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

**DEVELOPMENTS ON THE SAFETY OF MANUFACTURED NANOMATERIALS**

**TOUR DE TABLE FROM OECD DELEGATIONS (NOV. 2015- OCT 2016)**

**Series on the Safety of Manufactured Nanomaterials  
No.78**

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**OECD Environment, Health and Safety Publications**

**Series on the Safety of Manufactured Nanomaterials**

**No. 78**

**DEVELOPMENTS ON THE SAFETY OF MANUFACTURED NANOMATERIALS**

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**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, 2016**

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

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- No. 2, *Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 1st Meeting of the Working Party on Manufactured Nanomaterials (2006)*
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- Nos. 44-54, These items are the dossiers derived from the Testing Programme on Manufactured Nanomaterials which are located at:  
<http://www.oecd.org/chemicalsafety/nanosafety/testing-programme-manufactured-nanomaterials.htm>
- No.55, *Harmonized Tiered Approach to Measure and Assess the Potential Exposure to Airborne Emissions of Engineered Nano-objects and their Agglomerates and Aggregates at Workplaces. (2015)*
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- No.76, *Grouping and Read-Across for the Hazard Assessment of Manufactured Nanomaterials: Report from the Expert Meeting*
- No. 77 *Gold Nanoparticle Occupational Exposure Assessment in a Pilot Scale Facility: Nanomaterials Exposure Case Study*

No. 78 *Developments on the Safety of Manufactured Nanomaterials: Tour de Table from OECD Delegations (Nov.2015 - Oct. 2016)*

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

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

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

**This publication is available electronically, at no charge.**

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

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## FOREWORD

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

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

Based on the conclusions and recommendations of the Workshop [ENV/JM/MONO(2006)19] it was recognised as essential to ensure the efficient assessment of manufactured nanomaterials so as to avoid adverse effects from the use of these materials in the short, medium and longer term. With this in mind, the OECD Council established the OECD Working Party on Manufactured Nanomaterials (WPMN) as a subsidiary body of the OECD Chemicals Committee in September 2006. 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 November 2015- October 2016. 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.

## TABLE OF CONTENTS

ABOUT THE OECD.....	8
FOREWORD.....	10
RECENT AND PLANNED ACTIVITIES IN CHEMICALS REGULATORY AREA ON HEALTH AND ENVIRONMENTAL SAFETY ASPECTS OF MANUFACTURED NANOMATERIALS.....	12
AUSTRALIA.....	12
AUSTRIA.....	14
BELGIUM.....	19
CANADA.....	20
DENMARK.....	24
FRANCE.....	25
GERMANY.....	29
ITALY.....	37
JAPAN.....	38
NETHERLANDS.....	41
SWEDEN.....	47
SWITZERLAND.....	49
THAILAND.....	52
UNITED KINGDOM.....	55
UNITED STATES.....	58
THE EUROPEAN COMMISSION (EC).....	62
THE INTERNATIONAL COUNCIL ON ANIMAL PROTECTION IN OECD PROGRAMMES (ICAPO).....	67
UNITAR.....	68
ENVIRONMENTAL NGO.....	68

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

### **AUSTRALIA**

#### **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. Reforms to the regulation of industrial chemicals aim to ensure that the assessment effort would be more proportionate to the risks posed by such chemicals, while also maintaining Australia's robust health and safety standards (further details at <http://www.nicnas.gov.au/about-nicnas/nicnas-reforms>). In developing the implementation detail, consideration has been given to the regulatory approach to be adopted for nano-forms of industrial chemicals.

#### **New activities (e.g. regulatory changes, guidance, voluntary, etc.) been initiated to implement the OECD Council Recommendation<sup>1</sup>**

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.

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

To date, NICNAS has assessed one nanoscale substance for use in sunscreens. Testing recommendations were not made. The assessment report is expected to be published on the NICNAS website later this year ([www.nicnas.gov.au](http://www.nicnas.gov.au)).

#### **risk management approaches**

Risk management controls will be detailed in the assessment report expected to be published on the NICNAS website later this year.

#### **Developments related to good practice documents**

The joint Australia New Zealand regulator of food and food additives, Food Standards Australia New Zealand (FSANZ), has initiated work on the development of technical guidance material on nanomaterials

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

in food to assist applicants in meeting their obligations to provide information in line with FSANZ's Application Handbook.<sup>2</sup>

The Australian Department of the Environment and Energy is developing preliminary technical guidance for the environmental risk assessment of nano-enabled pesticides (also known as nanopesticides) in collaboration with the Commonwealth Scientific and Industrial Research Organisation (CSIRO), the Australian Pesticides and Veterinary Medicines Authority, and industry. The basis of this work is the 2014 paper by Kookana et al. '*Nanopesticides: Guiding principles for regulatory evaluation of environmental risks.*' The focus of this work is developing an overarching approach to problem formulation for nanopesticides focussing on their environmental durability, with consideration for potential differences in their risk profile compared to conventional formulations. The fate and behaviour of nanopesticides in the environment is likely to be dependent on both the nature of the encapsulation or nanomaterial carrier, and the durability of the pesticide active ingredient and carrier combination. This work is expected to be published within the next 12 months within the scientific literature.

Three simplified scenarios have been considered to aid the problem formulation process for the fate of nanopesticides in the environment:

1. Complete dissociation of the nanomaterial carrier/coating and the pesticide active ingredient on the time scale of application.
2. Semi-durable nanopesticide where the pesticide active ingredient is gradually released from the nanomaterial carrier or encapsulation.
3. Durable nanopesticide where the pesticide active ingredient does not dissociate from the nanomaterial carrier or encapsulation.

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

In 2015, FSANZ commissioned two reports on the potential use of nanotechnologies in existing food additives and in food packaging. The reports are now published on the FSANZ website.<sup>3</sup>

The Department of the Environment and Energy commissioned a research project, to determine the fate of nanoparticles in the environment. The project, completed in September 2015, *Transformation and release behaviour of fullerene nanoparticles in soils amended with biosolids*, investigated the degradation, transformation and partitioning of fullerenes. The project investigates the likelihood that nanoparticles will enter the environment through waste disposal, in particular, from the reuse of biosolids as agricultural amendments.

<sup>2</sup> 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>

<sup>3</sup> Reports on the use of nanotechnology in food additives and packaging:

<http://www.foodstandards.gov.au/consumer/foodtech/Pages/Reports-on-the-use-of-nanotechnology-in-food-additives-and-packaging-.aspx>

<sup>4</sup> "Behaviour of fullerenes (C60) in the terrestrial environment: Potential release from biosolids-amended soils" Navarro DA, Kookana RS, Kirby JK, Martin SM, Shareef A, Du J, McLaughlin MJ (2013) *Journal of Hazardous Materials* <http://www.sciencedirect.com/science/article/pii/S0304389413005876>

<sup>4</sup> "Fullerol as a Potential Pathway for Mineralization of Fullerene Nanoparticles in Biosolid-Amended Soils" Navarro, DA, Kookana RS, McLaughlin MJ, Kirby JK (2016) *Environmental Science and Technology Letters*. <http://pubs.acs.org/doi/abs/10.1021/acs.estlett.5b00292>

This study has resulted in two peer-reviewed papers in the scientific literature and a third paper is yet to be published.<sup>4</sup>

### **Public/ stakeholder consultations**

Extensive stakeholder consultation has been undertaken and continues to date. A NICNAS reforms implementation plan and three Consultation Papers have been released, public workshops have been held and written submissions accepted. (see <http://www.nicnas.gov.au/about-nicnas/nicnas-reforms>)

Stakeholder views will be taken into account in developing the regulatory model for industrial chemicals (including their nano-forms) to be presented to Government.

FSANZ has recently set up a Scientific Nanotechnology Advisory Group (SNAG) comprising experts in the fields of nanosafety, pharmacology, nano-food technology, toxicology and nanometrology. The SNAG will advise on the development of guidance for a range of stakeholders, future uses of nanotechnology in food and food packaging and national/international legislation and policy.

## **AUSTRIA**

### ***Highlight of developments since the 15th meeting of the WPMN***

- 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 call was launched spring 2016 targeting the EU-Project Prosafe for international and national projects. This EHS programme is owned by the Federal Ministry of Agriculture, Forestry, Environment and Water Management and Federal Ministry of Federal Ministry for Transport, Innovation and Technology and is handled by the FFG - Austrian Research Promotion Agency.
- The 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/uploads/media/Umsetzungsbericht\\_2012\\_EN.PDF](http://nanoinformation.at/uploads/media/Umsetzungsbericht_2012_EN.PDF)):
  - In cooperation with European partners, **enforcement activities in the field of REACH-regulation** have been launched in year 2014 including checks of safety data sheets for nanomaterial-relevant information and products with a “nano-claim”. The project is lead-managed by the Federal Ministry of Agriculture, Forestry, Environment and Water Management with support of the Environment Agency Austria and chemical inspectors. A considerable amount of 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.
  - Austria participated also together with nine further Member states in the **Prosafe Joint Action Nantechonology and Cosmetics** (supported by the Comission) to examine cosmetic products regarding their nanomaterial content and compliance with resulting labelling requirements (s.

[http://www.prosafe.org/index.php?option=com\\_content&view=article&id=57&Itemid=605](http://www.prosafe.org/index.php?option=com_content&view=article&id=57&Itemid=605)).

Testing for nanomaterials content was part of the project (cremes, liquides with TiO<sub>2</sub>, SiO<sub>2</sub>, AlO<sub>2</sub>, ZnO<sub>2</sub> or mixtures thereof). The project is lead-managed by the Federal Ministry of Health. The results were presented in a Workshop in Brussels in February 2015. Only few products not complying with the legal requirements were found.

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](mailto:renate.paumann@bmlfuw.gv.at)) and elaborated based on a broad stakeholder involvement (see also chapter 7). The implementation report on the Austrian Nanotechnology Action plan including an English translation has been finalised after a public consultation see <http://nanoinformation.at/oesterreichischer-aktionsplan/umsetzungsbericht-2012.html>

### **Developments related to good practice documents;**

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

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

The Workers' Compensation Board in co-operation with the central labour inspectorate developed a document in German language: Merkblatt M 310 Nanotechnologien Arbeits- und Gesundheitsschutz: <https://www.sozialversicherung.at/portal27/portal/auvaportal/content/contentWindow?action=2&viewmode=content&contentid=10007.672853>.

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

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 lead 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 is in the commenting process.

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

The 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](http://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** will start 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 NANO futures) 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 will thus provide strong links between human nanotoxicology and environmental nanotoxicology, using the option 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 **EC4SafeNano** project, starting in October 2016, 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](http://www.nanoreg.eu)). Furthermore, within NANoREG-project one of the Value Chain Case Studies (VCCS) with focus on TiO<sub>2</sub> coating (project name “GALANT”) was successfully finalised done with Austrian industry and scientific partners, in collaboration with Andy Booth/SINTEF/Norway.

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, 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.oew.ac.at/ita/nanotrust-dossiers>. The 9. conference on safety research regarding nanotechnologies and nanomaterials will be held on 17.11.2016.

The **European Center for Nanotoxicology** (EURO-NanoTOX) is a topic-oriented platform which is coordinated by the BioNanoNet Forschungsgesellschaft mbH. EURO-NanoTOX develops nanosafety strategies and serves as an international node for nanotoxicology. The 5<sup>th</sup> revised edition of the ENT-expertise-catalogue will be published in september 2017. See: <http://www.euro-nanotox.eu/>

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: Nov/Dec 2016), Austrian partner BioNanoNet is responsible for the nano-related safety-tasks. BioNanoNet together with international project partners is developing an integrated safety strategy to reduce the potential risk upon worker’s exposure to MNMs during production and manipulation processes, 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 **NANOAGENTOOLS** (start: 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).

