important pillar for the project in which RIVM collaborates with ECHA and JRC to develop a framework for read-across for nanomaterials. With this project ECHA prepares the development of REACH Guidance on this topic. A first draft of the framework was shared and discussed

[7] Recommendation of the Council on the Safety Testing and Assessment of Manufactured Nanomaterials

with ECHA's Nanomaterial Working Group where it was perceived as a good starting point for read-across of nanomaterials.

For the further development of Stoffenmanager Nano, TNO developed five good practice documents, describing workplaces with a minimised exposure by the application of control measures. In addition, TNO started collecting other published good practices developed by other institutes.

Within ISO TC 229's Working Group on Health, Safety and Environments (WG3) discussions have started on a preliminary work item (PWI) for the development of a document on Toxicokinetics of nanomaterials. Wim De Jong (RIVM) has taken the lead in this project. The intention is to prepare a document that describes how toxicokinetic studies for nanomaterials should be conducted.

Information on Integrated Testing Strategies and/or Alternative test methods

Within the COST action MODENA (Modelling Nanomaterial Toxicity, www.modena-cost.eu), actions have been initiated towards developing mathematical QSAR-type of models that allow predicting human health and environmentally relevant endpoints of toxicity of functionalised nanomaterials. Within MODENA, RIVM developed some generalised predictive models for metal-based nanomaterials. The models are based on a set of ecotoxicity data that was obtained by means of a literature search. Additional validation of the models showed that in general the models are able to predict around 75 % of the variance in the data. This can be considered as an encouraging first step towards development of QSAR-models for nanomaterials. Thereupon, a dataset of in vitro testing results of nanomaterials was made available within MODENA. This set of data too was modelled using similar approaches as for the ecotoxicity data. In this case, QSAR-models were generated capable of predicting around 80 % of the variance in the data whilst the whole dataset covered in vitro toxicity data spanning several orders of magnitude.

The European project MARINA (www.marina-fp7.eu) will be finalised in October 2015. The Netherlands' contribution included taking the lead in the development of a risk assessment strategy for nanomaterials and how grouping and read-across can be applied in this strategy. Scientific papers were drafted and submitted that describe the strategy (Peters et al.) and the grouping approach (Oomen et al.). The strategy describes a flexible and efficient approach for data collection and risk assessment which is essential to ensure safety of engineered nanomaterials.

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

Several Dutch partners (RIVM, TNO, Utrecht University, GeoChem, and Think Works) are involved in the European GUIDEnano project (www.guidenano.eu). The main objective of the project in the first 18 months was to deliver the first version of GUIDEnano Tool (v1). This is an intermediate version and includes the whole structure to predict exposure and hazard derived from the whole life-cycle of nano-enabled products, leaving the implementation of the full risk assessment framework and risk management for the second version of the tool. Based on available data and information collected from the literature and from ongoing and concluded European projects (e.g., NanoFate, MARINA, NANoREG), the different elements have been developed, including a strategy to determine environmental release, a tiered approach for building exposure scenarios and support exposure assessment, a fate model framework, a hazard assessment strategy, an initial strategy for risk assessment, and a list of potential risk mitigation strategies.

Under auspices of WHO/IPCS an expert group has been installed that will prepare an Environmental Health Criteria Document Principles and Methods of Assessing the Risk of Immunotoxicity Associated with Exposure to Nanomaterials. Henk van Loveren (RIVM) has been appointed as the chair of this expert group. A scoping meeting to decide on the content and outline of the document has taken place at RIVM in April, and writing tasks were assigned. The work has started, and a number of telephone conferences to

monitor the process have taken place. It is estimated that preparation of a draft ready for public consultation will take 1.5 years. OECD is involved in this endeavour as an observer.

RIVM is partner in the EU project NanoMILE (Engineered nanomaterial mechanisms of interactions with living systems and the environment: a universal framework for safe nanotechnology) (www.nanomile.eu-vri.eu). The project evaluates in depth the potential interactions of nanomaterials with cells, organs, and hosts, with the aim to evaluate mechanisms of interaction with biological systems and the environmental species. Basic to the project is a high quality characterisation of the nanomaterials, high throughput screening and systems biology for determining effects and pathways in the interaction of nanomaterials with biological systems. This information will be correlated with more classical toxicity assays. Identification of critical properties (physico-chemical descriptors) that confer the ability to induce harm in biological systems is key to allowing these features to be avoided in nanomaterials production (safety by design). The NanoMILE project is halfway and had a successful midterm review. RIVM is leader for the work package on human toxicology.

Research or strategies on life cycle aspects of nanomaterials

The contribution of TNO to the EU-project FutureNanoNeeds (www.futurenanoneeds.eu) has been continued. A framework was developed to forecast exposure of the next generation of nanomaterials using Bayesian networks. For a first tier in the framework, the life cycle of 7 nanomaterials and identified and described focal points in 5 so-called 'value chains', which describe the life cycle of nanomaterials in specific uses. Focal points highlight stages in the value chain that may increase or change the type of potential exposure to nanomaterials (e.g., significant nanomaterial transformation, or high concern activities). Within the work package on environmental fate and effects, RIVM contributes to the activities aimed at testing the adverse effects of homologues nanomaterial with regard to a number of specific endpoints and specific species (including microbes, daphnids, algae, and fish). The focus of these experiments was on testing the impact of size and shape of nanomaterials of similar chemical composition on toxicity. In addition, RIVM contributes to the evaluation of the effect of shape of nanomaterials on genotoxicity and immunotoxicity.

Information related to exposure measurement and exposure mitigation.

As part of the Dutch NanoNextNL project (www.nanonextnl.nl), a broad-scale workplace exposure survey covering different types of nanomaterials and exposure processes provided insight into the occupational nanomaterials' exposure scenarios and levels of exposure. In addition, experimental studies conducted under controlled conditions identified determinants of exposure and their effect. These data are used in improving and refining quantitative hazard and exposure assessment models.

