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

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

**Series on the Safety of Manufactured Nanomaterials
No. 81**

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OECD Environment, Health and Safety Publications

Series on the Safety of Manufactured Nanomaterials

No. 81

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

IOMC

INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

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

**Environment Directorate
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT
Paris, 2017**

Also published in the Series on the Safety of Manufactured Nanomaterials:

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

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 35 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 eleven 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 Organizations.

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
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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. This programme concentrates on human health and environmental safety implications of manufactured nanomaterials (limited mainly to the chemicals sector), and aims to ensure that the approach to hazard, exposure and risk assessment is of a high, science-based, and internationally harmonised standard. This programme promotes international co-operation on the human health and environmental safety of manufactured nanomaterials, and involves the safety testing and risk assessment of manufactured nanomaterials.

This document compiles information on developments on the safety of manufactured nanomaterials, which was provided by OECD delegations during the period March to August 2017. It aims to summarise relevant 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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SECTION I: RECENT AND PLANNED NATIONAL ACTIVITIES IN CHEMICALS REGULATORY AREA ON HEALTH AND ENVIRONMENTAL SAFETY ASPECTS OF MANUFACTURED NANOMATERIALS

AUSTRALIA

1. National developments on human health and environmental safety

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

The [National Industrial Chemicals Notification and Assessment Scheme's \(NICNAS\) current approach to regulating industrial nanomaterials](#) uses the existing regulatory framework applicable to conventional industrial chemicals, with some minor administrative adjustments. Significant reforms to the overall scheme are currently underway and, subject to Government agreement, are expected to be fully implemented by July 2018. The reforms to the regulation of industrial chemicals aim to ensure that assessment effort is proportionate to the risks posed by such chemicals, while maintaining Australia's current robust health and safety standards (further details at <https://www.nicnas.gov.au/have-your-say/nicnas-reforms>). In developing the implementation detail, consideration is being given to the future regulatory approach for nano-forms of industrial chemicals.

To date, NICNAS has assessed one nanoscale substance for use in sunscreens. Testing recommendations were not made. The assessment report was published on the NICNAS website (www.nicnas.gov.au).

Food Standards Australia New Zealand (FSANZ) has set up a Scientific Nanotechnology Advisory Group (SNAG) in relation to food safety and regulation, comprised of experts in the fields of nanosafety, pharmacology, nano-food technology, toxicology and nanometrology. FSANZ has convened two meetings with the SNAG where FSANZ work on technical guidance material and plans for a nanotechnology stakeholder forum were discussed.

2. Activities been initiated to implement the OECD Council Recommendation¹ (e.g. regulatory changes, guidance, voluntary, etc.)

Reforms to the overall regulatory scheme for industrial chemicals are currently underway (refer above). The implementation of these reforms will be consistent with the OECD Council recommendation.

3. Developments related to good practice documents

FSANZ has continued to progress the development of technical guidance material on nanomaterials in food to assist the Australian and New Zealand food industry understand the food regulatory requirements in line with FSANZ's food standards Application Handbook.²

¹ [Recommendation of the Council on the Safety Testing and Assessment of Manufactured Nanomaterials](#)

² The Application Handbook provides practical information on the procedure for making an application to FSANZ to vary the *Australia New Zealand Food Standards Code*:
<http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx>

AUSTRIA

Highlight of developments

- As a 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, which has been prolonged. The last two calls targeting Nano EHS were launched in spring 2016. On transnational level, the 1st transnational call ProSafe was facilitated by the Austrian Research Promotion Agency. Furthermore, on national level, the 4th national Nano EHS call was launched targeting a strength-weakness analysis of the Safe by Design-Concept. The Nano-EHS programme is owned by the Federal Ministry of Agriculture, Forestry, Environment and Water Management and the Federal Ministry of Transport, Innovation and Technology and is handled by the [FFG – the Austrian Research Promotion Agency](#).
- The implementation report 2012 of the “Austrian Nanotechnology Action Plan” recommends also to carry out coordinated enforcement of legislation which is relevant for nanomaterials (see http://nanoinformation.at/fileadmin/nanoinformation/migrated/content/uploads/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 companies 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 contain 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.
- On behalf of the Ministry of Health and Women’s Affairs a survey was done to “Surface-modified nanoparticles – use in cosmetics and in the food industry, health aspects, regulatory issues”. Often results of studies contradict whether surface modifications may decrease the toxicity of a nanomaterial or even increase. Although nanoparticles can be composed of two or more materials, current rules concerning labeling requirements and safety assessments of nanomaterials in the EU do not refer to substances which are used for surface modification of nanoparticles. The survey resulted in a Nano Trust dossier (see <http://epub.oew.ac.at/ita/nanotrust-dossiers>).

1. National developments on human health and environmental safety

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.

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>

2. Activities been initiated to implement the OECD Council Recommendation (e.g. regulatory changes, guidance, voluntary, etc.) .

No activities are planned at the time being.

3. Developments related to good practice documents

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

In the **committee 052 „Occupational health, ergonomics, safety techniques”** the **working group 052.73** with the titel “Nanotechnologies and Nanomaterials” was established: The aim is the compilation, collection and distribution of international standardisation documents (CEN and ISO; lead-managed by Austrian Standards Institute).

4. Information on any developments related to Integrated Approaches to Testing and Assessment (IATA)

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 was funded by the German Environmental Protection Agency and aimed 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). It has now lead to one of the first new nanospecific test guidelines of the OECD and has passed the 2nd commenting round recently

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

The transnational Nano EHS ERANET-SIINN project NanoFarm is a collaborative project between the University of Vienna (Department of Environmental Geosciences, contact Frank von der Kammer), the

Carnegie Mellon University (US), the University of Kentucky (US) and the University of Aveiro (PT). It aims to understand the benefits and impacts of inorganic nanopesticides as CuO. The project covers characterisation in environmental media, transformation and transport, plant uptake and trophic transfer as well as ecotoxicological effects.

The European Union and the United States organize on-going meetings and contacts on an expert level. This US-EU dialogue (www.us-eu.org), bridging NanoEHS research, has three goals: 1) Engage in an active discussion about environmental, health, and safety questions for nano-enabled products; 2) Encourage joint programs of work that would leverage resources; and 3) Support the communities of research. The Communities of Research (CoR) focus on specific question and activities within Nano EHS. **Albert Duschl** from the **University of Salzburg** was appointed as the European co-chair for the CoR Human Toxicity <http://us-eu.org/communities-of-research/search-communities-of-research/predictive-modeling-for-human-health/>

The **H2020 project ACENano** started in January 2017 and develops analytical tools for nanoparticle testing and risk assessment. The **University of Vienna** (Department of Environmental Geosciences, contact **Frank von der Kammer**) is scientific co-coordinator of the project and leads WP1, technical innovation. Specifically in WP1 the outcomes of the NanoEHS project DetectNano will be further developed into an instrumentation to identify ENPs based on their elemental fingerprints in collaboration with the producer and the ETH Zurich. BioNanoNet (Andreas Falk; as 3rd party of NANOfutures) collaborates in WP5 (guidelines, standardisation) and WP6 (dissemination, workshops).

In the H2020 project **PANDORA**, **Albert Duschl (University of Salzburg)** is partner and work package leader. The project is an ITN in which doctoral students work on effects of nanomaterials on the innate immune response. Since innate immunity is evolutionary old, it is highly conserved in the animal kingdom. This allows a direct comparison of human and environmental species (e.g. mussels, wood lice and earthworms). The project thus provides strong links between human nanotoxicology and environmental nanotoxicology, using the options available to both of these fields. <http://www.pandora-h2020.eu/>

In the FWF funded Elise Richter project Nanopesticides Dr. Melanie Kah from the University of Vienna (Department of Environmental Geosciences, contact Melanie Kah) investigates the advantages and problems arising from the use of organic, nano-enhanced pesticides (nanopesticides). Focus is on improvements in pesticide application and differences in transport, degradation and efficiency caused by the nano-specific formulations.

In the FWF funded project CNT-NOM Prof. Thilo Hofmann and Dr. Melanie Kah (Department of Environmental Geosciences, contact Thilo Hofmann, Melanie Kah) investigate the processes of natural organic matter adsorption to carbon nanotubes.

The University of Natural Resources and Life Sciences, Vienna (contact: Eva-Kathrin Sinner) leads a FWF funded project (2015–2018) called **Electroporation as method for inserting functional membrane proteins in mammalian cells**. This project aims at *in vitro* platforms based upon nanotechnology in order to provide reproducible nanoparticle assemblies and binding assays in the context of drug screening and discovery. Using cell-free synthesis and electroporation, organic nanoparticles are used to form phospholipid-based/polymeric vesicles, where functional membrane proteins are integrated. Such nanovesicles are suitable carrier systems that can be further used as models for biological membranes (e.g. to study nanomaterial-cell interactions) and, moreover, deliver functional (membrane) proteins into living cells.

The **EC4SafeNano** project, started in October 2016. It will network existing nanosafety platforms and other stakeholders around the definition and preparation of the European hub of services and support for stakeholders, EC4SafeNano. It will also develop active and effective dissemination and communication activities. **Albert Duschl (University of Salzburg)** is a partner in this project, which is intended to continue as a central European hub beyond the lifetime of the funded project.

The H2020 project **NanoFase** will develop a comprehensive modelling framework for nanomaterials in the environment, including release, transformation in waste streams, 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 lead by University of Vienna.

In the FP7 project **NANoREG** Austrian partners from BioNanoNet (contact: Andreas Falk, national coordinator) and from AIT - Austrian Institute of Technology GmbH are/have been 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, outputs are published as “factsheets” (www.nanoreg.eu). Furthermore, within NANoREG-project one of the Value Chain Case Studies (VCCS) with focus on TiO₂ coating (project name “GALANT”) was successfully finalised done with Austrian industry and scientific partners, in collaboration with Andy Booth/SINTEF/Norway. The final output of NANoREG is made public available, the link to the repository is available on www.nanoreg.eu

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 lead by UNIVIE.

The project **NanoTrust**, funded by the Austrian Federal Ministry for Transport, Innovation and Technology (BMVIT), the Federal Ministry of Health and Women’s Affairs, 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>.

NanoTrust organised the 13th **Asian Nanotech Camp** of the Asian Nanoforum (ANF) which has been held for the first time outside the Asian region (contact: André Gzásó). The Nanotech Camp took place from 3rd to 8th April 2016 in Vienna and Krems and was attended by 24 young scientists from 11 countries.

The Research Platform Nano-Norms-Nature (Head: Prof. Angela Kallhoff; PostDoc: Claudia Schwarz-Plaschg, Department of Philosophy, University of Vienna, <http://nano-norms-nature.univie.ac.at/>) investigates the prospects of nanotechnology in terms of environmental enhancement and the containment and prevention of negative side-effects. The platform organizes workshops and other events with international scholars from the fields of ethics, law, social and natural sciences to explore interdisciplinary approaches towards environmental nano-safety issues. Previous and upcoming events: workshop on “Making Nano ‘Safer by Design’” 18 May 2016; conference “Good Nano – Bad Nano: Who Decides?” 1-2 December 2016; workshop on “Standardization in the Nano-Field: For the Common Good?” 19 May 2017.

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 5th revised edition of the ENT-expertise-catalogue will be published in September 2017. See: <http://www.euro-nanotox.eu/> (contact: Andreas Falk)

In the H2020 pilot-projects **Inspired** (<http://www.nano-inspired.eu/>), **R2R-Biofluidics** (<http://www.r2r-biofluidics.eu/>), **Hi-Response** (<http://hiresponseh2020.eu/index.html>) and **Smart-4-Fabry** (start:), Austrian partner BioNanoNet is responsible for the nano-related safety-tasks. BioNanoNet is developing an integrated safety strategy together with international project partners, to reduce the potential risk upon worker's exposure to MNMs during production and manipulation processes, and to ensure the responsible implementation of nanomaterials (NMs) along the entire value chain of industrial innovation processes (contact: Andreas Falk).

BioNanoNet is partner in the H2020 MSCA-RISE project **NANOGENTOOLS** (start: January 2016; <http://www3.ubu.es/nanogentools/>), which aims at developing new methodologies for the identification and control of hazards associated with nanomaterials, ensuring consumer and society safety. It pursues the main objective of generating a common solid knowledge basis arising from the fruitful cross-sectorial synergy between forefront research centers in nanosafety and industry (contact: Andreas Falk).

The national project **SbD-AT** ("Safe-by-Design - Relevance and added value for Austrian companies"; start: January 2017), funded in the framework of Austrian Nano EHS programme and executed by **Brimatech**, BioNanoNet and the University of Vienna – Department Geosciences, aims to elaborate various aspects on potential implementation of Safe-by-Design concepts in nano-related industrial innovation processes, including possible barriers industry faces (contact: Sabine Jung-Waclik).