#### **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.

After three years project runtime, the FP7 funded project **NanoDiode** ([www.nanodiode.eu](http://www.nanodiode.eu)) has been successfully finalised (end on June 30<sup>th</sup>, 2016). The project focused on educational activities specialising in

the knowledge transfer of relevant nanotech information on several educational levels (secondary schools, universities, research facilities, etc). BioNanoNet organized several citizen dialogues and in-depth interviews to reach the goal of developing an innovative outreach and dialogue on responsible nanotechnologies in EU civil society. Additionally, NanoDiode organised two innovation governance workshops to discuss the project findings with policy makers and identify opportunities for the effective governance of nanotechnologies in Europe. (Contact: Andreas Falk).

**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](http://www.nanoobjects.info) and [www.nanopartikel.info](http://www.nanopartikel.info). **Albert Duschl** from the **University of Salzburg** is one of the experts who contribute within this project to the knowledge base.

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

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

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

**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**.

***Additional Information***

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

**BELGIUM****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 24<sup>th</sup> 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. A more complete overview of the registrations, respecting the confidentiality of the data, is planned in 2017.

More information about the registry can be found on the website [www.nanoregistration.be](http://www.nanoregistration.be).

**New activities (e.g. regulatory changes, guidance, voluntary, etc.) been initiated to implement the OECD Council Recommendation<sup>4</sup>**

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. First results are expected to be published in 2016.

**Developments related to good practice documents**

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

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<sup>4</sup> [Recommendation of the Council on the Safety Testing and Assessment of Manufactured Nanomaterials](#)

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

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

Research sponsored by the BE federal government and carried out by CODA, has been published:

Verleysen et al, “TEM and SP-ICP-MS Analysis of the Release of Silver Nanoparticles from Decoration of Pastry” *J. Agric. Food Chem.* 2015, 63, 3570–3578.

This research has, amongst many others, contributed to EFSA’s “Scientific opinion on the re-evaluation of silver (E 174) as food additive” (<http://www.efsa.europa.eu/en/efsajournal/pub/4364>).

**CANADA**

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

The consultation document on a Proposed Prioritization Approach to Address Nanoscale Forms of Substances on the Domestic Substances List was also published online for a 60 day public comment period (<http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=FA3C8DBF-1>), ending on September 25, 2016. The document outlines the Government’s approach to prioritizing nanomaterials which are considered in commerce in Canada (on Canada’s public inventory) for further action. It follows a previously published consultation document (*Proposed Approach to Address Nanoscale Forms of Substances on the Domestic Substances List*, available at: <http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=1D804F45-1>) which outlined the overall stepwise approach proposed by the Government of Canada to acquire and evaluate information on nanomaterials considered in commerce in Canada, and follow up with any necessary action. A stakeholder workshop was held on June 8, 2016 to discuss next steps and the proposed approach to prioritization.

Results of a mandatory information gathering survey (published on July 25, 2015) are now available at <http://gazette.gc.ca/rp-pr/p1/2015/2015-07-25/html/notice-avis-eng.php>. The purpose of the survey was to collect information to determine the commercial status of certain nanomaterials in Canada. The survey targeted 206 substances considered to be potentially in commerce in Canada at the nanoscale. Through the survey, information on 49 nanomaterials (i.e., unique CAS numbers) was received, from 79 companies. In addition, 61 companies expressed interest on 81 unique CAS numbers, but did not necessarily submit a survey response. Information requested in the survey included substance identification, volumes, and uses. This information will feed into the Government’s proposed approach to address nanomaterials on the *Domestic Substances List*.

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

Two substances were notified to the program since the WPMN15 – both were inorganic substances. For one of the two substances, no action was taken due to low expected exposures in accordance with the *New Substances Notifications Regulations (Chemicals and Polymers)* (NSNR). The other notified substance was subject to a Significant New Activity notice. A Significant New Activity notice is a control measure used to collect additional information on a substance if it is suspected that a significant new activity may result in the substance becoming toxic under the *Canadian Environmental Protection Act, 1999*.

**a. 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 (see above). As part of this activity, the Government is reviewing past nanomaterials SNAc notices to see if new information is available to refine the scope and information requirements. As a result of this review, 9 SNAc notices previously in place for nanomaterials have been reviewed and were rescinded since review of these notices found the rationale was no longer consistent with current SNAc policy and approaches. A further 24 are currently under review. This work is ongoing, and a complete review of all nanomaterial SNAcs is currently planned to be completed in 2016.

**Developments related to good practice documents(e.g. standards, technical guidance, technical reports, notable articles in the popular and technical literature);**

The Canada-led, ISO standards project, ISO/DTR 19716 *Nanotechnologies -- Characterization of cellulose nanocrystals*, was published by ISO in May 2016 and is available for order ([http://www.iso.org/iso/catalogue\\_detail.htm?csnumber=66110](http://www.iso.org/iso/catalogue_detail.htm?csnumber=66110)). 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.

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

Scientific research

Environment and Climate Change Canada continues to support various academic and departmental research projects. This research has to date included studying fate and effects of nanomaterials in the aquatic, sediment, soil, and air compartments. Funding in fiscal 2015-16 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 2015-2016, Environment Canada and Climate Change also partnered with the National Research Council of Canada to initiate a project on the development of test methods to identify surfaces of nanomaterials for the purposes of regulatory identification and to support risk assessments. In addition, Environment and Climate Change Canada is working with academic laboratories in Canada and Germany to prepare guidance to support testing of nanoparticles using the OECD Test Guideline for soil column leaching.

Health Canada continues its research efforts to investigate the effects of surface-modified silica nanoparticles. The aims of these projects are to: (1) study the importance of size and surface functionalization; and (2) provide a genotoxic profile and to identify mechanistic relationships of particle properties to elicited toxic responses. A manuscript reporting the in vitro genotoxic, cytotoxic and transcriptomic responses following exposure to silica nanoparticles 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 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. A manuscript summarising the results is under peer review. 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 currently undergoing peer review. In addition, Health Canada developed a putative Adverse Outcome Pathway (AOP) for lung fibrosis induced by multiwalled 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. The Canada-Netherlands WPMN project entitled “Strategy For Using Metal Impurities As Carbon Nanotube Tracers [ENV/CHEM/NANO(2016)16]” has been completed. This project is based on exposure research conducted under Health Canada’s CMP nanotechnology research initiative. The 2015 publication in *Environmental Science & Technology* received international media attention (*Chemical Watch News Article: Risk Assessment, “Health Canada Tracks Workplace Carbon Nanotube Exposure”*, October 15, 2015 at <https://chemicalwatch.com/43031/>).

Health Canada research is also investigating the utility of alternative testing strategies for nanomaterial hazard assessment. Results on the applicability of in vitro toxicoproteomics approaches for investigating the toxicity of carbon black and titanium dioxide were recently published in a peer-reviewed journal (<http://www.sciencedirect.com/science/article/pii/S1874391916301105>).

The Canadian Food Inspection Agency (CFIA) 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.

#### ***Public/ stakeholder consultations;***

A consultation document on a *Proposed Prioritization Approach to Address Nanoscale Forms of Substances on the Domestic Substances List* was published with a public comment period ending on September 25, 2016 (see Question 1). A stakeholder consultation workshop was held on June 8, 2016 in Gatineau, QC to outline the proposed approach described in the consultation document and to obtain

feedback on the proposed approach. Approximately 30 stakeholders were in attendance (with approximately 50 more participating via online webinar/teleconference), representing industry and industry associations, non-governmental organizations, academic institutions and other governmental organizations. The feedback received at this workshop will be used along with public comments received on the proposed prioritization approach, to finalise the approach to prioritization of nanomaterials in commerce in Canada.

A two-day conference was convened by Pollution Probe and the Trottier Institute for Sustainability in Engineering and Design (TISED) at McGill University in cooperation with Health Canada and Environment and Climate Change Canada on January 27-28, 2016 in Montreal, Quebec. The "National Consultation on Nanomaterials and Their Implications for Human Health and the Environment" brought together representatives from industry, academia, government, and civil society. It was designed to engage key stakeholders in high-level knowledge sharing and the identification of priority issues to advance the safe and responsible development and use of nanomaterials in Canada and internationally.

The workshop covered advances in four areas: science and knowledge, policy and regulation, public awareness and education, and stakeholder engagement.

***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;***

Canada, along with Government agencies in the United States, Non-Governmental Organizations and Industry, is engaged in a project to look at releases of nanomaterials from industrial consumer matrices (e.g., coatings). The objectives of the NanoRelease Consumer Products project are to develop protocols or methods (validated through interlaboratory testing) to measure releases of nanomaterials from solid matrices as a result of expected uses along the material life cycle for consumer products that contain the nanomaterials. The project is currently in the advanced stages of Phase 3 (Interlaboratory Studies). The objectives of Phase 3 of the project are to develop robust methods for producing and collecting samples of CNT-epoxy and CNT-rubber materials under abrasion and weathering scenarios, and to detect and quantify, to the extent possible, CNT release fractions. Selected laboratories in the US, Canada, Korea and the European Community have completed the generation and analysis of sanding and weathering samples and the results were presented at the Nanotech 2016 Conference in Washington DC in June 2016.

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" is currently being organized on November 30th, 2016, back to back with the next meeting of the WPRPW. This workshop will be an opportunity to reflect and discuss 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.

**Developments related to exposure measurement and exposure mitigation.**

Canada and the Netherlands are co-leading a project on metal impurities in carbon nanotubes. The final draft of the report "Strategy for Using Metal Impurities as Carbon nanotube Tracers" has been forwarded to the WPMN with a request that it be circulated to the Joint Meeting for declassification.

Canada and the US EPA are co-leading an analysis of the responses received from SG-08 member countries on the survey, *Consumer and Environmental Exposures to Manufactured Nanomaterials*. A first draft of the analysis will be submitted to SG-08 members in summer 2016, and will be presented at the Face-to-Face meeting at WPMN16. Revisions to the analysis will be based on feedback from SG-08 participants and next steps depend on the extent of revisions that are required.

## DENMARK

The Danish Government had allocated funding (approx. 3,2 mio € from 2012-15) for establishing activities aimed at gaining clarity about the consequences for consumers and the environment due to the use of nanomaterials. These activities were finished by the end of 2015<sup>5</sup>. The results show that, apparently, most nanomaterials do not seem to be as big a problem as many may fear. However, there is still a need for more knowledge. It cannot with certainty be concluded that nanomaterials do not pose a risk to health or the environment.

As part of the action plan The Danish Environmental Protection Agency (DK-EPA) has published 30 reports over the 4 years. These reports are available for download on the DK-EPA homepage<sup>6</sup>. The action plan was finished with a workshop for EU member states, scientists and other interested people. The workshop provided an overview of the results from the Action plan. The agenda and presentations from the workshop are available on the DK-EPA homepage<sup>7</sup>.

The Danish Nanoproduct register was established in 2014<sup>8</sup>. First year of registrations (1<sup>st</sup> of July 2014 to 30<sup>th</sup> of June 2015) consisted of 117 products registered by 8 companies. The deadline for the second year (1<sup>st</sup> of July 2015 to 30<sup>th</sup> of June 2016) of registration is 30<sup>th</sup> of August 2016, no information from second year of registrations is available yet.

Funding for the Danish Nanosafety Centre<sup>9</sup>, which contributes with new knowledge necessary for all stages of a risk assessment of nanoparticles in the workplace has been renewed until the end of 2018. The funding is in total 30 mio. Danish kroner (4 mio. €) for all the years.