To investigate the exposure of the consumer to nanomaterials in spray products, RIVM developed a new software model: ConsExpo nano (www.consexponano.nl). This model was adapted from the ConsExpo model for the estimation of exposure to regular substances in spray products. It has been developed in the context of the Dutch NanoNextNL project (www.nanonextnl.nl): "Predictive modelling of human exposure". ConsExpo nano combines models that estimate the external aerosol concentration in indoor air, with models that estimate the deposition in and clearance of inhaled aerosol from the alveolar region. It is a "work-in-progress" online tool that is designed to reflect the current state of knowledge on exposure to nanomaterials via inhalation. The tool will be further developed to accommodate developments in the state of the science.

Within the EU project MARINA (www.marina-fp7.eu), TNO reviewed existing exposure models. The available nanospecific models are mostly qualitative, control banding, or risk banding tools. Furthermore, several good quality quantitative exposure assessment models for conventional (non-nanospecific) chemicals were identified that might have potential to be extended or adapted for

nanomaterials. For this purpose, however, there is an urgent need for comprehensive exposure studies covering the whole life cycle of nanomaterials with a consistent collection and analyses of workplace exposure data and contextual information.

Within the EU project SUN (www.sun-fp7.eu) TNO contributed to the development of the model for the entire life cycle of nanomaterials that covers all relevant nanospecific characteristics of the SUN case studies. This model will be the basis for developing the life cycle assessment module of the SUN decision framework (SUNDS). Case studies are currently being conducted. Furthermore an overview of templates and SUN data libraries is compiled for nanomaterial inhalation, which describes dermal and dermal-to-oral exposure measurements, process-specific release potentials and exposure protection measures. These templates and data libraries will be used for data collection and model validation.

Additional Information

On 1 February 2015 the ProSafe project (www.h2020-prosafe.eu) started; a H2020 Coordination and Support Action mainly aimed at giving support to NANoREG (and other) nanosafety projects. Under the umbrella of ProSafe a Task Force of independent senior experts will evaluate and integrate the scientific results of NANoREG, the OECD Sponsorship Programmes and other relevant nanosafety projects. The results will be laid down in a "Joint Document". This document will serve as a reference document for a three-day scientific conference that will be organised in collaboration with the OECD in November 2016. Based on the Joint Document and the results of the scientific workshop, an EU policy oriented White Paper will be drafted that will give an overview of "what we know" and "what we don't know" based on the regulatory questions as defined by NANoREG. The "solution side" of the White paper will distinguish between the short to mid-term and the long term. Based on the acceptance of uncertainties rather than deny or ignore them, a short to mid-term approach will be elaborated to give sufficient guidance to policymakers and regulators, and include a Regulatory Framework and Toolbox. For the longer term, the way towards the implementation of safe-by-design and safe innovation will be elaborated. ProSafe projects will further aim to establish standard approached for (environment, health and safety) data management and incorporation of safe-by-design as an integral part of the core (nanomaterial) research activities. In this context ProSafe will define and organise a common project call together with national funding agencies for acceptance and further elaboration of the NANoREG safe innovation and safe-by-design concepts.

Consideration on the benefits of nanotechnologies

The European LICARA project was finalised in 2014. Guidelines for the sustainable competitiveness of nanoproducts were developed to support SMEs to make decisions about developing safe, sustainable nanoproducts. These guidelines are further supported by the qualitative LICARA nanoSCAN tool. The tool was tested with four case studies: a nanosilver coating, the use of nanosilver in microfiber cloths, the use of titanium dioxide for self-cleaning façade coatings, and the use of multi-wall carbon nanotubes in a fuel cell. The documents and tool are available at the TNO-website: www.tno.nl/licara.

SWITZERLAND

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

Since 2012, nanospecific information (physical-chemical properties) is requested for the registration of nanomaterials as new substances and for the notification of hazardous existing substances in nanoform, according to the Chemical Ordinance (ChemV, SR 813.11). The Swiss definition of nanomaterials is

similar to the recommendation of the European Commission with the difference that there is no number threshold and that the nanomaterial must be made on purpose for the delivery of a nanospecific effect. In addition to the nanospecific amendment to the ChemV, similar amendments were made to the Ordinance for plant protection products (PSMV, SR 916.161) and the Ordinance for biocidal products (SR 813.12). Moreover, nanomaterials must be declared in applications for admission of pharmaceuticals. Beside the mandatory requests on nanospecific data, Switzerland continuous to develop and to promote the use voluntary tools for strengthening industrial responsibility for the risk management of nanomaterials. This is particular important as long as the regulatory framework for nanomaterials is still evolving. Such tools, developed and implemented in Switzerland, are the guidance documents for (i) "responsible care", (ii) disposal of nanowaste, (iii) safety data sheet, and for (iv) the hazardous incidences. Moreover, the "Precautionary matrix for synthetic nanomaterials", which was presented at the categorization workshop in D.C. (September 2014), has been proven a very valuable tool for small, medium and larger companies who are dealing with nanomaterials. Switzerland aims to include synthetic nanomaterials in the existing notification and registration procedure for new chemicals. An easy one-step notification procedure is foreseen for industries producing or processing nanomaterials. The goal of this action is a better overview of application areas for nanomaterials.

Action Plan for synthetic nanomaterials

The "Action plan for synthetic nanomaterials" illustrates the work required in Switzerland for the safe handling of nanomaterials. It was adopted by the Federal Council in April 2008. The just mentioned tools were developed under this action plan. On 17 December 2014 the Federal Council decided to continue the action plan until 2019.

The action plan was developed by the Federal Office of Public Health (FOPH), the Federal Office for the Environment (FOEN) and the State Secretariat for Economic Affairs (SECO) in cooperation with an **inter-departmental task force** and the involvement of a **panel of scientific and economic experts**.