The project **SafeNanoKap** started in March 2017, which is funded in the framework of Austrian Nano EHS programme (duration until February 2018). The University of Natural Resources and Life Sciences, Vienna (contact: Marion Huber-Humer or Florian Part), in cooperation with the Austrian Academy of Sciences and the Polymerwerkstatt GmbH (<http://polymerwerkstatt.com>), aim at assessing the applicability of the so-called Safe-by-Design (SbD) concept using the business case on the development of food packaging that contain nanoscale additives. Polymer composites with engineered nanomaterials have a huge market potential but potential adverse environmental risks need to be minimized along the entire value chain of such advanced products (from design to waste disposal). For this, the strengths and weaknesses of the SbD concept shall be identified and summarised using the example of nanomaterial-containing coffee capsules.

DaNa 2.0 is a project financed by the German Federal Ministry of Education and Research (BMBF), which provides and extends a knowledge base on nanomaterials for the general public. The data base contains over 800 articles in German, English and French. All entries are based on carefully quality-checked scientific literature. DaNa 2.0 has become a prime information source for general nanotechnology and nanosafety topics, found under www.nanoobjects.info and www.nanopartikel.info. The project has just been extended to 2019. **Albert Duschl** from the **University of Salzburg** is one of the experts who contribute within this project to the knowledge base.

The so-called **IWWG Task Group on Engineered Nanomaterials in Waste** (IWWG: International Waste Working Group) was launched in 2014, where the University of Natural Resources and Life Sciences, Vienna, is one of the TG leaders (contact: Marion Huber-Humer or Florian Part). Its goal is to discuss and organize workshops and meetings about the fate of engineered nanomaterials in waste streams. End-of-life management strategies for ENM-containing products are urgently needed as many material flow models predicted that ENMs are likely to accumulate in waste streams (see also:

<https://www.tuhh.de/iue/iwwg/task-groups/engineered-nanomaterials-in-waste.html>). In addition, the Nano EHS project **NanoMia** (completed in April 2015; contact: Marion Huber-Humer or Florian Part) augmented that numerous knowledge gaps exist regarding environmental protection laws on nanomaterials as well as towards environmental monitoring of nanoscale emissions caused by waste management processes.

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

The recently established research platform **Nano-Norms-Nature** at the University of Vienna (one section at the Department of Environmental Geosciences, contact Antonia Praetorius and Thilo Hofmann) looks into scientific, environmental, regulatory and societal implications of nanotechnology.

Austria (BMVIT and AIT) was partner of the **ERA-NET SIINN** (“Safe implementation of innovative Nanoscience and Nanotechnologies”) and leader of WP3 (“Risk assessment and life cycle validation”). The ERA-Net 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 transnational Nano EHS ERA NET SIINN 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.

Information on development related to exposure measurement and exposure mitigation.

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

BELGIUM

1. National developments on human health and environmental safety

The Royal Decree concerning the placing on the BE market of substances produced in nanoparticulate state was published on 24th September 2014. This decree involves the registration of substances produced in nanoparticulate state as well as mixtures that contain one or more of these substances.

In August 2016, more than 350 registrations have been submitted, representing more than 150 different substances produced in nanoparticulate state.

In April 2017 a stakeholders meeting was organised, as kick off for the reporting process. The final report (based on the report from the FR registry) can be expected in autumn 2017.

More information about the registry can be found on the website www.nanoregistration.be

2. Activities been initiated to implement the OECD Council Recommendation (e.g. regulatory changes, guidance, voluntary, etc.)

In the framework of the national regulation on nanoparticles, the FPS Economy, Service of Metrology – National Standards started in July 2015 a pilot study on the comparability of nanoparticles size measurement at the national level. As the new regulation requires the registration of nanoparticles dimensions measured by a traceable method, with uncertainty budget associated, this comparison is also the opportunity for researchers and companies to improve comparability of their measurements through understanding of uncertainty contributions in specific measurement methods. The goal is to achieve comparability with different measurement techniques based on different physical principles. The study involves for the moment 3 different microscopy techniques (SEM, TEM, AFM) and 2 centrifugal separation (DCS) but is opened to further collaborations.

3. Developments related to good practice documents

The BE Service for Metrology, part of the Federal Public Service Economy, has recently been accredited according to ISO 17025 for the dimensional measurement of spheric, non-compressible nanoparticles smaller than 200 nm and with a measurement uncertainty of 3 nm.

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

The following research programmes are still on-going:

- 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

1. National developments on human health and safety

In July 2016, the Proposed Prioritization Approach to Address Nanoscale Forms of Substances on the Domestic Substances List was published for a 60 day public comment period (<http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=FA3C8DBF-1>), which ended on September 25, 2016. The document outlines the Government of Canada's approach to prioritizing nanomaterials which are considered in commerce in Canada (on Canada's public inventory) for further action under the *Canadian Environmental Protection Act (CEPA)*. This consultation followed a mandatory information-gathering survey, published under section 71 of CEPA, which identified 53 substances as being manufactured and/or imported at the nanoscale in Canada during the 2014 calendar year. Stakeholder comments are being reviewed. A final prioritization approach is anticipated for spring of 2018.

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

Three nano-related substances, one organic and two inorganic substances, were notified to the program since WPMN16. In addition, two pre-notification consultations (PNCs) were also initiated for nano-related substances. PNCs provide clarity on regulatory requirements prior to submission under the NSNR.

b. Development related to exposure measurement and exposure mitigation;

Canada and the Netherlands co-led a project on metal impurities in carbon nanotubes. The final report entitled "Strategy For Using Metal Impurities As Carbon Nanotube Tracers [[ENV/CHEM/NANO\(2016\)16](#)]" has been declassified.

In 2016, Canada and the US EPA co-led an analysis of the responses received from SG-08 member countries on the survey, *Consumer and Environmental Exposures to Manufactured Nanomaterials*. The draft analysis, entitled *Information used to characterize consumer and environmental exposures for human and ecological risk assessment: Analysis of a Survey*, was presented to the SG-08 at WPMN-16, and was subsequently submitted for declassification. This document is guiding the development of new projects on exposure measurement and mitigation by SG-08.

c. any updates, including 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. The purpose of this review is to ensure that existing SNAC's are underpinned by the best science available and reflect current program policies. 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 reviewed and were rescinded. A further 24 are currently under review.

2. Activities been initiated to implement the OECD Council Recommendation³(e.g. regulatory changes, guidance, voluntary, etc.) If yes, please explain.

See response to Question 1.

³ [Recommendation of the Council on the Safety Testing and Assessment of Manufactured Nanomaterials](#)

3. Developments related to good practice documents;

Canada's Health Department is contributing to the World Health Organization (WHO) Chemical Risk Assessment Network through participation in a collaborative project coordinated by the Dutch National Institute of Public Health and the Environment, RIVM, Netherlands, to develop a guideline document on principles and methods for assessing immunotoxicity following exposure to nanomaterials. Canada is participating in the development of Environmental Health Criteria Document on Principles and Methods to Assess the Risk of Immunotoxicity Associated with Exposure to Nanomaterials.

Canada's Health Department is also contributing to a Nanoinformatics Roadmap jointly led by the USA and EU.

A Canada-led project on 3D Tomography of nanomaterials using transmission electron microscopy was approved as a preliminary work item (PWI 22922) by ISO Technical Committee 229 – Nanotechnologies in November 2016.

A Canada-led ASTM project (WK56764 Characterization of Graphene Flakes Produced by Exfoliation) was approved in November 2016. This work is supported by a Graphene Special Interest Group with 3 industrial partners.

Canada's National Research Council (NRC) released a cellulose nanocrystal reference material in September 2016 (http://www.nrc-cnrc.gc.ca/eng/solutions/advisory/crm/list_product.html). Additional boron nitride nanotube and carbohydrate-based reference materials are under development. Several inter-laboratory comparisons for characterization of cellulose nanocrystals are in progress (NRC) or planned (FPInnovations); this pre-normative work provides input to standards development activities at ISO Technical Committees 229- Nanotechnologies and 6- Pulp, Paper and Board.

Two review articles developed as part of an IUPAC project on "Engineered Nanomaterials and Their Impact on Human Health" are in final stages of publication for Pure & Applied Chemistry. Titles: Engineered Nanomaterials and Human Health: Applications and Nanotoxicology and Engineered Nanomaterials and Human Health: Preparation, Functionalization and Analytical characterization.

Two Canada-led, ISO standards projects have been published and are available for order, including ISO/DTR 19716 Nanotechnologies -- Characterization of cellulose nanocrystals (May 2016) (<https://www.iso.org/standard/66110.html>) and ISO/TR 16196 Nanotechnologies -- Compilation and description of sample preparation and dosing methods for engineered and manufactured nanomaterials (October 2016) (<https://www.iso.org/standard/55826.html>). The underlying science and results of the Canada-Netherlands project entitled "Strategy For Using Metal Impurities As Carbon Nanotube Tracers" have been peer-reviewed and published in the Environmental Science and Technology journal "Detection of Carbon Nanotubes in Indoor Workplaces Using Elemental Impurities" ES&T, 2015, 49 (21), pp 12888–12896.

Canada also contributed to the following ISO standards that will be published in 2017-2018: ISO/DIS 19007 (WG 3/PG 17) In vitro MTS Assay for measuring the cytotoxic effect of nanoparticles; WG 3/PG 19 the use and application of acellular in vitro tests and methodologies to assess nanomaterial biodegradability.

4. Information on any developments related to Integrated Approaches to Testing and Assessment (IATA)

Canada is co-leading a proposal being submitted for consideration at WPMN-16 on *Advancing Adverse Outcome Pathway (AOP) Development for Nanomaterial Risk Assessment and Categorization*. Developed

in collaboration with several partners, this project aims to support the development of AOP frameworks that have the greatest potential to inform categorization and risk assessments of nanomaterials.

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

Scientific research

The NRC is expanding its nanomaterial characterization capabilities to include the development of reproducible and validated methods for quantification of surface functional groups using a range of complementary methods. Initial studies focused on silica nanoparticles are supported by the Government of Canada who will use the information for regulatory identification and to support risk assessment. Other studies are targeting carbon and cellulose based nanomaterials of interest to NRC's partners. The long term goal is to develop the validated methods necessary for the productions and characterization of one or more reference materials that can be used to benchmark surface quantification methods.

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 2016-17 continued 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. In addition, work continued in academic laboratories in Canada and Germany to prepare guidance to support testing of nanoparticles using the OECD Test Guideline for soil column leaching.

Canada's Health Department continues its research projects to investigate the effects of nanomaterials on human health and to characterize human exposure to nanomaterials. One project on surface-modified silica nanoparticles aims 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 was published in January 2016 ((Decan N, et al., *Mutat Res Genet Toxicol Environ Mutagen.*, 2016,796:8-22). Additional manuscripts reporting the toxicity results obtained to date are in preparation. Health Canada also investigated dissolution rate constants, half-lives, and static dissolution (solubility) at gastric pH (1.5) and neutral lung pH for nano zinc oxide, nano-anatase, nano-rutile and their bulk analogues (Avramescu et al., *Environ Sci Pollut Res.*, 2017, 24: 1553).

Canada's Health Department also completed a comprehensive study involving investigation of pulmonary toxicity responses induced by OECD-provided titanium dioxide nanoparticles of different sizes, surface modifications and crystalline structures (Rahman et al., *Mutagenesis*, 2017, 32 (1): 59-76). A peer-reviewed publication on the *in vitro* toxicity of OECD-representative silver nanoparticles has recently been published (Nguyen K et al, *Toxicol in vitro*, 2016, 33:163-173). Another manuscript on the inflammatory effects in mice from single and repeated inhalation exposures of OECD-representative zinc oxide nanoparticles used in sunscreen is in preparation. Two manuscripts describing the biodistribution and hepatic effects from intravenous exposure of mice to Cadmium telluride quantum dots are in preparation. In addition, Canada developed a putative Adverse Outcome Pathway (AOP) for lung fibrosis induced by multi-walled carbon nanotubes and developed strategies demonstrating the applicability of toxicogenomics data and AOP framework for deriving mechanisms-based point of departures in support of human health risk assessment of nanomaterials. The results were published (Labib S, et al., *Part Fibre Toxicol.*, 2016,13:15; Nikota J, et al., *Part Fibre Toxicol.* 2016,13(1):25). Two individual proposals for developing AOPs for lung emphysema and lung fibrosis induced by nanomaterials have been submitted to EAGMST committee (OECD) and have been approved to go forward.

Canada's Food Inspection Agency continues to support research projects that include (1) characterization of silver nanoparticles in food, feed and fertilizer using multiple techniques and (2) development of a real-time monitoring system during and post-enrichment for early detection of foodborne pathogens using functional colorimetric nanoparticles. Regarding (1), characterizing nanomaterials is complex, expensive and requires multiple techniques to confirm the particle chemical and physical properties. In addition regarding (2), emerging functional colorimetric nanoparticles technology has a great potential as a rapid and real-time screening/detection method. This project aims to develop a real-time monitoring system during the enrichment culture and rapid screening and/or confirmation of bacterial colonies/strains using bacterial colonies on selective agar after enrichment for early and accurate detection of pathogenic *E. coli*, *Listeria monocytogenes*, *Salmonella* and *Campylobacter* using functional nanoparticles.