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<sup>5</sup> <http://eng.mst.dk/about-the-danish-epa/news/news-archives/2015/dec/results-of-4-years-activities-on-nano-are-now-available>

<sup>6</sup> <http://eng.mst.dk/topics/chemicals/nanomaterials/results-from-the-better-control-of-nano-materials-initiative/>

<sup>7</sup> <http://eng.mst.dk/topics/chemicals/nanomaterials/results-from-the-better-control-of-nano-materials-initiative/list-of-presentations/>

<sup>8</sup> 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>

<sup>9</sup> <http://nanosafety.dk>

## FRANCE

**Highlight of Developments Since the last Meeting of yhe WPMN****National developments on human health and environmental safety**

France has held a National Environment Conference gathering representatives from industry, NGOs, local and national authorities, members of the Parliament. One of the three main topic for this National Conference was Risks to Health caused by environmental factors.

Nanomaterials have been some of the issues discussed during this Conference. The following decisions have been made:

- keep working on measurement of nanomaterials in the vicinity of industrial sites using nanomaterials in their process (improvement of the knowledge). This is done on a voluntary basis of operators
- hold meetings of a working group on proposals that could be made on a European level for labelling and restriction of nanomaterials (restriction could be for instance on non-necessary use in consumer products in contact with the skin)
- promote a safe regulatory approach in the European legislation of cosmetics
- extend the French nano-registry database access to waste regional committees
- gather experienced environment inspectors, carry out inspections in industrial sites using nanomaterials and issue a best reference document on preventing risks of unintended releases of nanomaterials in the environment.

**New activities (e.g. regulatory changes, guidance, voluntary, etc.) been initiated to implement the OECD Council Recommendation<sup>10</sup>**

France has been actively participating in the EU work on adapting EU legislation on chemicals to specific properties of nanomaterials, using OECD testing guidelines, as recommended in paragraphs I and II of the Recommendation of the Council on the Safety Testing and Assessment of Manufactured Nanomaterials.

**Developments related to voluntary or stewardship schemes**

Industry committed to enlarge the number of operators participating in the voluntary measurement campaign of nanomaterials released around industrial site.

**Information on:**

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

The substance evaluation under REACH of TiO<sub>2</sub> by France is included in the Community Rolling Action Plan. The evaluation has been postponed until the outcome of the ongoing appeal on the compliance check procedure.

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

INERIS is contributing in the revision of OECD guidelines for hazard assessment of nanomaterials and is especially involved in a technical work group convened for the purpose of developing a guidance document to address inadequacies of aquatic and sediment test guidelines (i.e. Guidance Document on Aquatic (and Sediment) Toxicology Testing of Nanomaterials). (To be filled by ANSES for a and c, and INERIS for b)

**b. risk management approaches; and**

A classification proposal for TiO<sub>2</sub> as Carc. Cat. 1B via inhalation has been transmitted to ECHA, under the Classification Labelling and Packaging (CLP) regulation. The public consultation was closed in last July. The classification proposal is going to be discussed soon by the RAC Committee of ECHA.

A consortium led by INERIS had built EC4SafeNano, a European project answering the call NMBP 27 “Promoting safe innovation through global consolidation and networking of nanosafety centres and strengthening the European industry through cooperation in nanosafety“. Starting in 2016, EC4SafeNano will promote a harmonized vision of risk assessment and management. It will share knowledge, tools (e.g. facilities, test methods) and expertise as well as structure collaborative work at a national and EU level. It will deliver expertise for the public and private sectors based on the highest level of collective knowledge and operational tools and methods. It will also provide services to industry and regulators to enable the safe development and commercialization of nanotechnology. Acting as a European hub of services and support, EC4SafeNano intends to interact closely with more than 50 world wide associated partners and national mirror hubs. Moreover, EC4SafeNano will engage an initiative aiming to set up a Joint Call with Member state representatives interested in supporting projects enhancing and demonstrating their capability at national level to deliver expertise in the above mentioned interests and activities.

AFNOR and INERIS had organised a workshop dedicated to the identification of both industry needs and available knowledge and practices on risk management at the workplace in the construction sector. Outcomes will contribute to the CEN TC352 which had started a new work item proposal on this topic.

**c. updates, including proposals, or modifications to previous regulatory decisions**

None, but discussion going on as regards improvements that could be made to the national registration scheme for companies importing or producing nanomaterials.

**Developments related to good practice documents**

France has set up a project team of 7 experimented people, from inspectorate and from the National Institute for Risk Assessment and Management.

The team is in charge of visiting industrial sites using nanomaterials, identifying best practices in preventing unintended releases of nanomaterials out of the boundaries of the site (dust collection, pressure reduction, filters,) and in managing waste produced by those industrial sites.

About 12 inspections will be carried out in sites in France, and some visits have been made in the United States.

This team will issue a guidance document by the end of the year, in which best reference techniques will be described. This document will be circulated to all French inspectors and to affected operators, and will be the basis for technical dialogue between inspectors and operators on site.

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

(To be filled by INERIS)

INERIS and TNO had organised a European workshop aiming to bring together the scientific, technical and regulatory community of users of in-vitro Air-Liquid Interface (ALI) assays and tools for inhalation toxicity studies, make a state-of-the-art on techniques used in ALI (atmosphere generation, exposure techniques at the ALI, cell response/read-out parameters), exchange experience (what is done, what are common tools/issues people are working on) and to raise discussion and build a roadmap on the way to go forward to achieve future implementations of these technologies in a regulatory context.

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

(To be filled by ANSES and INERIS)

Every year ANSES launch a call for research proposals on Environmental and Occupational Health. Launched within the framework of the national research program for environmental and occupational health (PNREST), this call for research proposals is to support public policies. It takes into account the research priorities of national plans for Environmental Health, Occupational Health, Cancer and Ecophyto (National Plan aimed to reduce pesticides use).

The PNR EST aims to motivate scientific communities to produce useful data at all stages of health risk assessment and thus to bring together research and scientific expertise. The program deals with the assessment and analysis of environmental risks to human health, in the general population and in the workplace. It will also support projects on risks for ecosystems and quality of environmental media. It is focused on research items raised by the ministries and State agencies involved in these these topics.

This call is funded with budgets allocated to ANSES by the Ministries in charge of the Environment and Labour. This funding is increased by the participation of several co-sponsors: ADEME, ITMO cancer and ministry in charge of agriculture under the Ecophyto plan (with ONEMA). The total budget each year is around 4,5 million Euros. Several research project on nanomaterials are funded each year.

INERIS is coordinating NanoReg2, a European project involving 42 partners across more than 15 countries aiming to create principles that will underpin the next generation of regulation. One of the greatest challenges in the changing nanomaterial landscape is how to deal with a rapidly diversifying system of manufactured nanomaterials (MNM) with respect to environmental and health safety assessments. NanoReg2 will meet this challenge by establishing Safe by Design (SbD) as a fundamental pillar in the discovery, screening and commercialisation of novel nanomaterials and nano enabled products. In addition, the project will achieve this by establishing a grouping strategy and an associated integrated testing strategy to support grouping. The project

will be supported through industrial case studies, that will implement a safe innovation approach. First industrial SbD case studies were initiated and first deliverables have finalised notably on the selection of manufactured nanomaterials, and criteria for grouping and on existing grouping strategies.

INERIS has engaged activities on the building of preliminary reference values for the toxicity and and ecotoxicity of nanoparticles. Criteria for the selection of bibliographic data were defined and applied to TiO<sub>2</sub>. Next steps will be to work on process for the derivation of preliminary reference data and to extend the work to other nanomaterials (Ag<sup>0</sup>, CeO<sub>2</sub>, ...).

In the context of a national initiative on the evaluation of nanomaterials released around industrial site, INERIS together with research centers and industrial partners, have developed a first approach already applied in some industrial sites and have engaged NanoIdent, a project funded by ADEME, aiming to optimise methods and tools dedicated to the evaluation of process emissions and the qualification and quantification of their environmental fate in the surrounding area.

#### **Public/ stakeholder consultations**

Among other actions and working groups, representatives of stakeholders have been participating in the National Environment Conference mentioned above. Public could follow debates on Internet and give its comments.

#### **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 together with research labs (Ecole des Mines de Nantes) and industrial partners (TREDI), have conducted NanoFlueGas, a project funded by ADEME, aiming to evaluate the efficiency of available incineration technologies for actual and new generations of nanomaterials. The project was designed to increase the knowledge on the behaviour of manufactured nanomaterials and the fate of nano-fillers during incineration processes. Three types of waste were selected for their different physical forms. An experimental incineration device (chiefly a primary chamber) was developed and fully fitted out, allowing to approximate at small-scale the conditions and Good Practices implemented industrially. The reproducible results obtained showed the presence of nanoparticles in the incineration chamber during normal operation (out start and stop phases), in variable quantities depending on the tested waste. It was also possible to evaluate the efficiency of a single filtering sleeve (100% PTFE) under realistic industrial operating conditions showing that more than 99% of abatement by number was obtained for carbon based nano-objects. Several research actions are currently conducted in the continuation of the NANOFlyeGas program.

INERIS has investigated the effect of weathering duration on a commercial photocatalytic nanocoating on the basis of its nanoparticle emission tendency into two media, air and water. It was found that increased weathering duration results in stepwise structural deterioration of the nanocoating, which in turn decreases the nanocoating life, changes the nanocoating removal mechanism, and increases the particle emission concentration. Emission of free TiO<sub>2</sub> nanoparticles was found to be weathering duration dependent. Three quantities were introduced: emission transition pace (ETP), stable emission level (SEL), and stable emission duration (SED). By linear extrapolation of these quantities from short weathering durations, complete failure of the nanocoatings could be predicted so as to the potential increase of nanoparticles release into the air.

INERIS has engaged experimental work studying the potential release of a commercial CeO<sub>2</sub> based nanocomposite used for wood protection during usage and after mechanical abrasion and its effect toward aquatic organisms.

### **Development related to exposure measurement and exposure mitigation.**

As the evaluation of the efficiency of collective protection equipment in workplace involving manufactured nanomaterials is of high concern, AFNOR, CEA, INRS and INERIS have organised a workshop dedicated to the mapping of stakeholder needs, the identification of available knowledge, tools and the presentation of existing voluntary schemes (eg. NanoCERT) or ongoing initiatives. It was noticed that end of 2016, the outcomes of ongoing initiatives will help to define standardization activities on this topic.

### **Past, current or future activities on nanotechnologies that are being done in your respective countries in co-operation on a multilateral basis, including with non-OECD countries.**

United States authorities have been kindly hosting the French project team on best reference techniques. Some meetings and exchanges have been held at the same time with EPA, NIOSH, CPSC, representatives from industry.

## **GERMANY**

### **Highlight of developments since the last meeting of the WPMN**

#### **A *Federal Ministry of Education and Research (BMBF)***

Since 2006, eight ministries have been charged with the task of publishing an action plan on nanotechnology at five year intervals. Within the interministerial steering group, led by the Federal Ministry of Education and Research, the ministries develop a common approach for bundling strategies for action and fields of application for nanotechnology, thus creating a framework for the research on and use of nanotechnology.

The action plan is divided into different fields of action. Under each field of action areas of need are listed and strategic goals for research and economic support and nanotechnology legislation and regulations are updated.

The third Action Plan Nanotechnology 2020, has been adopted by the Federal Cabinet in autumn 2016. The action plan will follow on from the Action Plan Nanotechnology 2015 and the Nano-Initiative – Action Plan 2010.

[https://www.bmbf.de/pub/Aktionsplan\\_Nanotechnologie.pdf](https://www.bmbf.de/pub/Aktionsplan_Nanotechnologie.pdf)

#### **B *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. The fifth phase of the dialogue was launched in June 2016 with a conference. The conference, where more than 300 participants acknowledged 10 years of successful work, was opened by Parliamentary State Secretary from BMUB. The results of phases 3 and 4 were

presented, analysed and discussed. Another important objective was to identify topics for additional expert dialogues, which will take place from autumn 2016.