The **objectives** of the action plan include:

1. development of regulatory framework conditions for the responsible handling of synthetic nanomaterials;
2. creation of scientific and methodical conditions aimed at identifying and preventing potential harmful effects of synthetic nanomaterials on health and the environment;
3. promotion of the public dialogue about opportunities and risks of nanotechnology;
4. better utilisation of existing tools for the development and rollout of sustainable nanotechnology applications.

The operational plan includes the four areas "science and methods", "regulation", "implementation", and "communication".

Science and methods: Focus on research projects with a regulatory relevance

Regulation: Further work on notification and registration schemes for nanomaterials, both mandatory and voluntary ones.

Implementation: surveillance of application and use of the regulatory tools and requirements, including information campaigns on regional and local level (industry and public).

Communication: Mainly relaunch/update of the website www.infonano.ch that contains up to date information on regulatory and safety aspects of nanomaterials. Promotion of safe and responsible innovation along the value chain of nanomaterial applications is a further theme of the communication strategy.

Information related to good practice documents

Nothing new for regulators, but increasingly important is the discussion on identity and grouping schemes for nanomaterials. FOPH recently published an article (***Sameness: The regulatory crux with nanomaterial identity and grouping schemes for hazard assessment***. In: Regulatory Toxicology and Pharmacology 72 (2015), pp. 569-571 DOI information: 10.1016/j.yrtph.2015.05.031) where in a first part, a concept for the grouping of physical-chemical similar nanomaterials is proposed. A second part deals with a new framework for testing strategies.

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

Federal Office of Public Health (FOPH) 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. Swiss researchers (at EPFL Lausanne, Empa St.Gallen, IST Lausanne) are contracted. They are contributing to three work packages, focusing on development of harmonized characterization protocols, modelling nanoparticle workplace exposure based on real workplace measurements, and for organizing round robins with the goal of establishing SOPs for (high throughput) in vitro test methods with potential future regulatory relevance. The high throughput methods are also in the focus of a CCMX (Competence Centre for Materials Science and Technology) project called nanoscreen, co-sponsored by FOPH, which, in addition, aims towards a better understanding of nanoparticle corona – cell interaction.

Links: www.nanoreg.eu; and http://www.ccmx.ch/research/materialschallenges/nanoscreen

The National Research Programme "Opportunities and Risks of Nanomaterials" (NRP 64) aimed to identify opportunities arising from the use of nanomaterials for consumers, environment and natural resources. At the same time it intended to bridge the gaps in our current knowledge on the potential risks of nanomaterials. The research projects (10 million Euro in total) started in December 2010 and came to an end this year. A synthesis report on the outcome of the multimillion research program is in preparation. The research carried out under this program will provide a scientific basis for recommendations and appropriate measures with regard to the production, use and disposal of engineered nanoparticles. It covers the five main areas biomedical applications, environment, food, energy, and construction materials.

Link: www.NRP64.ch

Information related to public/ stakeholder consultations

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 French- and German-speaking regions in Switzerland and attracted more than 60,000 people. Expo Nano is multimedia-based, interactive, and open for free to everybody. Target audience is the broad public. Focus events for specific target groups (e.g. schools, small companies) are regularly organized. Visitors

can experience different experiments where "nano-effects" are shown. Posters provide the theoretical explanation to the multimedia-experiments.

Link: http://exponano.ch

Infonano (Website): 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 stakeholders from industry, academia, society and administration. It presents all relevant governmental activities on nanotechnology and provide a structured entry into the world of nanotechnology. Among other topics, one can find international research highlights, safety of consumer products, regulatory activities of the ministries, and much more additional information.

Link: www.infonano.ch

Research or strategies on life cycle aspects of nanomaterials

Switzerland has several research groups that investigate life cycle aspects of nanomaterials (e.g. http://www.ifu.ethz.ch/ESD or http://www.empa.ch/plugin/template/empa/124/*/---/l=2). Moreover, the Federal Office of Public Health (FOPH) together with EMPA organized and hosted the SG9 workshop in Zurich in January 2015. The aim was to discuss and finalize the draft of the guidance manual on the combined use of LCA and RA for the assessment of benefits and risks of nanoenabled products. The Document is now declassified and available (ENV/JM/MONO(2015)30).

Information on past, current or future activities on nanotechnologies that are being done in co-operation with non-OECD countries.

On an annual basis, the german speaking countries Fürstentum Liechtenstein, Austria, Germany, and Switzerland held a 2-days workshop on regulatory issues of nanomaterials. This year, the 9th workshop was kindly hosted by Liechtenstein with the title: *Governance of Nanomaterials*. The European Commission provided a short update on the implications of REACH on the use of nanomaterials. Three lectures from researchers followed, dedicated to "material sciences", "human toxicity", and "ecosystem toxicity". The country representatives then reported from ongoing national activities and challenges in the implementation of nanospecific regulatory actions. Finally, a vivid discussion with stakeholders from NGO, industry and the government took place on the topic "expectations from stakeholders for a sustainable risk governance of nanomaterials". The next "Behördendialog" will be hosted by Switzerland in Spring 2016.

Link: http://innovationsgesellschaft.ch/en/regulierung-von-nanomaterialien-am-9-internationalen-nano-behordendialog-in-vaduz-diskutiert/

TURKEY

Currently there are 5 By- Laws in Turkey that are into force to ensure the protection of human health and the environment:

- By-law on Inventory and Control of Chemicals1
- By-Law On The Classification, Labelling And Packaging Of Substances And Mixtures (harmonizes 1272/2008/EC)
- By-law on Restrictions and Prohibition of Hazardous Substances and Mixtures 2

- By-law on Safety Data Sheets of Hazardous Substances and Mixtures (in parallel to REACH)
- By-Law On Test Methods Applied For Determining The Physicochemical Toxicological And Ecotoxicological Properities Of The Substances and Mixtures(harmonizes 440/2008/EC)

The By-law on Inventory and Control of Chemicals has published according to national needs and includes data gathering depends on the tonnages for substances which any manufacturer or importer who manufactures or imports a substance on its own or in a preparation, in quantities exceeding 1 tonnes per year.