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

Through the efforts of the Working Party on Resource Productivity and Waste (WPRPW), the OECD released in February 2016 the publication *Nanomaterials in Waste Streams: Current Knowledge on Risks and Impacts*. The report brings together individual chapters prepared by various experts: recycling of waste containing nanomaterials (Switzerland); incineration of waste containing nanomaterials (Germany); landfilling of waste containing nanomaterials (Canada); and nanomaterials released from wastewater treatment sludge (France). The purpose of this work was to provide an overview of the existing knowledge on the behaviour of nanomaterials during disposal operations and identify the information gaps. A one day OECD workshop on "Recent scientific insights into the fate and risks of waste containing nanomaterials" took place on November 30th, 2016, back to back with the next meeting of the WPRPW. WPRPW delegates and relevant experts and organizations took stock of recent knowledge on the risks and impacts of nanomaterials in waste streams and discussed advances in this fast evolving research area. At the sixth meeting of the WPRPW in June-July 2015, the Secretariat presented a proposal for an information-sharing platform that allows delegates to share research and findings related to nanomaterials. This information-sharing platform is also accessible to delegates of the WPMN.

DENMARK

1. National developments on human health and environmental safety

The Danish Nanoproduct register was established in 2014⁴. First year of registrations (1st of July 2014 to 30th of June 2015) consisted of 117 products registered by 8 companies. Second year of registrations (1st of July 2015 to 30th of June 2016) consisted of similar information, 100 products from 6 companies. The deadline for the third year (1st of July 2016 to 30th of June 2017) of registration is 30th of August 2016.

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

Several Danish Research institutions are participating in EU research projects on nanomaterials.

⁴ The statutory order is available on: <https://www.retsinformation.dk/Forms/R0710.aspx?id=163367> (in Danish) and as an unofficial translation on the following link: <http://mst.dk/media/mst/9500743/Bekendtg%C3%B8relse%20English%20unoff%20translation%20final.docx>

3. Additional Information

In December 2016 the Danish EPA published a report entitled "Requirements to Measurements of Nanomaterials and Nanoproducts". The report is available on the following link: <http://mst.dk/service/publikationer/publikationsarkiv/2015/dec/validering-af-nanomaalinger/>.

FRANCE

1. National developments on human health and environmental safety

France has submitted the harmonised classification folder on Tio2 (CLP) at the European level.

2. Activities been initiated to implement the OECD Council Recommendation⁵ (e.g. regulatory changes, guidance, voluntary, etc.)

INERIS has developed some preliminary guidance values on human toxicity (inhalation, ingestion) as well as for ecotoxicity for the case of TiO₂ at the nanoform.

INERIS has also, in collaboration with industries federations and the French Ministry in charge of Environment, developed a methodology to evaluate the environmental fate of industrial site producing or using nanomaterials. This methodology aims to be used by industries in order to qualify and quantify the release of manufactured nanomaterial from their processes as well as their impact in the surrounding area (air, soil, water, sediments).

3. Developments related to good practice documents

FRANCE has developed and put in place a good practices guidance for industries producing or using manufactured nanomaterials. This document gives an overview of practices on process effluents treatment as well as guidance on storage and waste management. Informations available on the website <http://www.ecologique-solidaire.gouv.fr/nanomateriaux>

4. Information on any developments related to Integrated Approaches to Testing and Assessment (IATA)

INERIS is coordinating the H2020 NanoReg2 (www.nanoreg2.eu), 42 partners and 10M€ of EU funds, aiming to define regulatory preparedness tools to be implemented for a safe innovation in nanotechnologies. For this grouping and testing strategies are developed on functionality, phys-chem properties, behaviour and effect issues. It is integrated in a safe by design implementation principle and its demonstrations is actually conducted on 7 industrial case studies. Results will be reported in OECD project aiming to build an overview of initiatives conducted in the framework of a safe innovation.

INERIS is also coordinating the H2020 EC4SafeNano (www.ec4safenano.eu) a networking project aiming to first map the needs in expertise addressing risk assessment and management in nanotechnologies but also map the resources available on nanosafety. Both survey are on-going. Results will be used to build

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harmonized expertise using available resources and addressing the needs. This project is open to interested parties who can participate as Associated Partners.

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

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

INERIS, is coordinating several projects addressing the life cycle on the products containing nanomaterials. In particular a new project has just started on the evaluation and optimisation of incineration capabilities of nano-enable products. This project is focusing on incineration of hazardous nano-enable products and follows a previous project which was focusing on the non-hazardous incineration route. INERIS is also conducting several projects addressing the release of manufactured nanomaterials during the use and the ageing of nano-enable products. Tests were conducted in construction market (eg. Cements, coated ceramics and painted wood) but also on transport markets (eg. tyre and road pavements) or cosmetic market (eg. sun screens).

- Current or future activities on nanotechnologies on a multilateral basis, including with non-OECD countries.

France, with the support of BIAC and the suggestions made by several delegates, has elaborate a proposal of new project aiming to move forward to ‘Safe by Design’ for sustainable innovation in nanomaterials and nano-enabled products, by conducting at a first stage, an overview of Hazard & Risk Assessment Tools and Frameworks and their applicability in industrial innovation case studies. Expression of interest will be launch based if the principle is agreed during WPMN17.

6. Additional Information

For example: any consideration on the benefits of nanotechnologies; consideration of ethical implications; other issues.

INERIS has conducted a technico-economic study on nano-silver market, balancing science and patent or industrial property views with sector applications. Next step will then be to focus on few sectorial applications where cost-benefice analyses as well as analyses of alternatives will be conducted.

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 Ministry for the Environment, Nature Conservation, Building and Nuclear Safety taking lead responsibility. The main objective is to facilitate the exchange of views among the stakeholders in the form of expert dialogues.

In June 2016, the 5th dialogue phase started with a conference to reflect on the past 10 years of

discussions and to collect topics for future debates. Among other topics, the use of nanomaterials in the construction sector was proposed and chosen for the next ExpertDialogue.

At the first Expert Dialogue of the 5th dialogue phase on “Opportunities and risks of the application of nanotechnologies in the construction sector”, organised by the BMUB in November 2016, participants discussed various aspects of the sustainable use of nanotechnologies in this sector.

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

<http://www.bmub.bund.de/en/topics/health-chemical-safety-nanotechnology/nanotechnology/the-nanodialogue/>

1. National developments on human health and environmental safety

Federal Environment Agency (Umweltbundesamt, UBA)

On 29th November to 1st December 2016, the joint scientific conference of the Horizon2020 Coordination and Support Action ProSafe and OECD “Science based support for regulation of manufactured nanomaterials” took place at the headquarters of OECD in Paris. Together with the coordination of ProSafe (Ministry of Infrastructure and Environment, NL as well as RIVM, NL) and the OECD secretariat, UBA was in charge of the scientific preparation and organization of the 3 day scientific conference. Main objective of the conference was the discussion of the regulatory relevance of new and State of the Art research and initiatives in the field of nanosafety and to identify the outstanding and future regulatory challenges. This included EU FP7 as well as Horizon 2020 research projects, but also non-EU research and activities related to OECD and ECHA. For this aim scientists, risk assessors, and legal advisors from EU member states and OECD member states and involved in FP7/H2020 projects or OECD WPMN activities met and discussed in groups the regulatory relevant areas of concern, including physicochemical identification and characterization, exposure, fate and kinetics, ecological and health effects as well as testing and assessment strategies. Currently a minutes report is compiled which summarizes the discussions at the conference and highlights the findings of the experts. It also includes summaries of the presented lectures and a plenary panel discussion. It features a compilation of conclusions and recommendations for regulatory questions regarding assessing risk for human health and environment and will feed into a White Paper with short and long term recommendations for policy makers. It is intended to publish the report as OECD document.

On 10th and 11th of October 2017, the German Ministry of the Environment and UBA will host a Scientific Stakeholder Meeting on Nanomaterials in the Environment at the headquarters of UBA in Dessau-Roßlau, Germany. This meeting will include platform and poster presentations on results of national, EU and international projects and activities on nanomaterials environmental safety to discuss the results in a regulatory context. The meeting will also give a forum for discussion between affected stakeholders. Therefore, target audience includes representatives of science, industry, regulation and policy making and NGOs.

Further information on the event and the possibility to register to the meeting can be found at: <http://www.umweltbundesamt.de/node/48591>

2. Activities been initiated to implement the OECD Council Recommendation⁶ (e.g. regulatory changes, guidance, voluntary, etc.)

⁶ [Recommendation of the Council on the Safety Testing and Assessment of Manufactured Nanomaterials](#)

Federal Environment Agency (Umweltbundesamt, UBA)

In cooperation with Canada, Germany (led by UBA) developed a SPSF which proposes a new activity regarding the development of a Guidance Document for the OECD Test Guideline No. 312 “Leaching in soil columns”. This new Guidance Document intends to give guidance on the utilization of this Test Guideline for investigating the mobility of nanomaterials in soil. In cooperation between Canadian and German laboratories experimental work already started. After submission (November 2016) and approval of the SPSF by the OECD WNT (April 2017) work will continue and a first version of the Guidance Document for commenting within the WNT will be drafted.

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.

The draft of the Test guideline went through a 2nd WNT commenting round in Q4 of 2016. Based on the comments, the draft Test Guideline was revised again and prepared for the upcoming WNT-29 in April 2017.

Federal Institute for Risk Assessment (BfR)

BfR is represented in the expert panel for the revision process of OECD Test Guidelines 412 and 413 and respective Guidance Documents such as GD 39 and GD 125. BfR scientists are also participating in the newly formed WPMN AOP Advisory Committee. As an additional input to both activities, we are currently reviewing the applicability of BAL parameters for inhalation toxicology testing of nanomaterials.

3. Developments related to good practice documents

Federal Institute for Materials Research and Testing (BAM)

The large EU/FP7 project SETNanoMetro ‘Shape-engineered TiO₂ nanoparticles for metrology of functional properties: setting design rules from material synthesis to nanostructured devices’ with BAM participation as leader of the work package ‘Characterization of individual TiO₂ NPs and films resulting from their assembly/aggregation’ has finished on March 31st, 2017 after 40 months duration. The publishable final report is in progress. Candidate reference nanomaterials with well-defined size and shape have been identified and a multitude of measurement procedures as standard operating procedures (SOPs) have been issued, three of them being prepared to be submitted as new work item proposal at national standardization bodies.

In the frame of the ongoing large EU/FP7 project NanoDefine ‘Development of methods and standards supporting the implementation of the Commission recommendation for a definition of nanomaterial’ BAM has been leading the work package responsible for ‘Evaluation and selection of techniques and methodologies’. Two main activities resulting from the evaluation of the state-of-the-art of the sizing techniques available for the nanomaterial classification can be reported in form of Open Access reviews published recently:

- ‘How reliably can a material be classified as a nanomaterial? Available particle-sizing techniques at work’, F. Babick et al., J Nanopart Res (2016) 18:158, DOI 10.1007/s11051-016-3461-7

- 'Reliable nanomaterial classification of powders using the volume-specific surface area method', W. Wohlleben et al., J Nanopart Res (2017) 19: 61. DOI:10.1007/s11051-017-3741-x

4. Information on any developments related to Integrated Approaches to Testing and Assessment (IATA)

Federal Institute for Risk Assessment (BfR)

BAuA and BfR decided on including investigations on nanofibers with special emphasis on fiber rigidity in their research program. The focus shall be on characterization, exposure assessment and inhalation toxicology.

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

Federal Institute for Occupational Safety and Health (BAuA), Federal Institute for Materials Research and Testing (BAM) and Federal Environment Agency (Umweltbundesamt, UBA)

In 2017, the German Ministry of the Environment will fund a new project on appropriate measurement techniques and concepts of particle size and particle size distribution of nanomaterials. This project will address the endpoint of particle size and particle size distribution which is a still open activity mentioned in the work plan of the WPMN. Within this project it is intended to update the OECD Test Guideline "Particle Size Distribution/Fibre Length and Diameter Distribution" by developing a new Guidance Document or alternative Test Guideline on particle size and particle size distribution specific for nanomaterials.

This project called "Development of a specific OECD Test Guideline to determine the particle size and number size distribution of Nanomaterials" will run from 2017 to 2020. It will be supervised by UBA and planned to be jointly executed by BAuA and BAM, Project Manager BAuA: Prof. Dr. Thomas Kuhlbusch (Coordinator). The project activities will be orientated on the OECD test Guideline on „Particle Size Distribution / Fibre Length and Diameter Distributions" and shall comprise, either as annex or as review, methods for the reproducible determination of the primary particle size and distribution and the number particle distribution of nanoparticles and nanofibers. The part of nanoparticles will be led by Dr. Harald Bresch (BAM), the part of nanofibers by Dr. Volker Bachmann (BAuA).