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/>

### **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 materials

### **Federal Environment Agency (Umweltbundesamt, UBA)**

In May 2016, UBA published a new background paper on “Nanomaterials in the environment – Current state of knowledge and regulations on chemical safety. In this paper, UBA outlines the necessary further development of chemicals regulations for nanomaterials with regard to the environment. It is addressed particularly to players and decision-makers involved in discussions related to the adaptation of the various regulations on chemical safety. The paper considers general aspects of regulatory needs such as the definition of nanomaterials, their characterisation, and the assessment of related risks. It also describes the current consideration of nanomaterials in the existing active substance regulations and the specific requirements for adaptations. Finally, it gives recommendations with regard to this topic.

The report is available at the web pages of the UBA:

[https://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/nanomaterials\\_in\\_the\\_environment.pdf](https://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/nanomaterials_in_the_environment.pdf)

As follow up of the OECD Expert Meeting on Environmental Fate and Ecotoxicology of Nanomaterials in Berlin (29<sup>th</sup> - 31<sup>st</sup> 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 first draft of the Test guideline went through a WNT commenting round in Q1 of 2016. Based on the comments, the draft Test Guideline is currently revised and documents for a 2<sup>nd</sup> WNT commenting round are in preparation.

On behalf of the German Head of Delegation, UBA summarized the results of the Sponsorship Programme on ecotoxicology and environmental behavior of nanoscale titanium dioxide. The summary is intended as public information on the outcomes of the studies. In addition, it includes an analysis of UBA on the need for adjustment of methods used to record ecotoxicology and environmental fate as well as on research needs identified based on the Sponsorship Programme on ecotoxicology and environmental behavior of nanoscale titanium dioxide. Currently the report is only available in German.

An English translation is underway:

<https://www.umweltbundesamt.de/publikationen/zusammenstellung-der-ergebnisse-des-sponsorship>

[On 10<sup>th</sup> and 11<sup>th</sup> of October 2017, the German Ministry of the Environment and UBA will host a scientific stakeholder meeting at the headquarters of UBA in Dessau-Roßlau, Germany called “Nanomaterials in the Environment”. This meeting will include platform and poster presentations on results of national, EU and international projects and activities of regulatory relevance with regard to environmental relevant legislations. 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.

### **Developments related to good practice documents**

E.g. standards, technical guidance, technical reports, notable articles in the popular and technical literature

### **Federal Institute for Occupational Safety and Health (BAuA)**

**The Federal Institute for Occupational Safety and Health (BAuA) has developed Nano to go! as a contribution to NANOVALID in the 7th EU research framework program.**

Nano to go! is a guide to good working practice for the safe handling of nanomaterials in laboratories and start-up enterprises. The objective was to provide practical support based on the EU directive 98/24/EC on the protection of health and safety of workers from chemical risks, taking into account a comprehensive state of knowledge from more than 10 years of international nanosafety research.

BAuA has compiled and designed “Nano to go!” as a robust folder with a flyer, a brochure and a USB flash drive. The brochure contains the guideline on “Safe handling of nanomaterials and other advanced materials in the workplace”, which have been developed with support from other project partners. Using a grouping approach for nanomaterials from the announcement 527 “Manufactured Nanomaterials” of the German Committee on Hazardous Substances, it provides decision criteria for determination and assessment of risks from nanomaterials and other advanced materials and the selection of appropriate safety measures. The criteria consider the physical condition of the nanomaterial in use (powder, bound in a matrix or dispersed in a liquid), its solubility in water and the potential for release of respirable particles. Special attention is given to fibrous materials which may release asbestos-like fibres and therefore may pose a significant risk to human health. The guideline provides risk-related control strategies and practical solutions for safe work which follow the STOP principle: substitution, technical measures, organisational measures and personal protection. The recommendations are supplemented by advice for storage, disposal and transport, placing on the market, prevention of risk from fire and explosion, and for checking the effectiveness of protective measures.

The flyer provides an overview of the contents of the brochure and the additional documents on the flash drive. The flash drive contains additional documents: Four field study reports give examples how to follow the recommendations and how to apply the safety measures in specific situations. The reports are complemented by an exemplary standard operation procedure (SOP) for good laboratory practice in OSH, by blank forms for operating instructions and for a sampling protocol, and by a dialogue guide for risk assessment at the workplace. Moreover, the flash drive provides documents for training. A short introduction on “Safety management and nanomaterials” and seven presentations in a train-the-trainer format illustrate current knowledge on nanomaterials, toxicology, information gathering, risk assessment and management, as well as basics on EU regulations for chemical safety.

Nano to go! addresses research institutions and SME industries in micro- and nanotechnology and those involved in the development of advanced materials. It supports researchers and safety experts, but also consultants and regulators in occupational health and safety. The presentations are tailored to lecturers at universities and supervisors, who perform instructional courses in companies.

The brochure and all additional documents are available for download:

- on the BAuA website: [www.baua.de/nanoToGo](http://www.baua.de/nanoToGo)
- on the NanoValid website: [www.nanovalid.eu/nanoToGo](http://www.nanovalid.eu/nanoToGo)
- on the NanoSafety Cluster website: [www.nanosafetycluster.eu/nanoToGo](http://www.nanosafetycluster.eu/nanoToGo)

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

**A German Environment Agency (UBA), Federal Institute for Risk Assessment (BfR), Federal Institute for Occupational Safety and Health (BAuA), Federal Institute for Materials Research and Testing (BAM), National Metrology Institute (PTB)**

**Review of the joint research strategy of the higher federal authorities: “Nanomaterials and other innovative materials: Application safety and environmental compatibility”**

As a contribution to the national Nanotechnology Action Plan 2020, the higher federal authorities have reviewed and updated their joint research strategy. The Research Strategy focuses on the safe use and environmental compatibility of nanomaterials and advanced materials. Publication of the strategy is scheduled for September. The strategy will be published at the websites of the above mentioned federal authorities.

In a long-term research strategy, the German higher federal authorities responsible for human and environmental safety – the German Environment Agency (UBA), the Federal Institute for Risk Assessment (BfR), the Federal Institute for Occupational Safety and Health (BAuA), the Federal Institute for Materials Research and Testing (BAM) and the National Metrology Institute (PTB) – are accompanying the rapid pace of development in new materials from the points of view of occupational safety and health, consumer protection and environmental protection. The strategy is therefore closely linked with public funding programmes for research on nanomaterials and other advanced materials, such as those of the Federal Ministry of Education and Research (BMBF) (“From Material to Innovation”) and the EU (“Horizon 2020”).

The research strategy builds on the outcomes so far of the joint research strategy of the higher federal authorities launched in 2008 and first evaluated in 2013, “Nanotechnology: Health and Environmental Risks of Nanomaterials”, while additionally covering other advanced materials where these pose similar risks to humans and the environment or where such risks need to be studied. It also takes up the idea of application safety in chemical products from the New Quality of Work (INQA) initiative of the Federal Ministry of Labour and Social Affairs (BMAS) and the concept of sustainable chemistry endorsed by the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB). Application safety and environmental compatibility are aimed for advanced materials and derived products in order to largely rule out unacceptable risks to humans and the environment.

The research strategy is to be implemented in projects and other research-related activities. These include governmental research, tendering and award of extramural research services, and participation in mostly publicly supported projects with third-party funding. Additional activities will take place as part of policy advice and the sovereign tasks of the agencies involved. Interdisciplinary and transdisciplinary approaches will be used to better connect risk and safety research with innovation research and material development. In keeping with the rapid pace of development in the sector, the time horizon for the research strategy is up to 2020. The research objectives address the research approaches likely to be actionable in this period. The research strategy will be supported by a working group and evaluated and revised by the end of the Nanotechnology Action Plan 2020.

<http://www.bfr.bund.de/cm/349/nanomaterials-and-other-advanced-materials-application-safety-and-environmental-compatibility-review-of-the-joint-research-strategy-of-the-higher-federal-authorities.pdf>

**B Federal Institute for Occupational Safety and Health (BAuA)**

The Federal Institute for Occupational Safety and Health (BAuA) has, in co-operation with the network NanoCarbon, launched a series of research projects, which focus on **risk assessment and a safe design of nanocarbon materials:**

**Project 1: Mode of toxic action of nanocarbons** (2015 – 2018), project manager: Prof. Thomas Gebel (BAuA), in co-operation with the working group “fibres and particles” of the Committee on Hazardous Substances.

Nanocarbon materials belong to a category of advanced materials comprising e.g. single-wall carbon nanotubes, multi-wall carbon nanotubes and graphene. This project focuses on the toxic effects of nanocarbons. These effects are dependent on the physical shape of the respective material influencing the critical mode of its toxic action. For instance, fibrous materials have to be discriminated from granular particulate materials. In case of a material consisting of rigid fibres in respirable form an asbestos-like action has to be assumed. With respect to other, e.g. non-rigid fibres, toxicity currently has to be assessed by animal testing. It is not known, which extent of flexibility is necessary that a fibre loses an asbestos-like action. Moreover, a high biopersistence would reduce the toxic potency of nanocarbons to a relevant extent. It is as yet unclear, if and how nanocarbons have to be chemically modified to reduce the general high biopersistence of these materials in biological systems.

This project aims to answer open questions with respect to the mode of toxic action of nanocarbons by carrying out adequate and targeted toxicological studies. Up to ten representative market-relevant materials shall be studied. The aim is to describe the toxicity of these materials qualitatively and quantitatively. It will be aimed at finding parameters influencing the biopersistence of nanocarbons. These studies shall contribute to the development of an assessment strategy to be established in a further project.

**Project 2: Dustiness and particle morphology of nano carbon materials** (2015 – 2018), project manager: Dr. Volker Bachmann (BAuA)

This project examines the cause for the differential dustiness of different nanocarbons. According to the current toxicological understanding, the factors ‘morphology’ and ‘rigidity’ are of fundamental importance in the evaluation of possible cancer risks by respirable, biopersistent fibres from innovative materials (such as carbon nanotubes and fibres). Three methods of activity-based analysis of dustiness will be used to determine the dusting propensity of various forms of nanoscale carbon compounds. Results will be correlated with a range of morphological characteristics in order to test whether there is a relationship between the morphologic characteristics of a material and its dusting propensity. Further, it will be analysed whether dusting propensity is a function of the rigidity of a material. The latter objective overlaps with the focus of another BAuA research project (F2365 - Development of an enforceable test method for determination of the rigidity of respirable biopersistent fibres). Results from both projects are the basis for a systematic evaluation of completed or yet to be initiated animal studies on the relationship of fibre geometry, biopersistence and rigidity. Furthermore, results will be of importance for the development of safe-by-design nanocarbon fibres.

**Project 3: Occupational safety aspects during manufacture and use of high-cycle fatigue performance resins for energy storage applications** (2015 – 2017), BAuA project manager: Sabine Plitzko

The aim of this project founded by the Federal Ministry for Economic Affairs and Energy is the development of carbon fiber-reinforced plastic materials (CFK) with high dynamic strength for the use in ultra-fast spinning flywheels as mechanical powers storages. By coupling the flywheels to an electric engine, they can be used as electrical short-term energy storage that represents a quickly implemented alternative to the reconstruction of existing energy storage systems and that helps to secure the network stability. As a result of years of development and optimization, rotors consisting of carbon nanofibers and reaction resins are already used for gas centrifuges and represented the ultimate of carbon fiber technology. Due to the load change requirements of energy storage further optimization of existing CFK-systems is necessary. By adding carbon nanotubes and further modifier, the reaction resins system should form a long lasting composite fiber structure with the needed load change and stability. The project contribution of BAuA focusses on occupational safety and health issues of this development: characterisation of the dustiness of the raw materials (e.g. MWCNT), emission from processes in the life-cycle of composites, measurement of worker-related exposure to particles and fibres.