The by-law consist already; 20 of chemical substances and groups of substances subject to restrictions listed in the Annex 17 of REACH.

In addition, "Draft By Law on Registration, Evaluation, Authorization And Restriction Of Chemicals" (KKDİK) that will harmonize 1907/2006/EC has been prepared.

It is foreseen that the KKDİK By-law will be published in 2015. By the implementation, "By-law on Inventory and Control of Chemicals" "By-law on Restrictions on the Production, Marketing and Use of Certain Dangerous Substances, Preparations and Articles" and "By-law on Safety Data Sheets of Hazardous Substances and Mixtures" will be repealed. Turkey plans to work on nanomaterial safety in the near future.

UNITED KINGDOM

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

Summary of work undertaken to assess workplace exposure and control measures during the manufacture and handling of engineered nanomaterials (Health and Safety Executive 2015). The objectives of the project were to: (1) Carry out visits to companies to assess exposure to airborne nanomaterials during their manufacture, handling and use; and (2) access the effectiveness of the controls used to reduce exposure to nanomaterials.

The key findings from the project work were: an increased understanding of some of the tasks and activities undertaken during the manufacturing, handling or use of nanomaterials and the potential for exposure to airborne nanomaterials; and existing good hygiene control practices can be used to reduce exposure to airborne nanomaterials. It is therefore important that in any work with nanomaterials, a thorough assessment is made of all control methods to be used.

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

Natural Environment Research Council (NERC) funded FABLE (From Airborne Exposures to Biological Effects: the impact of nanoparticles on health) project, in collaboration with University of

Birmingham, have undertaken in vivo inhalation studies of CeO2NPs and various Fe-oxide NPs. (Project finishes end 2015) Publication of results expected 2016.

NERC (+others) funded Risk Assessment for Manufactured Nanomaterials Used in Consumer Products (RAMNUC) project, in collaboration with Imperial College have undertaken in vivo inhalation studies on the effects of consumer product containing Ag (Project finishes end 2015) Publication of results expected 2016

National Institute of Environmental Health Sciences (NIEHS) funded (Respiratory Effects of Silver and Carbon Nanomaterials (RESAC) project, in collaboration with Imperial College, have undertaken in vivo inhalation studies on the effects of inhaled Ag NP aerosols (project finishes end 2015). Publication of results expected 2015

EU FP7 NANoREG – as part of work for this we will be undertaking in vivo inhalation studies with MWCNTs this autumn.

Research or strategies on life cycle aspects of nanomaterials

Swansea University - Nano(geno)toxicology Research. This research is 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 as well as the modification of current test systems to ensure compatibility for nanomaterial evaluation.

Assay adaptation activities include:

- Methodology adjustments for the micronucleus assay (OECD TG487) – this work is also being conducted in conjunction with the OECD WPMN project on the Adaptation of In Vitro Mammalian Micronucleus Test Guideline (TG 487) for Testing of Manufactured Nanomaterials.
- Development and the application of 3D culture models for genotoxicity and biological barrier penetration assessment of nanomaterials. This includes 3D models of the liver, lungs and skin.
- Nanomaterial panels that are under investigation include: Ultrafine superparamagnetic iron oxide nanoparticles with variations in oxidation state and surface chemistry. A variety of graphene-type nanomaterials with variations in shape, surface area and surface chemistry.
- A range of single-walled carbon nanotube samples that have varying length.
- 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.

- Under a Health Protection Research Unit (HPRU) lead by King's College entitled Health Impact of Environmental Hazards funded by National Institute for Health Research (NIHR) (2014-2019) which covers wide range of environmental hazards. The following

studies are being undertaken in relation to nanosafety: (i) review the exposure of members of the public from nanomaterials in consumer products, with a focus on potential inhalation exposures; and (ii), in collaboration with Imperial College, undertake in vitro studies of the toxicity of engineered nanoparticles.

UNITED STATES

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

EPA Regulatory Actions. Since January 2005, the U.S. Environmental Protection Agency (EPA) has received and reviewed more than 170 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 2, 2015 EPA issued a final SNUR for a polymer of terephthalic acid and ethyl benzene with multi-walled carbon nanotube and on June 5, 2015 a final SNUR for graphene nanoplatelets.

On April 6, 2015 EPA proposed one-time reporting and recordkeeping requirements for new and existing chemical substances that are nanoscale materials under the authority of section 8(a) of TSCA. Persons who manufacture or process these chemical substances as nanoscale materials would be required to notify EPA of certain information, including specific chemical identity, production volume, methods of manufacture and processing, use, exposure and release information, and available health and safety data. On June 11, 2015 EPA conducted a public meeting to receive public comments and to answer any clarifying questions regarding the rule.

On May 15, 2015, EPA's Office of Pesticide Programs issued a registration for a nanosilver-containing antimicrobial pesticide product named "NSPW-L30SS," or "Nanosilva" to be used as a non-food-contact preservative to protect plastics and textiles from odor- and stain-causing bacteria, fungi, mold and mildew. Documents and other information are available at: www.regulations.gov in Docket ID #EPA-HQ-OPP-2012-0594.

FDA Final Guidance on Use of Nanomaterials in Food for Animals. On August 5, 2015, the U.S. Food and Drug Administration (FDA) announced the availability of its final guidance for industry (GFI #220) entitled "Use of Nanomaterials in Food for Animals." A notice in the Federal Register was published. FDA issued this final guidance after taking into account public comment that was received in response to the draft guidance published in June 2014.

This guidance applies to ingredients intended for use in animal food and that consist entirely of nanomaterials, contain nanomaterials as a component, or otherwise involve the application of nanotechnology. The guidance addresses the legal framework for adding substances to food for animals and includes recommendations for submitting a Food Additive Petition (FAP) for a nanomaterial animal

food ingredient. The guidance encourages manufacturers to consult with FDA early in the development of their nanomaterial animal food ingredient and before submitting a FAP. Manufacturers usually do not have to submit a FAP if their food additive is generally recognized as safe (GRAS). However, FDA is not aware of any animal food ingredient engineered on the nanometer scale for which there is generally available safety data sufficient to serve as the foundation for a determination that the use of such an animal food ingredient is GRAS.