Federal Environment Agency (Umweltbundesamt, UBA)

In 2015 a research project was completed (UFOPLAN "Survey on possible environmental exposure of disposal of waste containing nanomaterials") where it was determined that in a waste incineration plant during a state of the art combustion process of with nanomaterials contained waste no higher emissions of nanomaterials in the purified exhaust gas were detected. Nanomaterials were mainly found in the solid residues of the combustion process (ashes and slags). The focus of a current UFOPLAN-project ("Investigations on the possible release of nanoparticles during the deposition and soil-related application of mineral waste") started in 2016 is to analyze how far nanoparticles during recovery and disposal of combustion residues could be released in the environment.

Federal Institute for Risk Assessment (BfR)

Since November 2016, BfR participates in the EU-project ACEnano. The project aims at developing a widely implementable tiered approach to NM physico-chemical characterization. This shall be achieved by creating a "conceptual toolbox" including a tiered approach for cost efficient NMs analysis to facilitate decision-making by choice of appropriate techniques and SOPs. The goal of ACEnano is to underpin the future of NM quality control, labeling and anti-counterfeiting. The main tasks of BfR are the systematical development and testing of methods for sample preparation offering the possibility to characterize the

chemistry of NPs under in situ conditions. This includes e.g. an accurate preservation of the cellular or extra-cellular structures of biological samples or the preservation of the chemical and isotopic content. Once the ideal sample preparation method is established, the materials are analyzed by chemical imaging (ToF-SIMS).

Federal Institute for Occupational Safety and Health (BAuA)

BAuA has started the research project: Evaluation of optical measure devices for the determination of particulate hazardous substances at workplaces (2016 -18), BAuA project manager: Sabine Plitzko: Following the tender, reported in the last Tour de Table for WPNM16, the project was assigned to a project team comprising the Institute of Energy and Environmental Technology e. V. (IUTA) Duisburg and the Institut für Gefahrstoff-Forschung (IGF), Bochum. The project was launched with a kick-off meeting in April 2017.

BAuA was granted a research project sponsored by the BMUB titled “Morphological Characterization of fibre shaped emissions for combustion processes”. (2017-2018) BAuA project manager: Dr. Asmus Meyer-Plath. The project will examine the suitability of currently available methods with only little development efforts for the collection, preparing and analysing of samples collected from exhaust fumes to identify and quantify emitted carbon nanotubes and fibres from combustion processes.

Additional Information

UBA publishes data sheets of applications of nanomaterials for which benefits for the environment are expected. The data sheets focus on the description of application and on ecotoxicological and health aspects. Already published Fact Sheets are available at the UBA website:

<https://www.umweltbundesamt.de/en/topics/chemicals/nanotechnology/good-to-know>

ITALY

1. National developments on human health and environmental safety

Italy participated to the revision of REACH Annexes for substances with nanoforms. It agreed on comments provided by EU Member States.

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

Italian experts involved in NANoREG and ProSafe EU projects attended to the Joint Scientific Conference ProSafe & OECD, which was held at the OECD Conference Centre (29 November-1 December 2016).

The NANoREG National coordinator (Ministry of Health), in collaboration with the Italian partners involved in dissemination activities, organized the final national workshop of the project (Rome, 14 February 2017). All the Italian partners participated at the workshop, presenting the main outputs obtained in the different work packages in which they were involved. A session was specifically dedicated on the future national perspectives in the field of nanotechnologies and nanosafety.

The Italian National Institute of Health (ISS) organized the session “RRI of Nanotechnologies: The RInnovaReNano Project” in the framework of NanoInnovation 2016 Conference (Rome, 20-23 September

2016), with the aim to describe the approach and the first results of this project. This is a two years project funded by the Lazio region to promote synergy between the regional entrepreneurial and ISS for the responsible development and safe use of nanomaterials.

ISS is responsible of the Work Package 5 (Knowledge management, dissemination and exploitation task) in the context of the H2020 project “ProSafe: Promoting the Implementation of Safe by Design”.

In the framework of WP5 dissemination activities:

- The ProSafe WP5 leader attended the final National Workshop of NANoREG project in Rome held at Ministry of Health (14/02/2017). Specifically, the WP5 leader highlighted in her presentation the strong link between PROSAFE, NANoREG and NanoReg2 projects, outlining the scientific support to the European legislation for the improvement of management of manufactured nanomaterials.
- ISS hosted the 5th Consortium Meeting of the ProSafe project in Rome (01-02/03/2017). This meeting was held to present the results of the Joint Scientific Conference of ProSafe and OECD (Science based support for the regulation of manufactured nanomaterials, Paris 29/11-01/12/2016) to the consortium members, to start the procedure for approval of the deliverables and to explain the state of art of the White Paper.

ENEA (Italian National Agency for New Technologies, Energy and Sustainable Economic Development) organized a session on “Toxicology and Ecotoxicology, human and ecological risk assessment of engineered nanomaterials: needs, goals and tools/methods for safer-by-design strategies” at the SETAC Europe (Society of Environmental Toxicology and Chemistry) Annual Meeting (Brussels, 7-11 May 2017).

ISS participates as Additional Partners to the EU H2020 "EC4SafeNano project: European Centre for Risk Management and Safe Innovation in Nanomaterials and Nanotechnologies".

JAPAN

1. National developments on human health and environmental safety

The Ministry of Economy, Trade and Industry (METI) publicised information on safety test data and management methods of manufactured nanomaterials, on METI's website⁷ firstly in 2010 (only in Japanese). Such information was voluntarily provided and annually updated by the manufacturers. METI publicised the updated information in 2016.

In December 2016, a committee established by the Ministry of Health, Labour and Welfare (MHLW) reported risk assessment for the prevention of impairment of workers' health caused by exposure to TiO₂ in nanoscale and non-nanoscale. In addition, MHLW launched development of measurement methods for airborne nanomaterials, carbon black and SW/MWCNT.

⁷ http://www.meti.go.jp/policy/chemical_management/other/nano_program.html

2. Developments related to good practice documents

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). In TC229/JWG2, JISC jointly (with ANSI, the American National Standards Institute) leads a New Work Item Proposal "Measurements of Particle Size and Shape Distributions by Transmission Electron Microscopy" (IS 21363), and also jointly (with ANSI) leads a New Work Item Proposal "Scanning Electron Microscope Measurements of Size and Size Distribution of Nanoparticles" (IS 19749), and leads a New Work Item Proposal "Systematic approach for characterization of nano-objects by asymmetric-flow and centrifugal field-flow fractionation" (TS 21362).

The National Institute of Advanced Industrial Science and Technology (AIST), as a member of the Technology Research Association for Single Wall Carbon Nanotubes (TASC), released "Guide to evaluating emission and exposure of carbon nanomaterials" (in Japanese) and "The comprehensive procedure document for the safety testing of carbon-based nanomaterials" (in Japanese) in February 2017. The former document includes the available practical methods for measuring airborne carbon nanomaterials released through mechanical processes of carbon nanomaterial composites and also presents measurement cases performed by TASC. The latter document includes the protocols of sample preparation, characterization and *in vitro* cell-based assay as a basic hazard assessment of carbon-based nanomaterials such as CNTs and graphene, as well as supplemental animal testing methods and case studies. The English editions of both documents are currently being prepared.

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 aimed to develop fundamental hazard assessment methodology leading to a tiered risk assessment approach for industrial nanomaterials. This programme completed at the end of March 2016⁸. The programme had two R&D themes: 1) establishment of equivalence criteria of nanomaterials and 2) establishment of an intratracheal administration method as low-cost and convenient method for hazard assessment to acquire basic hazard information. Some results of the R&D theme 2) above were presented at a WPMN information sharing seminar on *in vivo* inhalation toxicity screening methods for manufactured nanomaterials held at US EPA, Washington DC, in 21 September 2015. Based on the idea expressed in the seminar, METI is preparing to propose a WPMN project of making a new document concerning *in vivo* inhalation toxicity screening methods for manufactured nanomaterials. A domestic inter-laboratory comparison study on the procedure of intratracheal administration is currently underway.

METI also launched a three-year programme "Commercialising Carbon Nanomaterials for a Low Carbon Emission Society" in mid-2014. This programme completed at the end of February 2017. 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, AIST, as a member of TASC, released the following three documents (only in Japanese) regarding two types of SWCNTs and exfoliated graphene:

- "Safety data and introduction of a voluntary safety management regarding Super-growth single-wall carbon nanotubes (4th Edition)" released in June 2016

⁸ <http://metinanoen.aist-riss.jp/>

- "Safety data and introduction of a voluntary safety management regarding eDIPS single-wall carbon nanotubes (4th Edition)" released in June 2016

- "Information on environmental and health effects and exposure potential of exfoliated graphene for safety management (1st Edition)" released in February 2017.

METI is launching a new three-year project "R&D of methods for safety assessment of cellulose nanofiber (CNF)" (JFY 2017-2019). The technologies that will be developed in this project include measurement and sample preparation of CNF for testing in hazard assessment, in particular, intratracheal administration study and in vitro skin penetration test. In addition, methods of exposure assessment in the lifecycle of CNF and its applied products will be developed.

MHLW has promoted research on the human health aspect of several nanomaterials since 2003 through the Health and Labour Sciences Research Grants, etc. In JFY 2017, five research projects, including a basic research on development of methods for evaluating hazard and disposition of nanomaterials on human health, are progressing.

The Japan Bioassay Research Center has promoted the carcinogenicity test of the nanomaterials, commissioned by MHLW, which focused on the worker's health. Thirteen week inhalation study in rats and four week inhalation study in mouse were carried out in 2016 as the preliminary studies for inhalation carcinogenicity study of TiO₂. Inhalation carcinogenicity study of TiO₂ is on going in JFY 2016-2020.

From JFY 2011 the Ministry of the Environment (MOE) has been focusing their efforts on environmental risk of manufactured nanomaterials via understanding of their environmental fate and ecotoxicity. In JFY 2016 MOE continued collecting and reviewing existing literature on ecotoxicity of manufactured nanomaterials such as TiO₂, silver and CNTs to identify any harmful effects attributed to their particle sizes. For the purpose of developing methodologies for measurement of manufactured nanomaterials in the environment (i.e. , ambient air and surface water), in addition to its attempts for measuring nanoscale TiO₂ in a closed system and then in the open air outside of some waste shredders until JFY 2014, another attempts to CNTs in the ambient air was conducted in JFY 2015-16.

KOREA

1. National developments on human health and environmental safety

This could include recommendations, definitions, or discussions related to adapting or applying existing regulatory systems or the drafting of new laws/ regulations/amendments/ guidance; public/ stakeholder consultations, in particular:

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

- risk assessment decisions, including the type of: (a) nanomaterials assessed ; (b) testing recommended; and (c) outcomes of the assessment;
- development related to exposure measurement and exposure mitigation
- risk management approaches;
- any updates, including proposals, or modifications to previous regulatory decisions; and/ or

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

2. Developments related to good practice documents

For example: standards, technical guidance, technical reports, notable articles in the popular and technical literature.

In Ministry of Environment(MOE), characterization of silver nanoparticle using spICP-MS conducted in environment(published). In addition, the types and size distribution of nanomaterials in products and living environment were studied using spICP-MS et al..

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 (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.”, “Materials specification - Antibacterial silver nanoparticles”, and “Materials specification – Nanostructured Layer for Enhanced Electrochemical Bio-sensing Applications: Characteristics and measurements” These standard documents will complement the work of the OECD WPMN and other related framework documents.

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

- Information on research or strategies on life cycle aspects of nanomaterials, as well as positive and negative impacts on environment and health of nano-enabled applications;
- Current or future activities on nanotechnologies on a multilateral basis, including with non-OECD countries.

Based on the policy and research infrastructures developed from the 1st National Nano-safety Master Plan (2012-2016) at interministerial levels(including Korea Ministry of Environment, 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 make an official announcement by the first half year, 2017.

Based on the basic data and technology related to nano safety as results of the first plan, Ministry of Environment (MOE) plan to introduce effective safety management system of nanomaterials and nano products distributed during the second period. The secondary plan includes assessing the hazards of nanomaterials and evaluating and managing safety assessments of nanomaterials in nanoproducts.

Ministry of Trade, Industry and Energy (MOTIE) launched Tier 2 project (2013-2015) called “Development of safety evaluation based technology for nanoproduct to promote commercialization”. The project has 3 parts; Part 1(Establishment of database for product containing nanomaterials and inventory) includes nanomaterial/product safety inventory including safety data sheets for nanomaterials, and developing algorithm for certification of nanoproduct safety. Part 2 (Nanoproduct safety assessment by case studies) includes in vivo and ecotoxicological safety data production for nanoproducts which have different physicochemical properties, ionization and biopersistence of antimicrobial nanomaterials and preparing recommendation of reference dose for products containing nanomaterials. Part 3 (Development of testing methods and standardization of nanomaterials and product containing nanomaterials) includes development of product chemistry methods for nanoproduct, development of exposure assessment from nanoproduct, development of testing methods for nanorelease from nanoproduct and international cooperation with ISO/TC 229, OECD WPMN, and EU NanoReg.