**Project 4: Pilot project on building a supporting structure for the safe and sustainable development of nanoscale and other advanced materials** (2016 – 2020), project manager: Dr. Aline Reichow (BAuA)

Research institutes and start-up enterprises that actively develop nanomaterials and other advanced materials face difficulties in considering questions related to the safety of their materials for humans and the environment. First empirical results of research in the area of Regulation and Governance have

indicated that collaboration among scientists, regulators, representatives of industry and other interest groups in governance networks, that are build up and coordinated according to certain criteria, can contribute to the effective co-regulation of nanomaterials. Against this backdrop, this pilot project aims at developing a robust concept in form of a supporting structure for start-ups and research institutes. This structure shall enable learning processes on various levels. By means of two case studies and interviews three hypotheses are verified: Does the inclusion of start-ups in public-private governance networks support the safe and sustainable development of advanced materials when strong learning is observed? Is new knowledge generated and are, on this basis, rules developed when actors have developed relationships based on strong trust in each other? Do governance networks contribute to the effective regulation when actor interests and interaction is managed by a trusted, independent entity that operates at the intersection of science and policy?

### **C Federal Environment Agency (Umweltbundesamt, UBA)**

On behalf of UBA a survey on the possible environmental exposure of disposal of waste containing nanomaterials was conducted and now finalised. Aim of the study was the investigation of the behaviour of nanomaterials during the incineration using nanoscale TiO<sub>2</sub>. In order to optimize the application technique into the waste as well as the measurement technique, nanomaterials were incinerated in a small scale incineration plant. In addition, experiments were performed in a real existing waste incineration plant and a sewage sludge incineration plant. The final report is available in German with English abstract: <https://www.umweltbundesamt.de/publikationen/untersuchung-moeglicher-umweltauswirkungen-bei-der> UBA launched a new project entitled "Development of a method for the investigation of bioaccumulation of manufactured nanomaterials in filtering organisms". Aim of the project is to investigate and compare the bioaccumulative potential of nanomaterials of differing chemical nature in mussels. Additionally, the results of the projects are used to identify the need for adapting existing protocols for an appropriate investigation of the bioaccumulation of nanomaterials in filtering invertebrates. A draft test protocol will be developed. The project is intended for finalization in spring 2019.

### **D Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR)**

BfR is coordinating "NANOaers", a new ERA-NET SIINN project which will start in 2016. It aims to investigate fate and toxicity of aerosolized nanoparticles released from spray products in daily life scenarios. During these studies, a particular focus is laid on the influence of frequently used organic formulants on the toxicological properties of the products. The project employs three dimensional in vitro models of airway epithelium exposed at the air-liquid-interface and intends to establish a basis for regulation and standardization.

### **E Federal Institute for Materials Research and Testing (BAM)**

In a new project BAM is determining in collaboration with BAuA by means of dynamic electron microscopy (DySEM) the rigidity of nanofibers exposed at a surface. In addition new methods for measuring the dynamic mechanical behavior are developed. The results will be used by BAuA for reviews of this class of materials.

**Research or strategies on life cycle aspects of nanomaterials, as well as positive and negative impacts on environment and health of nano-enabled applications;  
Federal Environment Agency (Umweltbundesamt, UBA)**

UBA publishes data sheets of applications of nanomaterials for which benefit for the environment 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>

A new data sheet on the use of nanomaterials and nanoscale products for wastewater treatment was published

<https://www.umweltbundesamt.de/en/publikationen/use-of-nanomaterials-nanoscale-products-for>

A further datasheet on use of nanomaterials in power generation using renewable energies is underway.

**Development related to exposure measurement and exposure mitigation.**

**Federal Institute for Occupational Safety and Health (BAuA)**

BAuA has launched a research project for public tendering: **Evaluation of optical measure devices for the determination of particulate hazardous substances at workplaces** (2016 -18), BAuA project manager: Sabine Plitzko

In 2014, the German Committee on Hazardous Substances (AGS) significantly lowered the occupational exposure limit (OEL) for the alveolar fraction of granular and biopersistent particles (GBP). Surveillance of new OELs implies new requirements for instruments and is particularly challenging for materials with low material density. Assessment of procedures involving nanomaterials is especially difficult since they mostly occur as agglomerates with sizes above the upper size limit of online measurement devices for aerosols in the ultra-fine range (< 1µm). Therefore, optical measurement devices (e.g. optical particle counter – OPC) are likely to be more adequate.

The objective of this project is a comparison of optical measurement devices operating on the basis of different physical detection principles, under controlled and reproducible conditions. The measured particle number concentrations of the different instruments are compared. In addition, mass concentrations extrapolated from the particle number concentrations are correlated to mass concentrations, measured with the MPG II (reference procedure) on the basis of gravimetry.

This work will generate insights that are important for national and international activities on standardization and harmonization. The expected outcome of the project is the identification of suitable instruments and procedures that allow for a reliable determination of workplace exposure with regard to the lowered OEL for alveolar GBP.

**The FP7 SIINN ERA-NET project “nanoIndEx” – Assessment of individual exposure to manufactured nanomaterials by means of personal monitors and samplers** – has been closed with an international workshop hosted by BAuA at its Berlin site, Germany. The project results as well as two lectures of experts from outside the project were presented to an international audience. One of the central outcomes of the project is a new guidance document on the “Assessment of Personal Exposure to Airborne Nanomaterials”. The guidance document can be downloaded at:

[http://www.nanoindex.eu/wp-content/uploads/2016/06/Nano\\_Brosch%C3%BCre.pdf](http://www.nanoindex.eu/wp-content/uploads/2016/06/Nano_Brosch%C3%BCre.pdf)

Partners on nanIndEx were IUTA e.V. (lead), BAuA, IGF, University Duisburg-Essen (all Germany, kindly support by BMBF), IOM (United Kingdom, kindly supported by TSB, CEA (France, kindly supported by ANR), Fachhochschule Nordwestschweiz (Switzerland, kindly supported by FOPH) and the Catholic University of the Sacred Cross (Italy).

For more information visit: <http://www.nanoindex.eu>

**Past, current or future activities on nanotechnologies that are being done in your respective countries in co-operation on a multilateral basis, including with non-OECD countries.**

Include the nature of the collaboration, and the expected outcomes.

**Federal Institute for Occupational Safety and Health (BAuA)**

**BAuA contribution to the project “nanoGRAVUR”: Nanostructured materials – grouping approaches for workers, consumer and environmental protection and risk mitigation (2015 – 2018), BAuA project manager: Sabine Plitzko**

Nanomaterials may show a broad range of material properties although having the same chemical composition. This raises the question, e.g. in the context of substance registration under REACH or during a risk assessment at the workplace, whether test result from the hazard assessment and gained knowledge of an exposure assessment of a certain material can be used to derive occupational hygiene measures. Goal of the project nanoGRAVUR, sponsored by the Federal Ministry of Education and Research (BMBF) is the development of criteria for the grouping of nanomaterials in view of their hazard to humans and the environment. Fibrous materials are at the centre of concern, for some materials a high potential of risk has already been demonstrated by animal testing. The contribution of BAuA therefore focuses on the determination and assessment of the dustiness behaviour and the development of a procedure to determine the exposure to nanoscale fibrous materials at the workplace.

Within the project BAuA hosted a round-robin-test in its unique Fibre-Test-Centre. Goal is to improve DIN3492 on the assessment of Asbestos fibres. Using state-of-the-art imaging techniques the lower limit for counting fibres shall be lowered by one order of magnitude to 20 nm compared to the 0,2 µm in DIN3492. Three partners within the project are in the process to establish a new measurement strategy for “High Aspect Ratio Materials” (HARM). Partners for this task within nanoGRAVUR are BAuA and IFA of Germany and by separate invitation SUVA of Switzerland.

The Fibre-Test-Centre at BAuA Berlin consists of a cylindrical 240 litre chamber in which a homogeneous aerosol atmosphere can be realized. Different types of aerosol generators are available for different given tasks. Radial positioned probing tubes can be used to compare up to 8 different measurement instruments in parallel. The setup has been constructed with a long list of safety features which allow testing HARM with WHO fibre dimensions. Workplace measurements have been conducted to prove the effectiveness of the safety features. We welcome national and international partners to make use of this unique Fibre-Test-Center.

**ITALY****Developments related to good practice documents**

The experts from ISS and ISPRA, on behalf of the Ministry of Health (EU Member States Competent Authorities for REACH and CLP), are appointed for Partner Expert Groups (PEGs) in order to update the following specific sections of ECHA Guidance documents on nanomaterials

- Nanomaterials-related Appendix to the Guidance on Registration
- Guidance on Information Requirements and Chemical Safety Assessment (IR&CSA), nanomaterials-related Appendix to Chapter R.6: on QSARs and grouping of chemicals
- Updates to existing Appendices to Chapters R.7a and R7.c of the Guidance on IR&CSA (Endpoint specific guidance) on “recommendations for nanomaterials” regarding human health endpoints
- Updates to existing Appendices to Chapters R.7a, R7.b and R7.c of the Guidance on IR&CSA (Endpoint specific guidance) on “recommendations for nanomaterials” covering environmental endpoints

The update of these guidance documents will provide peculiar recommendations for nanomaterials on how to meet the REACH information requirements, to develop the use of relevant hazard data for human health and environment, to promote greater scientific understanding of hazard/risk assessment of nanomaterials.

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

The National Institute of Health (Istituto Superiore di Sanità, ISS) is coordinating the RinnovareNano project (regional funds), a two years action aiming to develop a national platform on risk assessment and regulation of nanomaterials and to facilitate public-private cooperation among the regional innovative realities and the ISS for a responsible development and a safe use of NMs. The platform will focus on the following areas: chemicals, pharma, biomed, cosmetics and agri-food. The project, started in the end of 2015, foresees the collaboration between the ISS and the Italian Association for the Industrial Research (AIRI). First results will be published at the end of 2016.

ISS is involved in WP1 of the Horizon2020 NanoReg2 project “Development and implementation of Grouping and Safe-by-Design approaches within regulatory frameworks”, that will establish safe by design as a fundamental pillar in the validation of a novel manufactured nanomaterials. In particular, WP1 is focused on regulatory orientated activities to establish a framework of grouping principles. The project is coordinated by INERIS, started in September 2015 and has a duration of 36 months.

The Italian Workers Compensation Authority (INAIL) is funding Nano-lab, a pilot project to develop novel communication tools for risk prevention and safety management of nanomaterials for people working in R&D laboratories. The tools will focus on 3 case studies (nanoparticles, graphene, nanowires). Risk management approaches will be available starting from Autumn 2016.

ENEA (Italian National Agency for New Technologies, Energy and Sustainable Economic Development) participates in the "EC4SafeNano project: European Centre for Risk Management and Safe Innovation in Nanomaterials and Nanotechnologies". The project aims to build an open collaborative network gathering expertise in risk management of nanotechnologies. In the network public research

organizations will be present. ENEA represents the Italian focal point of this network. The project, coordinated by INERIS, will start on November 1<sup>st</sup> 2016.

The SUN and CaLIBRAte projects are jointly organising a two-day Stakeholders Workshop in Venice, Italy. The meeting welcomes consortium members from the organizing projects as well as representatives from industry, regulatory and insurance sectors. It will be held on 28 February - 1 March 2017.