FDA's consideration of nanotechnology applications in food for animals is consistent with the Agency's previously-issued final guidance documents, as well as with broader federal guidance on regulatory oversight of emerging technologies and nanotechnology. FDA guidances and other information relevant to nanotechnology can be accessed online at: http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/default.htm.

Activities initiated to implement the OECD Council Recommendation

Issuing the proposed TSCA section 8(a) rule described above. Regulation of new chemical substances that are nanomaterials with consent orders and SNURs.

Information on:

a. risk assessment decisions, including the type of: (a) nanomaterials assessed ; (b) testing recommended; and (c) outcomes of the assessment;

EPA reviewed TSCA section 5 premanufacture notices for 15 carbon nanotubes, 3 quantum dots, and one metal oxide. Based on potential risk findings to human health and the environment, EPA issued consent orders and/or SNURs for all of these materials. See details in #4b for risk management approaches and #6 for required testing.

On February 2, 2015 EPA issued a final SNUR for a polymer of terephthalic acid and ethyl benzene with multi-walled carbon nanotubes and on June 5, 2015 a final SNUR for graphene nanoplatelets.

b. risk management approaches;

Because of limited data to assess nanomaterials, the consent orders and SNURS contain requirements to limit exposure to workers through the use of personal protective equipment, limit environmental exposure by not allowing releases to surface waters or direct releases to air, and limit the specific applications/uses to those described in the new chemical notification.

c. any updates, including proposals, or modifications to previous regulatory decisions; and

No, the approaches used given the level of available information are consistent with previous regulatory decisions.

d. new regulatory challenge(s) with respect to any action for nanomaterials.

Standards/methods for differentiating between different forms of the same chemical substance that is a nanomaterial.

Standardized testing for the physical properties that could be used to characterize/identify nanomaterials.

Differentiation between genuinely new nanoscale materials introduced in commerce and existing products which have been in commerce for decades or centuries.

Information related to good practice documents

Development of Protocols. On June 30, 2015, the National Institute of Standards and Technology (NIST) launched a new web site, http://www.nist.gov/mml/nanoehs-protocols.cfm, containing 14 protocols, defined as step-by-step, reproducible, and validated procedures. The number of these protocols will continue to increase. These protocols are for sample preparation and physico-chemical and biological measurements of engineered nanomaterials and nanotechnology-enabled products are applicable to nanotechnology environment, health, and safety research. NIST will work with its partners to bring these documents into the international standards process, where appropriate.

Also NIST is actively writing a guidance document on aquatic and sediment toxicological testing of nanomaterials using OECD test methods and participating in editing the Fish Dietary Accumulation Guidance Document for NMs.

Finally NIST experts actively participated in several OECD meetings during the year.

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

Consent orders and SNURs for carbon nanotubes and other nanomaterials typically contain required or recommended testing for a 90-day inhalation study and pchem properties such as particle size/ distribution, morphology, surface area, crystallinity, surface charge and surface chemistry. The 90-day study typically has at least a 90-day post-exposure observation period and evaluation of the broncoalveolar fluid. For carbon nanotubes blood and plasma endpoints indicative of cardiotoxicity are monitored.

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

National Nanotechnology Initiative (NNI). The NNI is a U.S. Government research and development (R&D) initiative involving the nanotechnology-related activities of 20 departments and independent agencies. The NNI today consists of the individual and cooperative nanotechnology-related activities of Federal agencies with a range of research and regulatory roles and responsibilities. The NNI brings together the expertise needed to advance this broad and complex field—creating a framework for shared goals, priorities, and strategies that helps each participating Federal agency leverage the resources of all participating agencies. With the support of the NNI, nanotechnology R&D is taking place in academic, government, and industry laboratories across the United States. www.nano.gov

EPA Office of Research and Development. The EPA Office of Research and Development (ORD) Program on Chemical Safety and Sustainability maintains a coordinated research program on the public health and environmental implications of emerging chemicals including engineered nanomaterials.

Aquatic Toxicity Testing of Nanomaterials. NIST scientists coauthored a recently published review paper related to their work on aquatic toxicity testing of nanomaterials using OECD methods. Petersen et

al., 2015, Adapting OECD Aquatic Toxicity Tests for Use with Manufactured Nanomaterials: Key Issues and Consensus Recommendations, Environmental Science and Technology, 49 (16), pp 9532–9547

Information on public/ stakeholder consultations.

On June 11, 2015, U.S. EPA conducted a public meeting to receive public comments and to answer any clarifying questions regarding its proposed TSCA section 8(a) rule for chemical substances that are nanoscale materials.

U.S. EPA hosted two OECD expert meetings in Washington DC, September 21 and 22, 2015: Inhalation test guidelines and guidance for nanomaterials, and an information-sharing seminar on *in vivo* inhalation toxicity screening methods for manufactured nanomaterials.

On April 8, 2015, NIST hosted a US federal employee-only meeting on the state of standards for nanotechnology-related environmental, health, and safety research and regulatory decision-making. One outcome of the meeting was a list of high priority needs for standards, defined to include reference materials, standard test methods, and validated protocols. Needs were also expressed for "test" materials and a data repository of standards information including the appropriateness of a given standard to end-users.

Information related to exposure measurement and exposure mitigation.