Next, Tier 3 project(2015-2017) called “Development of safety evaluation based technology for nanoproduct to promote commercialization” is formulation stage. MOTIE in collaboration with several research organizations are studying exposure assessment of graphene and carbon nano fiber in R&D facilities.

In addition, MOTIE is actively participating “Nanotechnology Development Masterplan (2016-2026) which includes safety aspects of nanotechnology.

Moreover, MOTIE launched project called “Development of highly usable nanomaterial inhalation toxicity testing system in commerce” which has been ongoing since 2015 to 2019. On this project, nanomaterial generator and inhalation toxicity chamber suitable for inhalation toxicity study will be developed. The test equipment are verified its performance after inhalation toxicity study in accordance with OECD test guideline and monitoring of homogeneity and concentration of nanomaterials in the chamber. This project is participated in the international cooperation with ISO/TC 229, OECD WPMN.

MFDS(Ministry of Food and Drug Safety) and NIFDS(National Institute of Food and Drug Safety Evaluation) conducted research project on the effect of ionization on the toxicity of nanoparticles from 2015 to 2016. The result of the research project was published in journals such as nanotoxicology, etc. In 2017, NIFDS performs the CFE assay (Colony Forming Efficiency assay) with nanomaterials such as carbon tube and TiO₂ for the verification of nano toxicity. In the field of nanomedicines, research areas incorporate the current viewpoint of other regulatory agency for nanomedicines, research trend of domestic industry-academia-research, digging out candidates for toxicity evaluation methods for commercial use, and working out a road-map. According to this road-map, we are preparing specific guidelines of nanomedicines for approval/reviews, and we look forward to promoting nanomedicine development for the pharmaceutical industries. In the field of nanofood safety, we have conducted the validation study on internal absorption assessment methods of organic nanofoods. Also, in the field 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.

MALAYSIA

1. National developments on human health and environmental safety

National Nanotechnology Centre (NNC), formerly known as National Nanotechnology Directorate was established on 13th January 2010 and officially began operations in July 2010 under the auspices of the Ministry of Science, Technology and Innovation. NNC serves as the National Focal Point for the coordination of research, development and all related activities of nanotechnology in Malaysia. NNC is also tasked to create awareness by creating a conducive environment that encourages invention, innovation and technology development in the nanotechnology community.

2. Activities initiated to implement the OECD Council Recommendation

Malaysia being full adherent to the OECD MAD system acknowledges the inclusion of nanomaterials in the scope. Test facilities have been made aware on some of the existing OECD Test Guidelines which may need to be adapted to take into account the specific properties of nanomaterials.

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

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

NNC is embarking on a 5-year project (2016-2020) to conduct risk assessment on nano-based products with reference to the OECD Series on the Safety Manufactured Nanomaterials reports, mainly; [ENV/JM/MONO\(2012\)40](#) on sample preparation and dosimetry; [ENV/JM/MONO\(2016\)7](#) on physical-chemical properties; [ENV/JM/MONO\(2014\)34](#) on genotoxicity; [ENV/JM/MONO\(2014\)1](#) on ecotoxicology and environmental fate; and [ENV/JM/MONO\(2015\)30](#) and [ENV/JM/MONO\(2016\)63](#) on risk assessment. Project outputs will be made available to the general public.

- **Current or future activities on nanotechnologies on a multilateral basis, including with non-OECD countries**

- i. On 28-29 September 2016, NNC organized a seminar on the OECD EHS programme in Putrajaya, Malaysia. Dr Eeva Leinala and Dr Peter Kearns were invited as key speakers to talk on chemical and nanomaterial management.
- ii. On 2-4 May 2017, the Asian and Pacific Centre for Transfer of Technology (APCTT-ESCAP) together with NNC jointly organized a Regional Conference on Nanotechnology in Putrajaya, Malaysia. Experts from several ESCAP member countries were present to share their views on nanotechnology for safe and sustainable development.
- iii. On 22-23 August 2017, NNC will be hosting the annual Asia Nano Forum Summit in Johor, Malaysia.
- iv. NNC is talking to UNITAR over the possibility of organizing a workshop/training on nanosafety in Malaysia in early 2018.

NETHERLANDS

Highlight of developments since the 16th meeting of the WPMN

- At the end of the NANoREG project all scientific data are made available via the NANoREG Results Repository.
- The separate chapters of the ProSafe Joint Document will be published as a special issue of NanoImpact.
- GUIDEnano and SUN projects present final versions of the tools to identify and mitigate possible health risks for workers, consumers and the environment associated to the use of nanotechnologies.

1. National developments on human health and environmental safety

Activities in the last phase of the **NANoREG project** included finalisation of the deliverables, presentation of data in the NANoREG Results Repository, preparation of the Draft Final Report to the European Commission, and the organisation of the NANoREG evaluation meeting.

Over 60 scientific deliverables result from the NANoREG project. The knowledge developed within the scientific Work Packages form the building blocks for the answers to the key regulatory questions on health and safety defined at the start of the project. The results also are the basis for the NANoREG Regulatory Framework and accompanying Toolbox.

All scientific data are available via the NANoREG Results Repository, which can be reached via the website www.nanoreg.eu. By doing so, the NANoREG Coordinator and Consortium expect to stimulate the exchange of Environmental, Health and Safety data between nanosafety projects and to create synergy between these projects. The Final Report – expected mid-May – presents the results of the project, in terms of products such as protocols and technical guidance documents, and knowledge such as a ranking of nanomaterials according to their level of toxicity.

During an evaluation meeting organised in October 2016, participants discussed the possibilities for integration of results of the NANoREG project in other projects, keeping in mind the regulatory and policy makers' perspective. The most important conclusions of this meeting are that proposals for modification of OECD Technical Guidelines will be forwarded to the OECD to be included in near future working programmes, that the harmonisation and/or further development of protocols should be prioritised by the NanosafetyCluster, and that data analysis and data curation will be necessary and possible by making the NANoREG data public available (the European projects NanoReg2 and caLIBRAte announced already to elaborate on analysis and exploitation of data generated by NANoREG).

The **ProSafe** White Paper will integrate key results from the NANoREG project including the Framework, the Toolbox, the Safe-by-Design concept, the issues identified in the ProSafe Joint Document, current research needs and policy recommendations. Activities for the NL-coordinated H2020 [ProSafe project](#) focussed on the OECD-ProSafe Scientific Conference that focussed on the draft Joint Document that served as a key document for the discussions. Involved scientists prepared short presentations including a set of questions.

The Joint Document addresses nine topics of concern varying from the physicochemical properties of nanomaterials and ecological effects to endpoints to a more abstract enquiry for risk assessment. For the latter topic, general frameworks and approaches for nanomaterials have been reviewed for their applicability in the field of nanomaterials and nanosafety. The separate chapters of the Joint Document are expected to be published as a special issue of the scientific journal NanoImpact. For the last months of the ProSafe project activities focus on writing the ProSafe White Paper and dissemination of NANoREG and ProSafe results.

A national project on health risks of nanomaterials in food was funded by the Netherlands Food and Consumer Product Safety Authority. Research was conducted on the oral intake of added titanium dioxide and its nanosized fraction from food products, food supplements and toothpaste by the Dutch population ([Rompelberg et al. 2016](#)), and on the **risk assessment of titanium dioxide nanoparticles via oral exposure**, including toxicokinetic considerations ([Heringa et al., 2016](#)). As indicated in the corresponding [news item](#) on the RIVM website, health effects due to exposure to titanium dioxide nanoparticles via food, food supplements and toothpaste cannot be excluded and further research to gain more insight on the likelihood of effects after long-term exposure is recommended.

2. Developments related to good practice documents

The Netherlands (RIKILT–Wageningen Research, RIVM and DSM) were leading the work under ISO/TC 229 on ISO/DTS 19590 “Nanotechnologies – Size distribution and concentration of inorganic nanoparticles in aqueous media via single particle inductively coupled plasma mass spectrometry”. This work has been published recently as [ISO/TS 19590:2017](#).

RIVM has initiated two research projects regarding occupational health and safety when working with nanomaterials. The first project evaluates over 40 existing tools for **occupational risk assessment** of nanomaterials, addressing user-friendliness and practical feasibility as well as scientific quality. The second project evaluates the Dutch Provisional Nanoreference Values (NRVs) against new scientific data on proposed Occupational Exposure Limits (OELs) for nanomaterials, and the applicability of the NRVs for process-generated nanoparticles and fraction of nanoparticles in conventional products. Final results of these two projects are expected to be publicly available before summer.

3. Information on any developments related to Integrated Approaches to Testing and Assessment (IATA)

The contribution of RIVM to the Horizon2020 project [NanoFASE](#) deals with the development of the nanospecific fate model SimpleBox4.0-nano ([SB4N](#)). SimpleBox is the environmental fate model that is used as the basic model for environmental fate assessment of chemicals within the REACH Regulation. The SB4N application is a nanospecific modification of SimpleBox, incorporating nanospecific formulations for the processes that specifically determine the environmental fate of nanomaterials. The detailed process formulations are derived within a part of the additional activities within NanoFASE. RIVM is involved in developing the process formulations for the aquatic compartment. Wageningen University and Research (WUR) is leading the work package on biota uptake of nanomaterials where exposure and uptake studies have been initiated in earthworms and in *in vitro* models for the human gastrointestinal tract.

Research institute RIKILT published work where a [Bayesian Network was developed](#) for the **prediction of the hazard potential** of nanomaterials to support human health risk assessment.

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

[GUIDEnano](#) and [SUN](#) are two FP7 projects with the aim to support the safe design and application of nanomaterials in nano-enabled products and processes. Both projects are drawing to a close (March/April 2017) and the tools are in their last stage of development. These tools can be used to aid industry and regulators to identify and mitigate possible health risks for workers, consumers and the environment associated to the use of nanotechnologies.

The third and last version of the GUIDEnano tool facilitates the user to perform a quantitative risk assessment of nanomaterials and nano-enabled products throughout their life-cycle according to the most recent scientific knowledge. The quantitative risk assessment includes insight into uncertainties originating from assumptions made in exposure and hazard assessments. The tool has been tested by means of case studies by industrial partners in the consortium and is currently undergoing some last changes to improve its user-friendliness. Discussions are ongoing at different levels ([NanoSafetyCluster](#), Dutch governmental authorities, industrial stakeholder meetings, etc.) on how to ensure the viability of the tool after the end of the project.

An event was organized at RIVM in March 2017 for stakeholders and potential users in the Netherlands to become acquainted with the GUIDEnano and SUN tools and to demonstrate their possibilities. A summary of the event will be available soon.

Under auspices of WHO/IPCS an expert group was installed that is preparing an Environmental Health Criteria Document Principles and Methods of Assessing the **Risk of Immunotoxicity Associated with Exposure to Nanomaterials**. Henk van Loveren (Maastricht University, formerly RIVM) has been appointed as the chair of this expert group. A scoping meeting and a subsequent workshop were organized in 2015 and 2016 respectively. A new version of the document is now almost ready for public consultation.

A finalising meeting to incorporate all comments is being planned for October 2017 at RIVM. OECD is involved in this endeavour as an observer.

Maastricht University (Department of Toxicogenomics), in collaboration with the National Autonomous University of Mexico, are performing collaborative research into the effects of **titanium dioxide nanoparticles as component of food additives**. Based on the classification of titanium dioxide as a possible inhalatory carcinogen (IARC, category 2B), studies were undertaken to investigate effects of oral uptake of the food additive E171 on the development of colon cancer. E171 comprises titanium dioxide particles, including nanoparticles. In a mouse model, facilitation of colon tumour formation was noted and toxicogenomic approaches revealed different potentially underlying pathways, e.g. immune, inflammation, signal transduction pathways. A next step is finding resources for a human intervention study to investigate if similar biomarkers (regulated genes or pathways) as those seen in animal and *in vitro* studies can be found in humans after exposure. METC permission has been granted.

The [NanoReg2](#) project, built around the challenge of coupling Safe by Design to the regulatory process, will 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. The project contributed to further implementation of the Safe by Design and Regulatory Preparedness concept, starting with awareness raising activities among innovators and regulators. In addition, some tools are being developed which support Safe by Design. Furthermore, a workshop was organised where several concepts were created for a so-called trusted environment, which is a means to exchange knowledge and information throughout the innovation process between companies, universities and research institutes (innovators) on the one side and governments (regulators, policy makers) and semi-governmental organisations (regulatory risk assessors) on the other side.