Moreover, always in Venice the Ca' Foscari University will organize the SRA (Society for Risk Analysis) Policy Forum on Risk Governance for Key Enabling Technologies. It will be held on 1 – 3 March 2017.

## JAPAN

- Japan is positively participating in ISO/TC229 activities. In March 2016, a Japan-led Technical Specification ISO/TS 19337 "Characteristics of working suspensions of nano-objects for *in vitro* assays to evaluate inherent nano-object toxicity" was published.
- Many of scientific research projects are still on going in Japan.

### **Developments related to voluntary or stewardship schemes**

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

### **Developments related to good practice documents**

METI firstly publicised information on safety test data and management methods of manufactured nanomaterials, on METI's website<sup>11</sup> in 2010 (only in Japanese). Such information was voluntarily provided and annually updated by the manufacturers. METI publicised the updated information in 2016.

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

In April 2012, a committee established by the Ministry of Health, Labour and Welfare (MHLW) began consideration of risk assessment for the prevention of impairment of workers' health caused by exposure to TiO<sub>2</sub> in nanoscale. In addition, MHLW launched development of measurement methods for airborne nanomaterials, carbon black and SW/MWCNT.

The Japanese Industrial Standards Committee (JISC), which is the national member body participating as a P-member in ISO/TC229 (Nanotechnologies), nominated the Convenor and Secretary of TC229/JWG2 (Measurement and characterisation) and has led the development of a TC229 document (Technical Specification) in TC229/WG3 (Health, Safety and Environmental Aspects of Nanotechnologies) that is ISO/TS 19337 "Nanotechnologies -- Characteristics of working suspensions of nano-objects for *in vitro* assays to evaluate inherent nano-object toxicity" and was published in March 2016. In TC229/JWG2, JISC leads revision of ISO/TS 10868 "Nanotechnologies -- Characterization of

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<sup>11</sup> [http://www.meti.go.jp/policy/chemical\\_management/other/nano\\_program.html](http://www.meti.go.jp/policy/chemical_management/other/nano_program.html)

single-wall carbon nanotubes using ultraviolet-visible-near infrared (UV-Vis-NIR) absorption spectroscopy" and jointly (with ANSI, the American National Standards Institute) leads a Preliminary Work Item "Nanotechnologies -- Measurements of Particle Size and Shape Distributions by Transmission Electron Microscopy" (PWI 21363), and also jointly (with ANSI) leads a Preliminary Work Item "Determination of size and size distribution of nano-objects by scanning electron microscopy" (PWI 19749), and leads a Preliminary Work Item "Characterization of nano-objects by asymmetric-flow and centrifugal field-flow fractionation" (PWI 21362).

An expert committee organised by the Ministry of the Environment (MOE), issued the "Guidelines for preventing the environmental impact of manufactured nanomaterials" to provide manufacturers with currently available information for the environmentally sound management of manufactured nanomaterials, in March 2009<sup>12</sup>.

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

The National Institute of Advanced Industrial Science and Technology (AIST), as a member of the Technology Research Association for Single Wall Carbon Nanotubes (TASC), released the English edition of "The protocols of preparation, characterisation and *in vitro* cell-based assays for safety testing of carbon nanotubes" in May 2014 that is available on the AIST-RISS website<sup>13</sup>.

#### **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, following the project "Research and Development of Nanoparticle Characterization Methods (Japanese Fiscal Year (JFY) 2006-2010)", funded by the New Energy and Industrial Technology Development Organisation (NEDO). This programme completed at the end of March 2016. 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, both of which are for safety management. In the summer of 2015, the Programme's website was fully updated with the new URL <http://metinanoen.aist-riss.jp/> to present its results as of June 2015. Some results of the R&D theme 2) above were presented at a WPMN horizontal expert workshop on toxicokinetics of nanomaterials in February 2014 and also at a WPMN information sharing seminar on *in vivo* inhalation toxicity screening methods for manufactured nanomaterials held at US EPA, Washington DC, in 21 September 2015. A domestic inter-laboratory comparison study on the procedure of intratracheal administration is currently underway. Preliminary results of the R&D theme 1) above were presented at a WPMN horizontal expert workshop on categorisation of nanomaterials in September 2014. Against a backdrop of the implementation of this programme, Japan led a WPMN Risk Assessment Pilot Project "Survey on approaches to develop or use concepts of grouping, equivalence and read-across based on physical-chemical properties of nanomaterials for their human health and ecosystem hazard assessment in regulatory regimes". The results from the survey was published as ENV/JM/MONO(2016)3 in the Series of Safety of Manufactured Nanomaterials (No.64).

METI also launched a five-year programme "Development of Innovation Carbon Nanotube Composite Materials for a Low Carbon Emission Society" in 2010. One of various R&D themes of the programme was "techniques suitable for voluntary safety management of CNTs by industries"<sup>14</sup>, which

<sup>12</sup> [http://www.env.go.jp/chemi/nanomaterial/eibs-conf/guideline\\_0903\\_enab.pdf](http://www.env.go.jp/chemi/nanomaterial/eibs-conf/guideline_0903_enab.pdf)

<sup>13</sup> <http://en.aist-riss.jp/assessment/2571/>

<sup>14</sup> <http://tia-nano.jp/en/core/area/nano-material.html>

focused on the development of toxicity testing and exposure assessment protocols for ensuring safety of CNTs and their applications, and whose results were released as the two documents described in 6. above and 10. below by AIST, as a member of TASC, in October 2013. The programme was converted into a three-year programme "Commercialising Carbon Nanomaterials for a Low Carbon Emission Society" starting in mid-2014. One of R&D themes of this successive programme is "to establish techniques for assessing release and exposure of carbon nanomaterials from their application products". Under this R&D theme, the following two documents (only in Japanese) regarding two types of SWCNTs<sup>15</sup> were released by AIST, as a member of TASC:

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

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 2016, 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 are on-going now (JFY 2016) as the preliminary studies for inhalation carcinogenicity study of TiO<sub>2</sub>. Inhalation carcinogenicity study of TiO<sub>2</sub> will be carried out in JFY 2016-2019.

From JFY 2011 MOE has been focusing their efforts on environmental risk of manufactured nanomaterials via understanding of their environmental fate and ecotoxicity. MOE has also been collecting and reviewing existing literature on ecotoxicity of manufactured nanomaterials such as TiO<sub>2</sub>, silver and CNTs to identify any harmful effects attributed to their particle sizes.

The National Institute for Environmental Studies (NIES) completed the 2<sup>nd</sup> nanotoxicology programme (JFY 2011-2015) which included *in vivo* toxicological studies of MWCNT, *in vitro* and *in vivo* toxicological study of silver nanoparticles in reference to dissolution of metal nanoparticles, toxicokinetics of fluorescence-labelled dendrimers and ecotoxicological study of TiO<sub>2</sub> nanoparticles using embryo and sac-fry fish.

### **1. Development related to exposure measurement and exposure mitigation.**

AIST, as a member of TASC, released the English edition of "Guide to measuring airborne carbon nanotubes in workplaces" in October 2013 that is available on the AIST-RISS website<sup>16</sup>. Researchers of AIST are currently engaged in on-site measurement of airborne nanoparticles released from processing of nanocarbon composite materials.

Aiming at developing methodologies for measurement of manufactured nanomaterials in the environment (i.e., ambient air and surface water), MOE initiated its attempts through measuring nanoscale TiO<sub>2</sub> in a closed system and then in the open air outside of some waste shredders. Another attempt has been initiated to measure nanoscale CNTs in the ambient air.

<sup>15</sup> <http://tia-nano.jp/en/core/area/carbon-nano.html>

<sup>16</sup> <http://en.aist-riss.jp/assessment/2571/>

## NETHERLANDS

- Publication of the End Term Report of the Netherlands nano/microtechnology research and innovation programme NanoNextNL.
- Publication of the report “Usage of (eco)toxicological data for bridging data gaps between and grouping of nanoforms of the same substance – Elements to consider”, a collaboration between ECHA, JRC and RIVM.
- Publication of the opinion paper “Towards a nanospecific approach for risk assessment” within the NANoREG project.
- A new software model Simplebox4.0-nano ([www.rivm.nl/simplebox](http://www.rivm.nl/simplebox)) was developed as a screening level model for environmental exposure assessment of nanomaterials.

### **National developments on human health and environmental safety**

After setting the basic conditions for its R&D work, developing standardised test methods and generating reliable and comparable nano-EHS data, the NANoREG project now focuses on developing the main “end products” of the NANoREG project: the Regulatory Framework and the NANoREG Toolbox. Among others the Framework includes a proposal for a nanospecific risk assessment based on a recent publication of work carried out under the umbrella of NANoREG. One of the annexes of the framework is a NANoREG harmonised terminology for environmental health and safety assessment of nanomaterials (April 2016). Recently the NANoREG consortium decided to make all nano-EHS data generated under the umbrella of NANoREG publicly available, thus setting an example for the nanosafety community to open up all available nano-EHS data.

The ProSafe project made good progress in organising the White Paper Process. A Task Force has been established under the leadership of Klaus Steinhäuser and Phil Sayre. This Task Force will evaluate the results of a great number of nanosafety projects and publications on their regulatory relevance. The Task Force is staffed with nine senior experts covering all relevant fields of interest. Basis for this evaluation is a “Road Map” that gives guidance to the members of the Task Force regarding the aspects to be evaluated. The evaluation will result in a draft “Joint Document” that will be discussed during a three day Scientific Conference organised in collaboration between the ProSafe project and the OECD (29 November 2016 – 1 December 2016 at the OECD Conference Centre in Paris). The final Joint Document, together with the Framework document and toolbox will be a cornerstone of the policy oriented White Paper that will be discussed in draft in March – April next year.

### **New activities (e.g. regulatory changes, guidance, voluntary, etc.) been initiated to implement the OECD Council Recommendation<sup>17</sup>**

In the framework of the OECD-WPMN NL took the lead in the evaluation of the methods applied in the “WPMN Programme for the Testing of Manufactured Nanomaterials” to determine physico-chemical properties of nanomaterials. During 2014-2015 international experts have scrutinized the methods applied by providing answers to a questionnaire. They concluded that some methods (may) have shortcomings for (certain) nanomaterials. On February 11, 2016, the report of the evaluation was published as part of the OECD “Series on the Safety of Manufactured Nanomaterials”: No. 65 - Physical-chemical properties of nanomaterials: Evaluation of methods applied in the OECD-WPMN testing programme.

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<sup>17</sup> [Recommendation of the Council on the Safety Testing and Assessment of Manufactured Nanomaterials](#)

As lead countries, Netherlands and the US, are reviewing TGs 412 and 413 in view of the discussion in and recommendations from the WNT. The revised drafts will be reviewed by the Joint Expert Group during the summer and further discussed during a face-to-face meeting that will be held in the Arlington, VA (31 October – 1 November 2016).

As part of the work by CEN (TC352 WG3) on the broad task of “Guidance on detection and identification of nano-objects in complex matrices”, RIKILT (Wageningen UR) is contributing with the single particle ICP-MS method.

The Netherlands (RIVM, DSM and RIKILT–Wageningen UR) 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”, where the technical aspects were covered by RIKILT.

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

In 2014, the Netherlands has started a substance evaluation of silver within the REACH process. The focus in this evaluation is on the environmental fate and toxicity of the nanoforms of silver in relation to ionic silver. In MSC-47 (April 2016) the MSs adopted the final decision on this substance evaluation, in which further comparative testing is requested on nanosilver and ionic silver.

**Developments related to good practice documents**

In a collaboration by ECHA, JRC and RIVM a stepwise approach was developed to explore possibilities to scientifically justify the use of toxicity data for one nanoform to fulfil data requirements for a different nanomaterial of the same substance. The resulting report “Usage of (eco)toxicological data for bridging data gaps between and grouping of nanoforms of the same substance – Elements to consider” was published in March 2016 and will be used in the development of specific REACH Guidance on grouping and read-across of nanomaterials.