A number of studies have been sponsored by the U.S. Consumer Product Safety Commission (CPSC):

1. Nanomaterials emitted from laser printers – A project funded by CPSC and the National Institute for Occupational Safety and Health (NIOSH) with research conducted at the Harvard School of Public Health.

    a. Platform for exposure assessment of ENM released during printing
    b. In vitro assessment of particles released from printers
    c. Sisler et al. Nanotoxicology, 2014 - http://informahealthcare.com/nan; ISSN: 1743-5390 (print), 1743-5404 (electronic)

2. Nanosilver from manufactured children's products

    d. Tulve et al Int J Hyg Environ Health 218 pg345-357 (2015)

3. Nanocopper in pressure-treated wood products

    e. EPA Final Micronized Copper Public Doc EPA 600R_14_365

Information on past, current or future activities on nanotechnologies that are being done in co-operation with non-OECD countries.

Along with U.S. EPA and other agencies, FDA participated in 2015 *EU-U.S.: Bridging NanoEHS Research Efforts* joint workshop, sponsored by the U.S. National Nanotechnology Initiative (NNI) and the

European Commission held in March 2015 at Venice, Italy. FDA is co-chairing the newly formed Characterization CoR along with EU and is planning future research activities in collaboration with the members of the CoR.

The Global Summit in Regulatory Science (GSRS15) Nanotechnology workshop is being hosted and held in EFSA premises in Parma, Italy, on October 11th, 2015, in collaboration with other regulatory (EMA, ECHA, FDA), research & standards (NIST (US), JRC (EU) NMI (Australia)) agencies. The goal of this workshop is to discuss regulatory science relevant to nanomaterial characterization, prioritize the list of standards needed for regulatory review, and come up with teams to develop these standards. In order not to duplicate the existing and previous efforts, representatives involved in the standards development from OECD, ISO, ASTM, NIST and other entities will present the current status of research and knowledge to come up with future action plan. NNI member agencies were invited to participate.

THE EUROPEAN COMMISSION (EC)

Developments on human health and environmental safety including recommendations, definitions, or discussions related to adapting or applying existing regulatory systems or the drafting of new laws/ regulations/amendments/ guidance materials

a) Nanomaterial definition

The European Commission (the EC) has launched in 2014 a review of its Recommendation 2011/696/EU on the definition of nanomaterial to refect "… in the light of experience and of scientific and technological developments" whether adapations are required. The policy services asked the in-house science service of the European Commission, the Joint Research Centre (JRC), for scientific advice on the question. In June 2015, the JRC released the third report in a series of three, providing its scientific-technical evaluation of options to clarify the definition and to facilitate its implementation. The new report is entitled 'Towards a Review of the EC recommendation for a definition of the term "nanomaterial" – Part 3: Scientific-technical evaluation of options to clarify the definition and to facilitate its implementation' (EUR 27240, http://publications.jrc.ec.europa.eu/repository/bitstream/JRC95675/towards%20review%20ec%20rec%20def%20nanomaterial%20-%20part%203_report_online%20id.pdf)

The new report builds on the first two reports (presented in TdT before) , which were published in 2014: Part I: Compilation of information concerning the experience with the definition (EUR 26567) and Part2: Assessment of collected information concerning the experience with the definition (EUR 26744). The findings of Report 1 and 2 indicate that there is room for improvement to facilitate implementation and clarify communication. Based on these scientific-technical findings the third report describes options on how these improvements can be achieved. These are currently considered by the European Commission, taking into account the current and future applications of the nanomaterial definition in legislation. Consultation with the public and the stakeholders on the findings is planned for the end 2015/beginning 2016, with the review (and potential revision of the Recommendation) concluding in the first half of 2016.

b) The Topical Scientific Workshop on Nanomaterials

A flash report report on the Topical Scientific Workshop on Nanomaterials held on 23-24 October 2014 at ECHA.has been provided already in the last TdT, now also completed with full information on the proceedings published since the last WPMN:

The workshop brought together close to 200 experts in the field of risk assessment of nanomaterials representing academia, policy makers, industry and NGOs. The workshop provided a unique platform for academia and regulators to discuss how to address current challenges from the regulatory perspective which can be reflected and employed in the ongoing and future research topics on nanomaterials. The discussions were reinforced by information of the recent developments and of risk assessment methodologies applied in chemicals management both within and outside the European Union.

The workshop illustrated well the strategic objectives of ECHA, to serve as a hub for building scientific and regulatory capacity in the area of regulatory challenges. The anticipated outcome of workshop was early emergence of new and/or improved approaches in the context of risk assessment of nanomaterials. The outcome of the workshop clearly matched the expectations and its output will form a cornerstone in the guidance developments for the implementation of the REACH, CLP and Biocidal Products Regulations.

The proceedings of the workshop have now been published together with all presentations and background materials are available on ECHA's website;

http://echa.europa.eu/news-and-events/events/event-details/-/journal_content/56_INSTANCE_DR2i/title/topical-scientific-workshop-regulatory-challenges-in-risk-assessment-of-nanomaterials

b) Other

The internal work in the European Commission on the revision of REACH requirements for nanomaterials and the transparency measures, indicated in the previous rounds, continues; there were however no milestones reached in the interval since WPMN-14.

Information on:

e. risk assessment decisions, including the type of: (a) nanomaterials assessed ; (b) testing recommended; and (c) outcomes of the assessment;

In the interval since February 2015, the following opinions on nanomaterials of the Scientific Committee on Consumer Safety (SCCS) were published:

f. Silica, Hydrated Silica, and Silica Surface Modified with Alkyl Silylates (nano form) - SCCS/1545/15 - 20 March 2015 http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_175.pdf

g. Revision of the opinion on 2,2'-Methylene-bis-(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol)(nano form) Submission III (S79)
SCCS/1546/15 - 25 March 2015 - Revision of 25 June 2015 http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_168.pdf

(Note that all past SCS opinions on nanomaterias can aso be found at the same webpage http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/index_en.htm)

h. risk management approaches;

The European Commission recently prepared Draft Commission Regulation amending Annexes IV and VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products, on Zinc Oxide nano and non nano and Carbon Black nano and submitted it for comments under WTO notification scheme.

i. new regulatory challenge(s) with respect to any action for nanomaterials

The following information refers also to the past slightly more distant than January 2015 but has not yet been shared in this circle and should be of interest: In the context of the review programme of existing biocidal active substances performed under Article 89 of the Biocides Regulation (EU) No 528/2012, only 2 actives substances have been so far identified as nanomaterial, in accordance with the definition set in Article 3(1)(z) of Regulation (EU) No 528/2012:

- Silver adsorbed on silicon dioxide as a nanomaterial in the form of a stable aggregate with primary particles in the nanoscale (http://echa.europa.eu/documents/10162/21680461/bpc_opinion_heiq_ags-20_en.pdf). Its assessment is still on-going;

- Silicon dioxide as a nanomaterial formed by aggregates and agglomerates.