Within the (EU) FP7-project [NANOSOLUTIONS](#) two tasks were performed by TNO. The first task considered deriving characterisation factors (effect factor, fate and exposure factor) for quantum dots (QDs), which were subsequently integrated into a Life Cycle Assessment (LCA) QDs in printing ink.

The second task was to predict the potential health effects of CuO nanoparticles (NPs) after entering the airways, in both healthy and asthmatic individuals. In conclusion, it was demonstrated that combining the MucilAir™ model with an air exposure system is a practical and relevant approach to assess nanoparticle inhalation toxicity *in vitro*.

Last November [EC4SafeNano](#) started as a three year H2020 project. The EC4SafeNano initiative is an ongoing effort to build a European Centre for Risk Management and Safe Innovation in Nanomaterials and Nanotechnologies. EC4SafeNano aims to bridge the gap between scientific knowledge on hazard and risk, and ‘fit-for-purpose’ risk management tools and strategies supported by measurement and control methods. The consortium comprises 15 partners from 11 European Member States with significant expertise on risk assessment and management. The overall objective of the EC4SafeNano project is to develop a sustainable distributed Centre of European organisations that offers services for Risk Management and Safe Innovation for Nanomaterials & Nanotechnologies. The Centre will be structured as a hub-based network managed by a core group of public-oriented bodies providing risk management and safe innovation support to all stakeholders. The Centre will seek financial support from the stakeholders and service users to sustain its operability in the longer term.

The contribution of TNO to the EU-project [FutureNanoNeeds](#) has been continued. A framework was developed to forecast exposure of the next generation of nanomaterials using Bayesian networks. 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 immunotoxicity: inflammasome activation and dendritic cell maturation.

The FP7 project [NanoDefine](#) consists of 28 partners and is coordinated by Research institute RIKILT. The project aims to explore and develop conceptual and technical tools for the classification of any materials according to the European definition of a nanomaterial. It is addressing the issues on the availability of suitable measuring techniques, reference material, validated methods, acceptable for all stakeholders (authorities, policies, industries). It will integrate an interdisciplinary approach and a close international cooperation and networking between academia, concerned industries and standardization bodies. Within this project [a summer school](#) will be organized on the so-called NanoDefiner eTool.

Research institute RIKILT is partner in the EU project [ACEnano](#). The project will introduce confidence, adaptability and clarity into nanomaterial risk assessment by developing a widely implementable and robust tiered approach to nanomaterials physicochemical characterisation that will simplify and facilitate contextual (hazard or exposure) description and its transcription into a reliable nanomaterials grouping framework.

RIVM has been involved in drafting the **NanoSafetyCluster** [2017-2021 Action Plan](#).

RIVM is partner in the EU project “Performance testing, calibration & implementation of a next generation system-of-systems risk governance framework for nanomaterials” ([caLIBRAte](#)) that started on 1 May 2016. The caLIBRAte project aims to establish a state-of-the-art risk governance framework for assessment and management of human and environmental risks of manufactured nanomaterials and nano-enabled products. The framework will be a web-based “system-of-systems” (SoS) linking different tested calibrated models and methods for screening of apparent and perceived risks, for control banding, decision support tools, and risk surveillance, risk management and risk guidance documents. After selection of models in the first year of the project, testing and calibration of these models is planned for the coming year, using available environmental health and safety data as well as data generated in the project. By engaging stakeholders caLIBRAte will develop an up-to-date, user-friendly and reliable risk governance framework.

SWEDEN

National Platform for Nanosafety

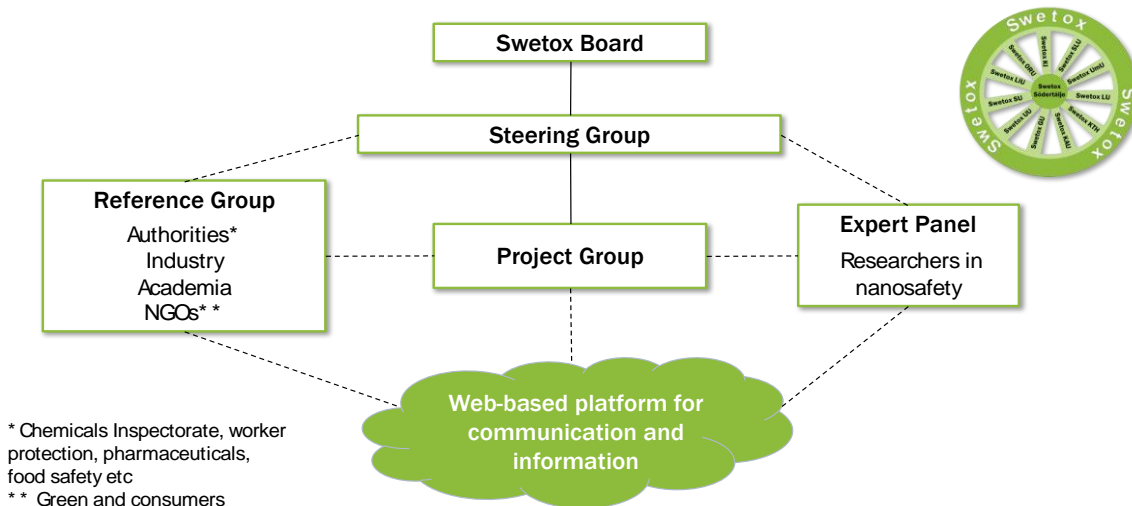
The Swedish Government has commissioned Swetox, a national academic centre for research on chemicals safety in collaboration with 11 Swedish universities, to develop a National Platform for Nanosafety. Its goal is to facilitate information exchange and communication between academia, authorities, industry, NGOs and other stakeholders working in the area nanosafety and also to identify hurdles that hinder safe management of nanomaterials. The platform was funded for 2016 with a likely extension until end of 2020 with 5M SEK per year (around 600 000 € per year). The platform initiative is a follow up of a proposal from a Government Commission on Nanosafety published in 2013.

An action plan 2016-2018 was developed and, in a first round, discussed with the Swedish Chemicals Agency and other agencies responsible for legislation in the area of nanosafety. In particular, agencies expressed an interest of getting scientific support via the platform in decision making, in regulatory work within the EU, and work in OECD in the area of nanosafety.

A stakeholder meeting was held to discuss how the platform could be of best support to broader groups of stakeholders. Based on these discussions the organization of the platform was established; to the project team at Swetox will be attached (1) an expert panel with scientist from different research areas related nanosafety and (2) a reference group with stakeholder representatives. To improve transfer of knowledge from academia and improve collaboration and communication between stakeholders a web portal will be created. The work to develop the web portal including a relevant and searchable database with scientific and regulatory information on nanosafety, a Q&A section etc. is currently in progress.



National Platform for Nanosafety at Swetox organisation



In March 2017, the Swedish National Platform for Nanosafety, SweNanoSafe, arranged its first conference together with the Swedish partners of NANoREG, the Swedish Mistra Environmental Nanosafety Programme and the Swedish Chemicals Agency. The theme of the programme was “From Research to Regulation”.

At the conference, an overview of the NANoREG project and its key outputs was provided together with a presentation of the Swedish contributions to NANoREG and an overview of NanoReg2 and CaLIBRAte. Additional presentations included an overview of current nanosafety research, an overview of the Swedish Mistra Environmental Nanosafety Programme, a regulatory update from the Chemicals Agency and a commentary from the Center for International Law (CIEL). Short scientific talks were also given from the Swedish participants of the NANoREG project and researchers in the Mistra Environmental Nanosafety Programme. The conference programme further included panel discussions between various stakeholders and reflections on the conference from a policy perspective. A conference report and presentation slides will soon be available at <http://swetox.se/en/presentations-from-swenanosafes-first-annual-conference/>.

Swedish Nano Registry

The Swedish Chemicals Agency was commissioned by the government to investigate a way of formulating a reporting requirement to provide information on nanomaterials in chemical products and articles to the Swedish Products Register. Several previous reports have indicated a need for knowledge regarding the use of nanomaterials and the quantities concerned. The investigation includes proposals for statutory changes, an impact assessment and an analysis of the EU legislation.

The Swedish Chemicals Agency proposes that those who report chemical products to the products register shall, in addition to the information that is currently reported, also provide further information regarding any nanomaterials contained in the product. The proposal covers nanomaterials which have been intentionally added to the product, regardless of concentration. Nanomaterials are defined in accordance with the recommended definition of the European Commission. Although, this proposal does not cover nanomaterials that are naturally occurring or unintentionally produced.

Exemptions from the reporting requirements are proposed for companies with a turnover of less than SEK 5 million per year during a period of evaluation. These companies should only need to tick a box if they believe that their products contain nanomaterials. During the period of evaluation, the same exemption should also apply to nanomaterials in the form of pigments.

The product groups, which are already exempt from the reporting requirements in the Products Register, will remain exempt for any purposes of this proposal. Those product groups are waste, food and animal feed, pharmaceuticals, cosmetics and tattoo ink.

An important position in the investigation is that any proposed measures should only be aiming to create an overview of the nanomaterials used in Sweden. Thus it should be possible to identify and distinguish nanomaterials from the data collected. It will be possible to use these data to keep statistics on the use of nanomaterials. These statistics can be used in enforcement as well as the basis for future regulatory development within environment, health and safety. It can also be used to monitor trends, fulfilment of environmental objectives, development of indicators and research.

The Swedish Chemicals Agency does not propose any reporting requirements for nanomaterials in articles as a part of this report. It is however suggested that such reporting requirements may be studied in a separate investigation. The plan is to have the reporting requirements in place during 2018 and the first reporting in February 2019.

Three review reports on “Nanomaterials and -toxicokinetics, -genotoxicity and –inhalation”

The Swedish Chemicals Agency have published three literature review reports on Nanomaterials and toxicokinetics, Nanomaterials and genotoxicity and also Nanomaterials and inhalation. The reports have been submitted as a contribution to the large review in the NANoREG project.

Uptake and biodistribution of nanoparticles – a review

[Rapport 12/16](#)

Nanomaterials and genotoxicity – a literature review

[Rapport 13/16](#)

Interactions between inhaled nanomaterials and biomolecules in the lung – a study of the risks of systemic effects

[Rapport 14/16](#)

THAILAND

1. National developments on human health and environmental safety

The Thailand Industrial Standards Institute (TISI) organized a public hearing to review the TISI Standards Master Plan 2017-2021 on Oct 20, 2016. The plan will reflect the new direction of the government economic plan of Thailand 4.0 and the new S-Curve. NANOTEC submitted its proposal for 5 additional industrial standardization manuals related to nanotechnology by 2021:

- Preparation of Material Safety Data Sheet for nanomaterials
- Standard Guide size measurement of nanoparticles using AFM
- Nanotechnology – compilation and description of toxicology screening methods for nanomaterials
- Guidance on methods for nano and microtribiology
- Occupational risk management applied to engineered nanomaterials Part 2: Using of control banding approach

The National Science Technology and Innovation Policy Office (STI) with support from NANOTEC conducted a public hearing session on the new Nanosafety and Ethics Strategic Plan 2017-2021 on Dec 22, 2016. The session included a panel discussion and group activities. The plan will focus on 3 strategies: Knowledge Management (accessibility to information), regulation and standards, public engagement. The plan is expected to be put forth for final approval in May/June 2017.

2. Activities been initiated to implement the OECD Council Recommendation⁹ (e.g. regulatory changes, guidance, voluntary, etc.)

Since the NanoQ label inception in 2012, several companies have received the label in areas related to anti-bacteria coating properties for color, plastic, and fabric sector. There is also an interest to issue NanoQ for cosmetic products. But the association thinks it is best to first request the company to seek Thai FDA approval then they can seek NanoQ application.

On-going collaboration with the 4 NANO Plus+ Centers) and the Training of Trainers on Nanotechnology (TTN) members to include aspects of nanosafety in their workshop programs. This year 4 workshops on aspects of nanosafety have been conducted in which over 300 participants included students, community representatives, and local administration officials have attended.

NANOTEC participated in providing input to the WPMN projects on phys-chem in December 2016

To identify and share relevant literature on:

- a) Existing decision trees/frameworks for chemicals (in OECD, academia, government labs, etc.);
- b) Existing standards and guidelines (i.e.: OECD, ISO, ASTM, BAM, CEN); and
- c) Evaluation tools (Data Quality, Ranking Systems)

Dr. Wannee Chinsirikul, Executive Director NANOTEC was invited to give a talk on "Nanotechnology Policy in Thailand towards Standardization" at the 4th International Roundtable on Nanotechnology (CHInano 2016 Conference and Expo) October 25-28 in Suzhou, China.

Co-organized the NanoSafety Seminar 2016 on November 28 at Greenery Resort Khao Yai as part of the NanoThailand 2016 conference. Speakers from Indonesia, Japan, Korea, Malaysia, Singapore, Switzerland, Taiwan, and Thailand participated in giving presentations from country report to specific research projects.