For the further development of Stoffenmanager Nano, TNO developed five good practice documents, describing workplaces with a minimised exposure by the application of control measures.

Within ISO TC 229’s Working Group on Health, Safety and Environments (WG3) it has been decided to prepare a new work item proposal (NWIP) for the development of a document on Toxicokinetics of nanomaterials. The NWIP will be submitted before the end of 2016. The Netherlands (RIVM) has taken the lead in this project. The intention is to prepare a document that describes how toxicokinetic studies for nanomaterials should be conducted.

Recently a review prepared at RIVM was published on regulatory testing for immunotoxicity of nanomedicinal products. The aim of the study was to compare the current regulatory immunotoxicity testing requirements with the accumulating knowledge on immunotoxic effects of nanomaterials and more specifically nanomedicinal products, in order to identify potential gaps in the safety assessment. This comparison showed that some immunotoxic effects are not readily detected by using current testing practices. Improvements are suggested that include the use of multiple assays that are customized for specific nanomaterials.

Within the FP7 NANoREG project a risk assessment strategy was developed for nanomaterials. Within this strategy, which is based on six key elements for risk assessment, approaches towards (Quantitative) Structure Activity Relationships ((Q)SARs), grouping and read across are integrated and expanded to guide the user in prioritising those nanomaterial applications that may lead to high risks for

human health. In addition, the approach aids in identifying and generating the type of data that is needed for scientific justification of (Q)SARs, grouping and read-across, which may lead to regulatory acceptance of nanospecific applications of these tools. The approach is described in the opinion paper “Towards a nanospecific approach for risk assessment”.

RIKILT–Wageningen UR worked together with the Joint Research Centre (Ispra, Italy) on the EFSA project *Inventory of Nanotechnology applications in the agricultural, feed and food sector*. This resulted in two publications focussing on the regulatory aspects (Regulatory aspects of nanotechnology in the agri/feed/food sector in EU and non-EU countries) and on the (potential) use of nanomaterials in agriculture, animal feed and food production (Nanomaterials for products and application in agriculture, feed and food). The latter shows the widespread application of nanomaterials and a trend towards combinations of inorganic and organic (nano)materials.

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

For environmental exposure assessment of nanomaterials the screening level model SimpleBox4.0 was adapted for use with nanomaterials. Simplebox4.0-nano is now publicly available online at [www.rivm.nl/simplebox](http://www.rivm.nl/simplebox). Recently, the analysis of the model for uncertainty and variability has also been published. The model will be under further development in the EU-project NanoFASE which provides an opportunity to give input on regulatory requirements and compatibility for inclusion in such a model.

Within the COST action MODENA (Modelling Nanomaterial Toxicity, [www.modena-cost.eu](http://www.modena-cost.eu)), actions have been initiated towards developing mathematical QSAR-type of models that allow predicting human health and environmentally relevant endpoints of toxicity of functionalised nanomaterials. Within MODENA, RIVM developed some generalised predictive models for metal-based nanomaterials. MODENA will end this year. A closing conference is planned for October 2016.

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

Several Dutch partners (RIVM, TNO, Utrecht University, GeoChem, and Think Works) are involved in the European GUIDEnano project (<http://www.guidenano.eu/>). The second version of the GUIDEnano tool is now available and is currently evaluated by performing case studies, which involve environmental and human inhalation exposure. For these cases, quantitative risk assessment throughout the whole life cycle is already possible, including an overview of the associated uncertainties. For the hazard as well as the exposure assessment, the tool guides the user to score the quality and relevance of the studies selected. Meanwhile, the consortium partners are continuing work on implementing similarity rules: the comparison of the physico-chemical properties of the exposure relevant materials with those from the selected studies. In the third and final version of the tool, these scores will also be translated into uncertainty, where relevant. In addition, this version will include ‘activity cards’: descriptions of exposure scenarios for common production and use processes of nanomaterials and nano-enabled products and their associated default values.

Under auspices of WHO/IPCS an expert group has been installed that will prepare an Environmental Health Criteria Document Principles and Methods of Assessing the Risk of Immunotoxicity Associated with Exposure to Nanomaterials. Henk van Loveren (Maastricht University, formerly RIVM) has been appointed as the chair of this expert group. A scoping meeting to decide on the content and outline of the document was organized by the WHO Collaborative Centre on Immunotoxicology and Allergic Hypersensitivity at RIVM in April 2015, and a subsequent workshop was organized in April 2016, also at RIVM, to review a first draft of the document. In the fall of this year, it is envisaged that a further refined draft is ready, and that cases, i.e. risk assessments on specific particles will be made, according to the

concepts laid down in the manuscript. It is estimated that preparation of an integral draft ready for public consultation will take another 1.5 years. OECD is involved in this endeavour as an observer.

RIVM is partner in the EU project NanoMILE (Engineered nanomaterial mechanisms of interactions with living systems and the environment: a universal framework for safe nanotechnology) ([www.nanomile.eu-vri.eu](http://www.nanomile.eu-vri.eu)). The project evaluates in depth the potential interactions of nanomaterials with cells, organs, and hosts, with the aim to evaluate mechanisms of interaction with biological systems and the environmental species. Basic to the project is a high quality characterisation of the nanomaterials, high throughput screening and systems biology for determining effects and pathways in the interaction of nanomaterials with biological systems. This information will be correlated with more classical toxicity assays. Identification of critical properties (physico-chemical descriptors) that confer the ability to induce harm in biological systems is key to allowing these features to be avoided in nanomaterials production (safety by design). The NanoMILE project is in its last year (ending March 2017). RIVM is leader for the work package on human toxicology.

Five Dutch partners (RIVM, TNO, Public Impact, DSM and GeoChem) take part in NanoRegII. RIVM is work package leader on development of the so-called Safe Innovation Approach that brings together how both industry and regulators could better secure human and environmental safety of innovative nanomaterials. This development elaborates on the Safe-by-Design concept developed in NANoREG and the practical implementation for industry as under development in ProSafe. In this WP it is regarded which type of information should be generated per stage of innovation, how trusted environments can be created in order to allow exchange of information and expertise between innovators and regulators and which barriers and incentives will be faced. TNO will secure that the data management as established in NANoREG will be continued in NanoRegII.

TNO is partner in the EU project NANOSOLUTIONS (Systematic investigations of the mechanisms and effects of engineered nanomaterial interactions with living systems and/or the environment) ([nanosolutionsfp7.com](http://nanosolutionsfp7.com)). The project aims to provide a means to develop a safety classification for engineered nanomaterials (ENM) based on an understanding of their interactions with living organisms at molecular, cellular and organism levels. The objective is to determine the “biological identity” of ENM, and subsequently develop a computer program that can predict from the properties of ENM their ability to cause health or environmental hazards. TNO is participating amongst others in the work package which addresses the crucial issue of ‘normal’ versus ‘diseased’ or susceptible states. This issue is of particular importance because realistic exposure scenarios need to take into account the possibility of a pre-existing illness (e.g. asthma/allergy) that could be exacerbated by exposure to engineered nanomaterials (ENM).

Starting November 2016, a virtual European centre will be constructed to assist Member States, EU agencies, industries and other stakeholders with all nanosafety related issues. EC4safenano, a consortium with 14 participants from different European countries (including TNO), will map demands and resources in order to develop a catalogue of services. Six thematic networks will be activated, by networking already existing networks. National initiatives, like Nanocentre in the Netherlands, will be connected in order to share experiences and knowledge. The consortium invites any interested party to become an associate member.

TNO participates in the European NanostreeM project that explores health risks caused by exposure to nanomaterials in the semiconductor industry. This high-tech sector operates on the nanoscale, but so far, it has not been systematically mapped whether or not exposure to nanomaterials occurs. The project is aiming for guidance how to assess the nanorisks, taken in consideration the special circumstances in the sector (e.g. very low amounts, clean rooms conditions).

Several Dutch institutes (RIVM, TNO, WUR) are partners in the Horizon 2020 project NanoFASE (Nanomaterial fate and speciation in the environment). NanoFASE started on 1 September 2015 and aims to deliver an integrated Exposure Assessment Framework, including methods, parameter values, models and guidance that will allow Industry to assess the full diversity of industrial nano-enabled products to a standard acceptable in regulatory registrations. The project constitutes a combination of generation of novel fate data on specific nanomaterials, development and validation of process-based models for specific pathways of nanomaterials in the environment, and development of spatial and generic models for quantifying nanomaterial fate. In the latter case, the generic fate model Simplebox, developed by RIVM and currently applied as the generic fate model for risk assessment of chemicals within REACH, was modified to take the characteristics of nano-specific transformation and distribution processes explicitly into account. The newly developed model, Simplebox4Nano, is expected to be suited as a generic model in future nano-specific risk assessment, allowing quantification of the key fate processes of nanomaterials. WUR is leading the work package on biota uptake of nanomaterials

The FP7 project NanoDefine consists of 28 partners and is coordinated by RIKILT–Wageningen UR. The project aims to explore and develop conceptual and technical tools for the classification of any materials according 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.

The EMPiR/Euramet project InnanoPart (Metrology for innovative nanoparticles) will provide industry with techniques and methods for the measurement of nanoparticle number concentration and surface chemistry. In this project RIKILT–Wageningen UR participates on measurement with single particle-ICPMS and multi-element single particle ICPMS, and the development of data-analysis software for non-spherical NPs.

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. The project has particular focus on optimization, calibration and demonstration of existing models and methods that support the risk governance framework. Testing and calibration will be made on existing as well as new data generated in the project covering both material characterization, human and environmental exposure, and (eco-)toxicology from both in vitro and in vivo studies. Next generation computational risk assessment and communication models are anticipated in the framework. The framework will finally be demonstrated by industrial case studies.

**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 contribution of TNO to the EU-project FutureNanoNeeds ([www.futurenanoneeds.eu](http://www.futurenanoneeds.eu)) has been continued. A framework was developed to forecast exposure of the next generation of nanomaterials using Bayesian networks. For a first tier in the framework, the life cycle of 7 nanomaterials and identified and described focal points in 5 so-called ‘value chains’, which describe the life cycle of nanomaterials in specific uses. Focal points highlight stages in the value chain that may increase or change the type of potential exposure to nanomaterials (e.g., significant nanomaterial transformation, or high concern activities). Within the work package on environmental fate and effects, RIVM contributes to the activities aimed at testing the adverse effects of homologous nanomaterial with regard to a number of specific

endpoints and specific species (including microbes, daphnids, algae, and fish). The focus of these experiments was on testing the impact of size and shape of nanomaterials of similar chemical composition on toxicity. In addition, RIVM contributes to the evaluation of the effect of shape of nanomaterials on genotoxicity and immunotoxicity.