On 23rd April 2014, a decision of approval of "Synthetic amorphous silicon dioxide (nano)" (EC No: 231-545-4 CAS No: 112926-00-8) has been adopted by the Commission after its assessment[8]. This approval covers synthetic amorphous silicon dioxide as a nanomaterial in the form of stable aggregated particles of particle size > 1 μm, with primary particles of nanosize. The used assessed was limited to indoor areas by professional operators for the control of cockroaches such as Oriental cockroaches (Blatta orientalis) and German cockroaches (Blattella germanica), and applications onto surfaces including inaccessible locations such as wall voids, ceiling voids, floor cavities, pipe ducts and electrical conduits. The assessment report anticipated developments and as a consequence, the assessment and approval might be reviewed in the light of the evolution of knowledge and guidance on the assessment of nanomaterials. Some information and the assessment report is available on the European Chemicals Agency's website (http://dissemination.echa.europa.eu/Biocides/factsheet?id=1378-18).

Should other nanomaterial form of active substances in the review programme exist, notifications must be made to the European Chemicals Agency by 30 October 2016 in accordance Article 14(2) of Regulation (EU) No 1062/2014, in order to be supported by an application of approval. After that date, unsupported nanomaterial actives substances will have to be withdrawn from the EU market under specified timings.

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

a. Two projects selected under the Horizon 2020 Research Framework Programme (H2020) have started in September:

[8] Commission Implementing Regulation (EU) No 408/2014 of 23 April 2014

1. *NanoREG II: Development and implementation of Grouping and Safe-by-Design approaches within regulatory frameworks* (selected under the call "NMP-26-2014: Joint EU & MS activity on the next phase of research in support of regulation"

2. *NanoFASE: Nanomaterial FAte and Speciation in the Environment* (selected under the call NMP-28-2014 - Assessment of environmental fate of nanomaterials).

b. Horizon 2020 calls for research proposals for 2016-17:

1. NMBP-26-2016: Analytical techniques and tools in support of nanomaterial risk assessment.

2. NMBP-27-2016: Promoting safe innovation through global consolidation and networking of nanosafety centres and strengthening the European industry through cooperation in nanosafety.

3. NMBP-28-2017: Framework and strategies for nanomaterial characterisation, classification, grouping and read-across for risk analysis.

NMBP-29-2017: Advanced and realistic models and assays for nanomaterial hazard assessment.

More here: https://ec.europa.eu/programmes/horizon2020/sites/horizon2020/files/05ii.%20LEIT%20NMBP_2016-2017_pre-publication.pdf

c. Other:

1. DG RTD NMP initiative EU Nanosafety cluster also continues their activities. More details at: www.nanosafetycluster.eu. The 2015 edition of the "Compendium of Projects in the European NanoSafety Cluster" is available: http://www.nanosafetycluster.eu/uploads/files/pdf/2015_NSC_Compendium.pdf .
2. The activities of the cluster were reviewed in Brussels on December 2014: http://www.nanosafetycluster.eu/nsc-meetings/nanosafety-cluster-review-meeting-belgium-2014.html
3. The US-NNCO and European Commission DG Research and Innovation 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 fourth workshop was held in Venice (IT) on 12-13 March 2015 where a seventh Community of Research on characterization was announced (chairs: K. Dawson, A. Patri).

Information on public/ stakeholder consultations;

As indicated, consultation on findings of the review of EU nano-definition is planned in the near future, with format and precise time still to be determined.

Additional Information

An interesting paper published

Valeria Amenta, Karin Aschberger, Maria Arena, Hans Bouwmeester, Filipa Botelho Moniz, Puck Brandhoff, Stefania Gottardo, Hans J.P. Marvin, Agnieszka Mech, Laia Quiros Pesudo, Hubert Rauscher, Reinhilde Schoonjans, Maria Vittoria Vettori, Stefan Weigel, Ruud J. Peters. Regulatory aspects of nanotechnology in the agri/feed/food sector in EU and non-EU countries. Regulatory Toxicology and Pharmacology 73 (2015) 463-476.

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

THE BUSINESS AND INDUSTRY ADVISORY COMMITTEE TO THE OECD (BIAC)

Contribution by BIAC members: ACC, CEFIC, JCIA, NIA, VCI

Part I: ACC Contribution

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 May 2015, the ACC Nanotechnology Panel (www.nanotechnology.americanchemistry.com) (the ACC Panel) provided comments to Environment Canada and Health Canada concerning its proposed approach to address nanoscale forms of substances on the domestic substances list. In August 2015, the Panel submitted comments to the U.S. Environmental Protection Agency (EPA) on its proposed reporting and record keeping rule under Section 8(a) of the Toxic Substances Control Act. The proposed rule and public comments submitted to EPA are available at http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2010-0572-0001.