In 216 EPISKIN Academy and several research agencies including NANOTEC organized 2 seminars to address the need to minimise the use of animal testing in Thailand. The first seminar was on New Paradigm and Alternative Methods in skin irritation testing and the 2nd seminar was on Understanding and acceptance of alternative methods.

Organized the seminar on "Industrial Standards and manual guidelines for sustainability of Thai industries" on 31 March at Thailand Science Park.

Conducted nanosafety training session for two companies in April.

3. Developments related to good practice documents

For example: standards, technical guidance, technical reports, notable articles in the popular and technical literature.

NANOTEC submitted its proposal for 5 additional industrial standardization manuals related to nanotechnology by 2021:

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- Standard Guide size measurement of nanoparticles using AFM
- Nanotechnology – compilation and description of toxicology screening methods for nanomaterials
- Guidance on methods for nano and microtribiology
- Occupational risk management applied to engineered nanomaterials Part 2: Using of control banding approach

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

Published Papers:

Ultra-sensitive NO₂ sensor based on vertically aligned SnO₂ nanorods deposited by DC reactive magnetron sputtering with glancing angle deposition technique.

Texture orientation of silver thin films grown via gas-timing radio frequency magnetron sputtering and their SERS activity

pH-Responsive polymeric micelles based on amphiphilic chitosan derivatives: Effect of hydrophobic cores on oral meloxicam delivery

Surfactant effect on the physicochemical characteristics of γ -oryanol-containing solid lipid Nanoparticles

Determination of silver in personal care nanoproducts and effects on dermal exposure

(Research paper) Interaction evaluation of silver and dithizone complexes using DFT calculations and NMR analysis.

(Research paper) Human primary erythroid cells as a more sensitive alternative in vitro hematological model for nanotoxicity studies: toxicological effects of silver

5. Additional Information

For example: any consideration on the benefits of nanotechnologies; consideration of ethical implications; other issues.

Collaborate with Nanotechnology Association of Thailand with support from Asia Nano Forum (ANF) of Singapore to organize the Nanosafety Seminar 2016 on November 28 at the Greenery Resort Hotel. Speakers from 8 nations participated in the seminar.

Effort to collaborate with Leibniz Institute of Photonic Technology (IPHT), Jena, Germany via "Germany: Funding to Establish Joint Research Programs with International Partners".

Name of joint research project: Innovative Intracellular Nanosensors and their Toxicology

Continue effort to initiate collaboration with Minister of Science, Technology and Innovation (MOSTI, Malaysia) in Physical-chemical analysis Toxicology testing. Participated at the UN APCTT – APCTT regional workshop on nanosafety and sustainable development in Malaysia

UNITED KINGDOM

Highlight of developments since the last meeting of the WPMN

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

- Information on research or strategies on life cycle aspects of nanomaterials, as well as positive and negative impacts on environment and health of nano-enabled applications;
- Current or future activities on nanotechnologies on a multilateral basis, including with non-OECD countries.

Human Health

Public Health England's current MN safety research activities include:

1. Experimental assessment of inhalation exposures from consumer spray products available in the UK containing engineered nanomaterials (funded by National Institute for Health Research); and

2. Nanotoxicology inhalation studies on:
 - a. carbon nanotubes (continuation of work funded under EU NANoREG project);
 - b. effects of ceria nanoparticles on typical and allergen/asthma disease model and effect of co-exposure to diesel exhaust particulates;
 - c. effect of lung surfactant proteins on uptake and translocation of NPs including gold NPs; and
 - d. uptake and translocation of NPs from fusion/fission fuel cycle including tritiated particles (new EU Transat project commencing Sept 2017).

Environment

NanoFASE project: Pathway analysis for environmental release of nonoenabled products.

A full life-cycle pathway analysis of a range of MNs has been conducted within the NanoFASE project (EU H2020, led by the UK's Natural Environment Research Council).

- The aim of the research is to identify the points in the life cycle at which releases of MNs to waste streams and the environment may occur.

A review has been compiled by considering different usage scenarios working with industrial partners in the NanoFASE consortium, external stakeholders and literature review. The MNs evaluated were TiO₂, Cu₂O, Cu, ZnO, Ag, Fe₃O₄ and FeO.

The comprehensive analysis will serve to prioritise subsequent experimental, analytical and modelling developments in the project and in other actions focussed on the environmental fate and effects of nanomaterials.

NanoFASE project: A framework for assessing release, fate and exposure of nanomaterials in the natural environment - Specification for the NanoFASE model

A recent report outlines the structure of the soil-water MN fate model.

- a. It describes the proposed spatial structure and how this will be broken down into distinct components (classes) which will each simulate MN transport and transformations within specific environmental compartments;
- b. The structure and hierarchy of these classes within each environmental compartment under consideration (soil, river, lake/reservoir, estuary, coastal and sea) is described, along with an outline of the modelling approach to be taken within each; and
- c. Initial model structure will be completed in the new period, incorporating regular input and feedback from relevant stakeholders.

UNITED STATES

1. National developments on human health and environmental safety

This could include recommendations, definitions, or discussions related to adapting or applying existing regulatory systems or the drafting of new laws/ regulations/amendments/ guidance; public/ stakeholder consultations, in particular:

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

Under section 5 of the Toxic Substances Control Act (TSCA), the U.S. Environmental Protection Agency (EPA) reviewed TSCA premanufacture notices for 7 carbon nanotubes, and a nanocellulose material. Based on potential risk findings to human health and the environment, EPA issued consent orders and/or significant new use rules (SNURs) for all of these materials. See details in #1c for risk management approaches and #4 for required testing.

On November 17, 2016 EPA issued 3 final SNURs, on single-walled carbon nanotubes, a bimodal mixture of multi-walled and other classes of carbon nanotubes (since withdrawn and pending a notice and comment proposed rule), and carbon nanotubes.

- b) development related to exposure measurement and exposure mitigation;

The U. S. National Institute for Occupational Safety and Health (NIOSH) published an updated nanomaterial exposure assessment technique. Eastlake A, Beaucham C, Martinez K, Dahm M, Hodson L and Geraci C [2016]. Refinement of the Nanoparticle Emission Assessment Technique into the Nanomaterial Exposure Assessment Technique (NEAT 2.0), *Journal of Occupational & Environmental Hygiene*. Sep; 13(9):708-717. ISSN:1545-9632.

- c) risk management approaches;

On January 12, 2017, EPA issued a final regulation requiring reporting of existing exposure and health and safety information on nanoscale chemical substances in commerce pursuant to its authority under TSCA section 8(a). This rule requires companies that manufacture, import, or process certain chemical substances already in commerce as nanoscale materials notify EPA of certain information, including specific chemical identity; production volume; methods of manufacture; processing, use, exposure and release information; and available health and safety data.

Since January 2005, EPA has received and reviewed more than 190 new chemical notices for nanoscale materials under TSCA including fullerenes, quantum dots, and carbon nanotubes. EPA has issued consent orders and 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.

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.

- d) any updates, including proposals, or modifications to previous regulatory decisions; and/ or

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

- e) 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.

2. Activities been initiated to implement the OECD Council Recommendation¹⁰ (e.g. regulatory changes, guidance, voluntary, etc.)

If yes, please explain

A final regulation requiring reporting of existing exposure and health and safety information on nanoscale chemical substances in commerce pursuant to its authority under TSCA.

Regulation of new chemical substances that are nanomaterials with consent orders and SNURs.

3. Developments related to good practice documents

For example: standards, technical guidance, technical reports, notable articles in the popular and technical literature.

NIOSH provided a summary of the occupational safety and health challenges of nanotechnology for the last 15 years. Schulte PA, Roth G, Hodson LL, Murashov V, Hoover MD, Zumwalde R, Kuempel ED, Geraci CL, Stefaniak A, Castranova V, Howard J1 [2016] Taking stock of the occupational safety and health challenges of nanotechnology: 2000-2015. Journal of Nanoparticle Research Jun; 18(6):159.

4. Information on any developments related to Integrated Approaches to Testing and Assessment (IATA)

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

¹⁰ [Recommendation of the Council on the Safety Testing and Assessment of Manufactured Nanomaterials](#)

study typically has at least a 90-day post-exposure observation period and evaluation of the bronchoalveolar fluid. For carbon nanotubes blood and plasma endpoints indicative of cardiotoxicity are monitored.

U.S. federal agencies, including the Environmental Protection Agency, the Army Corps of Engineers, and the National Institute of Standards and Technology, are leading and/or participating in nanomaterials-related OECD test guidelines projects and other activities, such as the “Evaluation of *in vitro* methods for human hazard assessment applied in the Organisation for Economic Cooperation and Development’s (OECD’s) Working Party on Manufactured Nanomaterials (WPMN) Sponsorship Programme.”

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

- Information on research or strategies on life cycle aspects of nanomaterials, as well as positive and negative impacts on environment and health of nano-enabled applications;
- Current or future activities on nanotechnologies on a multilateral basis, including with non-OECD countries.

The US Army Engineer Research and Development Center Environmental Laboratory (ERDC-EL) developed a tiered testing framework to aid in characterizing the risks that nano-enabled technologies pose to the environment. The framework and accompanying tool, called NanoGRID (Guidance for Risk Informed Deployment), guides users to the appropriate test methods to identify potential nano-releases from products and to determine the magnitude of subsequent exposures and hazards in the release environment. The framework is published (Collier et al, 2015) and the tool will be available mid-2017.

Collier ZA, Kennedy AJ, Poda AR, Cuddy MF, Moser RD, MacCuspie RI, Harmon A, Plourde K, Haines CD, Steevens JA. 2015. Tiered Guidance for Risk-Informed Environmental Health and Safety Testing of Nanotechnologies. *Journal of Nanoparticle Research* 17:155.

6. Additional Information

For example: any consideration on the benefits of nanotechnologies; consideration of ethical implications; other issues.

The US Army Engineer Research and Development Center in collaboration with the Society for Risk Analysis hosted the conference on Risk Governance of Key Enabling Technologies, including nanotechnology. The main focus of the meeting was on discussing risk governance approach that integrates quantitative experimental information alongside qualitative expert insight to characterize and balance the risks, benefits, costs, and societal implications of emerging technologies.

THE EUROPEAN COMMISSION (EC)

Highlight of developments since the last meeting of the WPMN

1. National developments on human health and environmental safety

Regulatory development:

- Work continues on the potential modification of technical Annexes to REACH to (better) address nanomaterials. The Commission proposal is expected to be discussed with Member States in July 2017, at which time the draft will also be notified under WTO. Adoption of possible revised Annexes in beginning of 2018, with further transition arrangement regarding full application.
- Following the review of the Commission Recommendation on the definition of nanomaterial (2011/696/EU) minor revision of the recommendation is anticipated. Public consultation is planned in 2017 prior to any changes. The revised recommendation will be providing basis for the update of the nanomaterial definitions in EU regulations (REACH, food, cosmetics).
- The European Commission has assessed the merits for establishing a specific nano-registry at EU level. The impact assessment with conclusions can be found [here](#). The mandatory registry has not been selected as the most appropriate solution, but the Commission has considered that Nanomaterials Observatory at EU level should be established to enhance transparency and information on nanomaterials and their use, and [entrusted](#) the European Chemicals Agency (ECHA) to set it up. The development of the observatory will in tiers; public launch of the observatory is planned in June 2017.
- Implementation:
- ECHA board of appeal has issued several decisions related to the appealed compliance check decisions under REACH:
 - A-008/011-2015 (4 related decisions on silicic acid, aluminum sodium salt)
 - A-011-2014 on titanium dioxide

Imminent decision is expect also on silicon dioxide substance evaluation case A-014-2015. Decisions can be found at <https://www.echa.europa.eu/about-us/who-we-are/board-of-appeal/decisions>

- ECHA has updated its guidance and best practice support documentation by recent publication of
 - [How to prepare registration dossiers that cover nanoforms: best practices](#)
 - [Guidance on information requirements and chemical safety assessment Appendix R7-1 for nanomaterials applicable to Chapter R7a Endpoint specific guidance](#)
 - [Guidance on information requirements and chemical safety assessment Appendix R7-1 for nanomaterials applicable to Chapter R7b Endpoint specific guidance](#)
 - [Guidance on information requirements and chemical safety assessment Appendix R7-2 for nanomaterials applicable to Chapter R7c Endpoint specific guidance](#)

- [Guidance on information requirements and chemical safety assessment: Appendix R.6-1 for nanomaterials applicable to the Guidance on QSARs and Grouping of Chemicals](#)
- Under Biocides Regulation's review programme, 2 nanomaterials have been approved (synthetic amorphous silicon dioxide CAS 112926-00-8, Pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated, CAS 68909-20-6), while for two the review is presently ongoing (Silver as nanomaterial, CAS 7440-22-4; Silver adsorbed on silicon dioxide).
- Cosmetics: EU Scientific Committee on Consumer safety is presently finalizing opinion on nano-TiO₂ as UV-filter in sprays ([SCCS/1583/17](#)) while the opinion on Titanium Dioxide (nano form) coated with CetylPhosphate, Manganese Dioxide or Triethoxycaprylylsilane as UV-filter in dermally applied cosmetic ([SCCS/1580/16](#)) is final.

2. Developments related to good practice documents

EC Joint Research Centre published several reports related to nanomaterial characterisation, risk assessment, classification of powders etc. that can be found [here](#).

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

Three projects selected under the Horizon 2020 Research Framework Programme (H2020) have recently started.

Under the call “NMBP-26-2016: Analytical techniques and tools in support of nanomaterial risk assessment”:

- ACE Nano: “Analytical and Characterisation Excellence in nanomaterial risk assessment: A tiered approach”
- npSCOPE: “The nanoparticle-scope : a new integrated instrument for accurate and reproducible physico-chemical characterisation of nanoparticles”

Under the call “NMBP-27-2017: Promoting safe innovation through global consolidation and networking of nanosafety centres and strengthening the European industry through cooperation in nanosafety”:

- EC4SAFENANO: “European Centre for Risk Management and Safe Innovation in Nanomaterials Nanotechnologies
- There are two running Horizon 2020 calls for research proposals for 2017 (second stage):
- NMBP-28-2017: Framework and strategies for nanomaterial characterisation, classification, grouping and read-across for risk analysis. (Regulatory Research)
- NMBP-29-2017: Advanced and realistic models and assays for nanomaterial hazard assessment

More information on these calls can be found here:

http://ec.europa.eu/research/participants/data/ref/h2020/wp/2016_2017/main/h2020-wp1617-leit-nmp_en.pdf

Other developments in EU research:

- The ProSafe project organised, jointly with OECD-WPMN, a Conference on “*Science based support for regulation of Manufactured Nanomaterials*”. Paris, 29/11/2016 to 01/12/2016.

Prosafe and NANOREG are now successfully completed. Results will be publicly available.

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

The 2017 edition of the "Compendium of Projects in the European NanoSafety Cluster" is under preparation. The 2016 one is available: <https://www.nanosafetycluster.eu/home/european-nanosafety-cluster-compendium.html>

- 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 EU-US Communities of Research. More on <http://us-eu.org>. The sixth workshop will be held in Birmingham, UK in September 2017.

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

BIAC

1. National developments on human health and environmental safety

Cefic participates actively in the EU Commission Competent Authorities Subgroup on Nanomaterials (CASG-Nano), contributing to all the relevant discussions:

- Amendments of the REACH Annexes to adapt them to nanomaterials: Cefic has provided comments and Industry's position on this topic in several occasions to achieve an efficient and pragmatic regulation on nanomaterials.
- Review of the Recommendation of the definition of nanomaterials: Cefic has participated in the discussions and provided input.

Cefic also participates in the ECHA Nanomaterials Expert group and actively participates in the discussions.

The German Chemical Industry Association (VCI) and its member companies are engaged in the process of implementing the REACH regulation, in sector specific legislations addressing nanomaterials, in the safe handling of nanomaterials throughout the value chain (workplace safety), and in updating and prioritizing the agenda on safety research on nanomaterials together with the federal government. The chemical industry is deeply engaged in research projects on the safety of nanomaterials.

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

3. Developments related to voluntary or stewardship schemes

The German chemical industry is deeply engaged and contributing in the German "Nano-Dialog" initiated by the German government and led by the German Federal Ministry of Environment (BMUB).

4. Information on any developments related to Integrated Approaches to Testing and Assessment (IATA)

NIA is actively engaged in a number of European research projects aiming to support IATA and safe by design approaches such as NanoReg2 and caLIBRAte.

VCI keeps supporting independent scientific literature reviews on the safety of nanomaterials concerning toxicology, health effects, emission, fate and behaviour in the environment, and ecotoxicological effects. On the basis of this project several peer reviewed scientific papers have been or will be published.¹¹ On the basis of this scientific evaluation VCI has analyzed consequences on

¹¹ Harald Krug: "Nanosafety Research — Are We on the Right Track?", <http://dx.doi.org/10.1002/anie.201403367>; Stephan Wagner, Andreas Gondikas, Elisabeth Neubauer, Thilo Hofmann und Frank von der Kammer: „Spot

regulation and the risk assessment on chemical substances and the environment and worked recommendation on safety research including strategies, project governance, and research priorities.¹²

5. Research programs 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 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 scenarios. Since the 16th WPMN, the project's weathering group has produced one journal article and has publicly released its data, the references/links for which are, respectively:

- Wohlleben et al 2017 NanoRelease: Pilot interlaboratory comparison of a weathering protocol applied to resilient and labile polymers with and without embedded carbon nanotubes. Carbon 113:346-360. <http://www.sciencedirect.com/science/article/pii/S0008622316309824>.
- [NanoRelease Data Hub](https://materialsdata.nist.gov/dspace/xmlui/handle/11256/250) – public release of data from the weathering module of NanoRelease Consumer Products. <https://materialsdata.nist.gov/dspace/xmlui/handle/11256/250>.

Publications and data from the project's sanding module, as well as a project “capstone paper” are expected in the coming months.

The ACC Panel continues to support the development of a proposal for an ISO Technical Report describing available collection methods and analytical methods and instruments to quantify manufactured nanomaterials, and their aggregates and agglomerates, in the environment. The report would discuss considerations for distinguishing manufactured nanomaterials from background levels of naturally occurring nano-scale particles and would cover available approaches for sampling air, surface water, sediment, soil, and estuarine and marine waters and sediments.

Cefic has developed the AMBIT tool for Read Across.

AMBIT is an open-source cheminformatics system for high-quality chemical safety predictions. It is based on a ‘predictive toxicity model’ or computational non-testing toxicology approach and applies the principles of read-across and categorization. Read-across is a scientific method for predicting unknown properties of one chemical from known properties of similar chemicals. Categorization combines similar chemicals into chemical categories, or groups, of molecules to allow for read-across. It uses existing data to minimize cost and time-consuming testing as well as testing on animals.

the Difference: Engineered and Natural Nanoparticles in the Environment — Release, Behavior, and Fate”, <http://dx.doi.org/10.1002/anie.201405050>;

Lars Michael Skjolding, PhD; Sara Nørgaard Sørensen, MSc; Nanna Bloch Hartmann, PhD; Rune Hjorth, MSc; Steffen Foss Hansen, PhD; Anders Baun, PhD: “A Critical Review of Aquatic Ecotoxicity Testing of Nanoparticles – The Quest for Disclosing Nanoparticle Effects”, (Correspondence Author: Prof. Anders Baun), Applied Chemistry (International Edition) <http://dx.doi.org/10.1002/anie.201604964>

¹² The paper “Conclusions and recommendations from the project „Health assessment, exposure and environmental effects

of nanomaterials: literature review and assessment” is available on the website of VCI: <http://www.vci.de>.

The tool is not specific for nanomaterials at the moment.

http://cefic-lri.org/lri_toolbox/ambit

6. Additional Information

NIA has launched a Funding Tracker Service aiming to highlight R&D funding opportunities for the development of nanomaterials into multiple sectors, with the focus on SME funding programmes, such as the SME Instrument, Eurostars and other mechanisms. The Funding Tracker is to help industries find new collaborative opportunities and develop projects and proposals. The Funding Tracker also includes opportunities and mechanisms for important innovation and commercialisation partners such as universities and larger companies.

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

Key documents:

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

Regulatory documents:

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

These documents have been discussed with the public as well as with national and European authorities, and were also communicated to the OECD Working Party on Manufactured Nanomaterials (WPMN).

The Joint Research Centre (JRC) of the European Commission and the European Association of pigment producers (Eurocolour) have published a joint report of “Basic comparison of particle size distribution measurements of pigments and fillers using commonly available industrial methods” in November 2014.¹³ On the basis of this report and on current research projects a tiered measurement strategy for the implementation of the recommendation for a nanomaterial definition of the European Commission is in discussion.

¹³ <http://publications.jrc.ec.europa.eu/repository/handle/JRC92531>

7. Research programs or strategies designed to address human health and/ or environmental safety aspects of nanomaterials; (e.g. government, national labs, academic, and industry)

- Research projects on the safety of nanomaterials are conducted by the VCI member companies. The German chemical industry is engaged in several projects of the Framework Programme (FP)7 of the European Commission (e.g. NanoReg, Marina, SINN, Nanosafe II, Nanoderm, IMPART, NEST Particle Risk) and the German Federal Ministries (e.g. NanoCare, NanoNature, NanoGEM, TRACER, and projects that have determined the emission of nanoparticles from endproducts in typical life cycle stages).

The German chemical industry, VCI together with the scientific chemical associations continuously review and analyse safety research needs and is therefore in permanent dialogue with the German Federal Ministry of Research (BMBF), the German Federal Ministry of Economy and Energy (BMWi), and federal authorities to derive programs on nanomaterials safety research.

Documents on safety research:

- Roadmap for Safety Research on Nanomaterials (updated in 2012)
- Environmental Aspects of Nanoparticles
- 10 Years of Research: Risk Assessment, Human and Environmental Toxicology of Nanomaterials
- Conclusions and recommendations from the project "Health assessment, exposure and environmental effects of nanomaterials: literature review and assessment"

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

The German chemical industry is engaged in the review process on research and strategies on life cycle aspects of nanomaterials within the OECD WPMN SG 9.

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

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

A special focus is given on workplace safety. On the basis of the "Tiered Approach to an Exposure Measurement and Assessment of Nanoscale Aerosols Released from Engineered Nanomaterials in Workplace Operations" of VCI, the German Federal Institute of Occupational safety and health (BAuA), the German Social Accident Insurance Institution for the Raw Materials and Chemical Industry (BG RCI), and the Federal Institute for Occupational Safety and Health (IFA) of the German Social Accident Insurance (DGUV) a guidance of the Committee on Hazardous Substances (AGS) at BAuA worked out a publication in 2013 aiming at deriving best practices for exposition measurement and is currently communicated at scientific and political level that is also the basis for the BIAC sponsored SG 8 project that already has been endorsed by the WPMN.

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

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

E.g. *in-vitro* and *in-silico* methods and high throughput methods

- [The PETA International Science Consortium Ltd.](#) [member of The International Council for Animal Protection in OECD Programmes (ICAPO)] is currently funding Professor Dr. Barbara Rothen-Rutishauser of the Adolphe Merkle Institute at the University of Fribourg, Switzerland to develop a non-animal system to predict the development of lung fibrosis in humans following exposure to nanomaterials. The Science Consortium is also funding [MatTek Corporation](#) to create a three-dimensional reconstructed human alveolar tissue model to be used in the study. The results from this project were presented at the 2017 Society of Toxicology Meeting in a poster entitled '[An Integrated Approach to Assessing the Inhalation Toxicity of Nanomaterials](#)'. Manuscripts from the project are currently in preparation and will be submitted for publication in peer-reviewed journals later this year. The progression of the project can be followed on our website: <http://www.piscltd.org.uk/nanoworkshop/>
- The PETA International Science Consortium Ltd. and the US NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) co-hosted a webinar series that concluded with a face-to-face meeting in September 2016. The focus of the webinars and the meeting was to address current practices for acute inhalation toxicity testing, looking towards the development and implementation of approaches to reduce and replace acute inhalation testing in mammals for both global regulatory agencies and non-regulatory purposes. Four working groups have been formed to implement the recommendations from the workshop, each with a specific focus, *i.e.* 1) development of a database of existing acute systemic toxicity data; 2) preparation of a state-of-the-science review on mechanisms and assays for acute inhalation toxicity; 3) optimization of *in silico* models; and 4) proof-of-concept testing using a battery of *in silico* and *in vitro* assays. The general information and approaches developed are intended to be applicable to the testing of nanomaterials and other substances. Presentations from the webinars and the meeting are available on our website: <http://www.piscltd.org.uk/acute-inhalation-toxicity/>
- The PETA International Science Consortium Ltd. held a contest to award a VITROCELL[®] system (valued at up to \$100,000) for the proposal best demonstrating its application in the reduction and replacement of animals in inhalation testing. We are currently reviewing the proposals and the winner will be announced in May 2017. Details at: <http://www.piscltd.org.uk/vitrocell-prize/>
- As part of a collaborative effort between the Joint Research Centre (JRC), the U.S. EPA and the OECD, an Adverse Outcome Pathways (AOP)-Wiki was created to provide an interactive and virtual platform for AOP development. Working with the organizers of the AOP-Wiki, the Science Consortium launched a data challenge to encourage new contributors to add to the AOP-Wiki using available data. The full list of winners is available on our website: <http://www.piscltd.org.uk/aop-prize/>
- The PETA International Science Consortium Ltd. [through ICAPO] is working with Health Canada on the development of an AOP for lung fibrosis (AOP 273). The AOP proposal titled '[Secretion of inflammatory cytokines leading to lung fibrosis](#)' has been accepted by the OECD's Extended Advisory Group on Molecular Screening and Toxicogenomics (EAGMST) for further development.