In both sets of comments, the ACC Panel urged the U.S. and Canadian authorities to collaborate as closely as possible in order to maximize information sharing, to avoid duplication, and to continue to work together on nanomaterials assessment in the spirit of the Nanotechnology Work Plan of the Canada-U.S. Regulatory Cooperation Council. The Work Plan called on the governments *"to increase alignment in regulatory approaches for nanomaterials . . . in order to reduce risk to human health and the environment, promote the sharing of scientific and regulatory expertise, and foster innovation."*[9]

Information on related to good practice documents

While not developed for the purposes of implementing the OECD Council Recommendation, a group of individuals representing current and former Panel members authored a paper titled "Comparative assessment of nanomaterial definitions and safety evaluation considerations" (RegToxPharm 73 (2015) 137-150; doi:10.1016/j.yrtph.2015.06.001). The paper presents an analysis of the elements in both regulatory and advisory (i.e., guidance) definitions of "nanomaterial" from authorities around the world and then discusses which elements are most important for identifying nanoscale materials that may warrant closer examination in terms of the potential for impact to human health and/or the environment. The paper can be used by national authorities, industry, and other stakeholders to inform their assessments of nanomaterials.

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

The ACC Panel continues to provide support for management of the NanoRelease Consumer Products project, the ultimate goal of which is to develop standardized, agreed to methods for measuring and characterizing the release of nanomaterials from solid matrices. Laboratories in six countries are conducting inter-laboratory methods development for releases associated with sanding and weathering

[9] See http://nanoportal.gc.ca/default.asp?lang=En&n=5a56cb00-1.

scenarios, and they will soon have results ready for public release. In May, a paper authored by members of the project's Steering Committee titled "Measuring Nanomaterial Release from Carbon Nanotube Composites: Review of the State of the Science" (doi.org/10.1088/1742-6596/617/1/012026) was published.

In addition, the ACC Panel sponsored two international meetings that advance the global research agenda on important aspects of nanomaterials: the Gordon Research Conference "Environmental Nanotechnology" (June 21-26, 2015; https://www.grc.org/programs.aspx?id=14914) and the 7th International Symposium on Nanotechnology: Occupational and Environmental Health (18-22 October 2015; https://www.nanoeh2015.co.za/).

Consideration on the benefits of nanotechnologies

The ACC blog "American Chemistry Matters" (http://blog.americanchemistry.com/) has featured two stories this year about the benefits of nanotechnology. One concerned silver nanowires in clothing that could harness the body's motion to charge personal electronics, and the other was about nano-enabled advances in medicine. ACC blog articles reach nearly 20,000 readers through various means. More blog posts about breakthroughs in nano-related research and development are planned for this year and 2016.

Information on past, current or future activities on nanotechnologies that are being done in co-operation with non-OECD countries.

BIAC members routinely work on multi stakeholder projects with partners around the world both as individual members and through associations. An example is work done through ISO TC229 where non-OECD country partners include representatives from Iran, Malaysia, and Singapore, among others. Project topics include ones pertaining to terminology, metrology, and EHS.

THE INTERNATIONAL COUNCIL ON ANIMAL PROTECTION IN OECD PROGRAMMES (ICAPO)

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

The PETA International Science Consortium Ltd. [member of The International Council for Animal Protection in OECD Programmes (ICAPO)] organized an international workshop in February 2015, attended by representatives from industry, government, academia, and NGOs with expertise in *in vivo* and *in vitro* (lung) systems, respiratory toxicology, nanotoxicology, and human health risk analysis. The goal of the workshop was to review the state-of-the science and determine the technical needs to develop an *in vitro* system that is predictive of pulmonary fibrosis. Following the workshop a 'Request for proposals' was initiated to choose a lab(s) that can develop the system based on workshop recommendations. PETA's Science Consortium is currently funding Professor Dr. Barbara Rothen-Rutishauser of the Adolphe Merkle Institute at the University of Fribourg, Switzerland and Professor Dr. Vicki Stone of the School of Life Sciences at Heriot-Watt University, Edinburgh, U.K. to jointly develop the test method. The Science Consortium is also funding MatTek Corporation for the development of a three-dimensional reconstructed human alveolar tissue model to be used in Professors Rothen-Rutishauser

and Stone's work. The project design will take into consideration the tools set forth by the OECD such as the 'Guidance on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials' [ENV/JM/MONO (2012)40]. Proceedings from the workshop will be submitted for publication in the later part of 2015.

The Society for Risk Analysis Emerging Nanoscale Materials Specialty Group (ENM SG) convened a workshop in September 2014 to examine the use of Alternative Testing Strategies (ATS) for nanomaterials from a risk analysis perspective. The goal of the SRA Nano Risk II workshop was to explore ways to increase confidence in the use of ATS for testing nanomaterials and how to incorporate ATS into the risk assessment process in a multiple models approach designed to increase the weight of evidence. Three white papers were invited on the topics of a multiple models approach in human health risk assessment, ecological risk assessment, and exposure assessment, as well as a case study and a State of the Science report. PETA's Science Consortium is the lead author on the white paper developed for exposure assessment and a contributing author on the final workshop report that will be shared with the OECD and is currently under review to be published in the international journal Risk Analysis. Through ICAPO, the PETA International Science Consortium Ltd. is working with Health Canada on the development of an AOP for lung fibrosis. The AOP proposal titled 'Induction of secretion of inflammatory cytokines leading to lung fibrosis' was accepted by the OECD's Extended Advisory Group on Molecular Screening and Toxicogenomics (EAGMST), for further development in June 2015. This AOP encompasses a variety of pro-fibrotic materials, including nanomaterials, which share the key events leading to lung fibrosis. As part of a collaborative effort between the European Commission's Joint Research Centre, the U.S. Environmental Protection Agency, and the OECD, an AOP-Wiki has been created to provide an interactive and virtual platform for AOP development and to help scientists worldwide develop AOPs. Working with the organizers of the AOP-Wiki, the PETA International Science Consortium Ltd. is launching a data challenge to encourage new contributors to add to existing entries in the AOP-Wiki using available data. Participants will be judged on the number and merit of their contributions added to the AOP -Wiki between September 15, 2015 and March 15, 2016. Both the number and merit of contributions will be judged by a panel, including scientists participating in the OECD's EAGMST, and prizes totalling up to $8,000 will be awarded to the winner(s).