### **Development related to exposure measurement and exposure mitigation**

To investigate the exposure of the consumer to nanomaterials in spray products, RIVM developed a new software model: ConsExpo nano ([www.consexponano.nl](http://www.consexponano.nl)). This model was adapted from the ConsExpo model for the estimation of exposure to regular substances in spray products. It has been developed in the context of the Dutch NanoNextNL project ([www.nanonextnl.nl](http://www.nanonextnl.nl)): “Predictive modelling of human exposure”. ConsExpo nano combines models that estimate the external aerosol concentration in indoor air, with models that estimate the deposition in and clearance of inhaled aerosol from the alveolar region. It is a “work-in-progress” online tool, which is designed to reflect the current state of knowledge on exposure to nanomaterials via inhalation. In the new version of the tool (version 1.1) two major changes have been implemented, based on comments and suggestions from (external) users. First, apart from a spray scenario, the user is able to choose a *custom scenario* in which a known air concentration of aerosols (containing nanomaterials) can be entered directly into the tool. With this option, the user is able to calculate an alveolar load in lungs from any inhalation exposure (outside spray exposure), which makes the tool applicable for a wider range of exposure scenarios, including scenarios at the workplace. Furthermore, the possibility is included to enter exposure parameters of an animal hazard study with known adverse effects after inhalation exposure to the nanomaterial of interest (or a similar nanomaterial). In this way, the external dose of nanomaterials to which the animals are exposed, can be converted into an internal exposure dose (i.e. the alveolar load). In this way, a comparison can be made between exposure related adverse effects of the animal study and the dose that is expected after human inhalation exposure, which gives a first indication of the risk after that specific exposure to nanomaterials. The tool will be further developed to accommodate developments in the state of the science.

Several Dutch partners (TNO, RIKILT–Wageningen UR and RIVM) contribute to the EU project SUN (Sustainable Nanotechnologies) ([www.sun-fp7.eu](http://www.sun-fp7.eu)). The project addresses the entire life cycle of nanotechnologies to ensure holistic nanosafety evaluation and incorporate the results into tools and guidelines for sustainable manufacturing, which are easily accessible by industries, regulators and other stakeholders. The project incorporates scientific findings from over 30 European projects, national and international research programmes and transatlantic co-operations. It aims to develop (i) methods and tools to predict nanomaterials exposure and effects on humans and ecosystems, (ii) implementable processes to reduce hazard and exposure to nanomaterials in different lifecycle stages, (iii) innovative technological solutions for risk management in industrial settings, and (iv) guidance on best practices for securing both nano-manufacturing processes and nanomaterials ultimate fate, including development of approaches for safe disposal and recycling. In summary, SUN stands for an integrated approach for the long-term sustainability of nanotechnologies through the development of safe processes for production, use and end-of-life processing of nanomaterials and products, as well as methods reducing both adverse effects and exposure to acceptable levels.

### **Additional Information**

In June 2016 the End Term Report of the Netherlands nano/microtechnology research and innovation programme NanoNextNL was published. This report is written before the finalization of this programme (December 2016) to enable incorporation of the outcomes into further activities concerning innovation. NanoNextNL was organized into 10 themes, including a theme dealing with Risk Analysis and Technology Assessment (RATA) led by RIVM. One of the important goals was to establish collaboration between the RATA theme and the other innovation themes. One of the developments in the NanoNextNL programme was the initiation of a new Safe-by-Design concept. This concept provides guidance on how to consider

safety aspects during early stages of development of nanotechnology and especially nanomaterials. A unique set of Safe-by-Design tools was established for application in science and industry. The lessons learned and the hands-on experience from the NanoNextNL programme formed direct input for the development of the Safe-by-Design concept in the EU-project NANoREG.

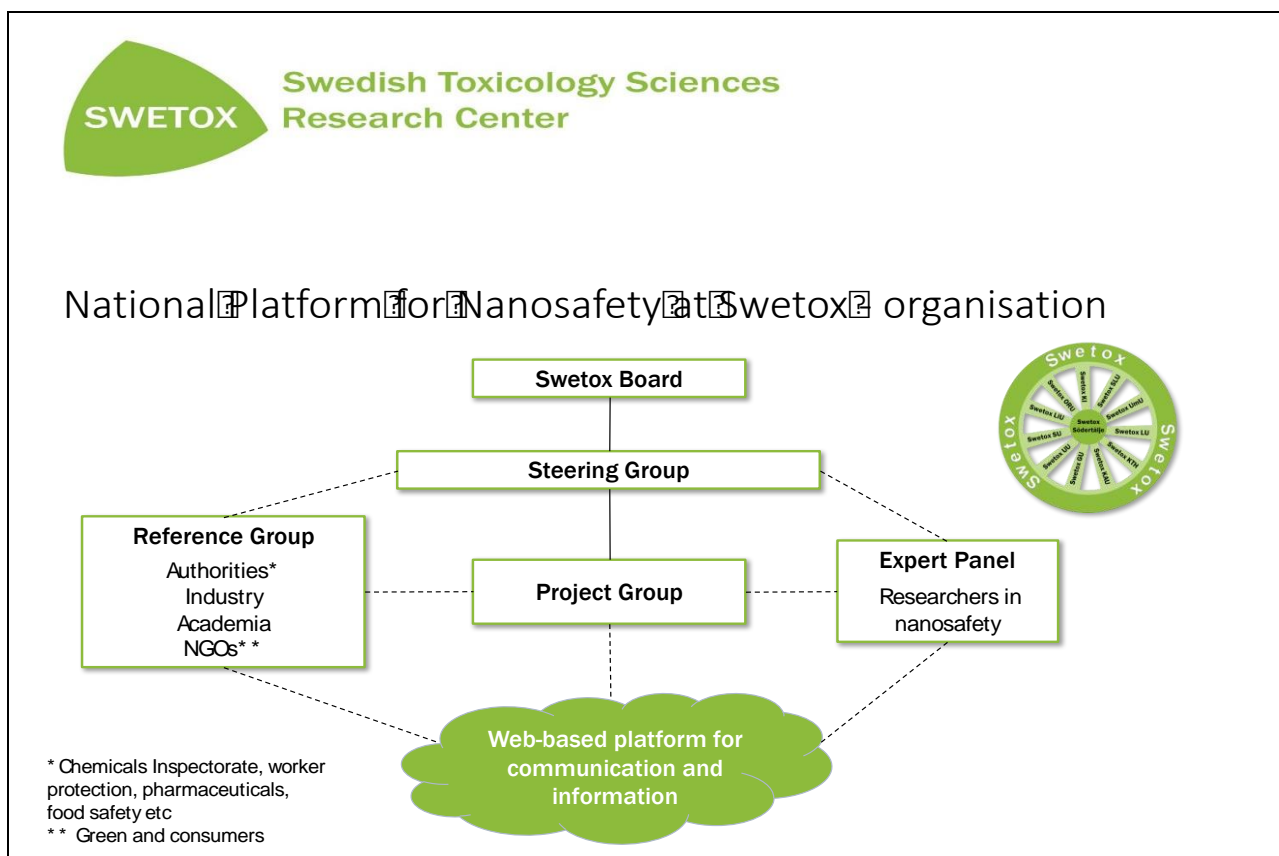
## **SWEDEN**

### **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 is 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.

During spring 2016 an action plan 2016-2018 was developed and, in a first round, discussed with the Swedish Chemicals Inspectorate 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.

In May, 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.



### Swedish nano registry

In January 2015 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 development of new nanomaterials is fast and the industry is growing rapidly. Nanomaterials can be used within a wide range of applications due to the special properties often exhibited by these materials. However, some nanomaterials, unlike the same material in other sizes, have been shown to have negative effects on health and environment. Furthermore, nanomaterials have long been an area without explicit regulation and many institutions perceive a need for a better overview of the market in order to assess the need for action.

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 pigment.

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.

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

The Swedish Chemicals Agency will later in 2016 publish 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 of the NANoREG project

## **SWITZERLAND**

### **Developments related to voluntary or stewardship schemes**

Switzerland pursues the development and promotion of voluntary tools for strengthening industrial responsibility for the risk management of nanomaterials. This is particular important as long as the regulatory framework for nanomaterials is still evolving. Such tools, developed and implemented in Switzerland, are e.g. the guidance documents for (i) “responsible care”, (ii) disposal of nanowaste, (iii) safety data sheet, and (iv) hazardous incidences. The “Precautionary matrix for synthetic nanomaterials”, also available as an online tool, has been proven a very valuable tool for small, medium and larger companies that are dealing with nanomaterials.

### **Information on:**

#### **updates, including proposals, or modifications to previous regulatory decisions**

Since 2012, nanospecific information (physical-chemical properties) is requested for the registration of nanomaterials as new substances and for the notification of hazardous existing substances in nanoform, according to the Chemical Ordinance (ChemV, SR 813.11). The Swiss definition of nanomaterials is similar to the recommendation of the European Commission with the difference that there is no number threshold and that the nanomaterial must be made on purpose to exhibit a nanospecific effect. In addition to the nanospecific amendment to the ChemV, similar amendments were made to the Ordinance for plant protection products (PSMV, SR 916.161). The Ordinance for biocidal products (SR 813.12) is harmonized

with the EU regulation. Moreover, nanomaterials must be declared in applications for admission of pharmaceuticals.

Switzerland aims to including synthetic nanomaterials in the notification and registration procedure for new chemical substances. Therefore, one of the upcoming revisions of the Chemical Ordinance will include a notification procedure for producers and processors of nanomaterials. The goal of this action is to have a better overview of currently used nanomaterials and their application. It will also ensure that risk management systems can be checked. Moreover, it will support the development of a solid scheme for nanomaterial identities.

### **New regulatory challenge(s) with respect to any action for nanomaterials**

An ongoing challenge are regulatory decisions on similarity of nanomaterials. Regulators and industry need clear rules for identification and grouping of nanomaterials that may lead to a streamlined quantitative hazard evaluation. Therefore, we are currently developing a pragmatic definition of identities for nanomaterials. Subsequently, we want to combine the identities into entities of similar physical-chemical properties. Testing strategies (ideally based on AOPs) will then be tailored to these entities in order to only applying the in vivo tests that are really necessary for the risk assessment. An outline of the approach can be found under doi:10.1016/j.yrtph. 2015.05.031 (Walser et. al 2015: Sameness, the regulatory crux with nanomaterial identity and grouping schemes for hazard assessment. Reg Tox Pharm) or in the available presentation, held at the grouping workshop in Brussels earlier this year.

### **Developments related to good practice documents**

Regarding existing substances and preparations, the Chemicals Ordinance obliges manufacturers to review their safety for humans and the environment as part of the self-monitoring process. A new guidance document on best practice of the self-monitoring process has been successfully tested with industry and the few amendments are currently being integrated. The release of the final version is expected later this year.

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

Switzerland supports further development of ITS and Alternative Testing Strategies. An ongoing collaboration with a small research enterprise is investigating the potential of nanospecific AOP to be included in future test strategies. Results are expected early 2017. Research programmes or strategies designed to address human health and/ or environmental safety aspects of nanomaterials

Beside the active involvement in the FP7-programme NanoReg, Switzerland supports a research programme, called NanoScreen<sup>18</sup> on further development of in-vitro assays. NanoScreen is directly linked with attempts and institutions in the U.S., for example NIST and NCL, and in Europe (ETPN) that are working along the same lines, i.e. a harmonized (and ideally standardized) in-vitro assessment of nanomaterials. In addition, NanoScreen aims toward a better understanding of nanoparticle corona – cell interaction. It is a 5 year project that started last year.

Switzerland also supports the transnational call of “Prosafe” (<http://www.h2020-prosafe.eu/>) on the topic “Implementing Safe-by-Design concepts for nanomaterials in industrial innovation processes”. Funding agency for Switzerland is the Swiss Commission for Technology and Innovation CTI. The call is closed by now and the selection of the successful proposals will be communicated by the end of 2016.

### **Public/ stakeholder consultations**

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<sup>18</sup> <http://www.ccmx.ch/research/materialschallenges/nanoscreen-reliable-and-rapid-in-vitro-safety-assessment-of-nanomaterials/>

Industry is currently being consulted on their perspective on the notification and registration scheme under the Swiss chemicals legislation.

The consultation on the guidance document on the responsible care (“self monitoring”) of nanomaterials being produced or used in industry is finished and the viewpoints will be implemented into the final version prior to its release.

*Infonano (Website)*: Since April 2012, the main information platform for nanotechnology “InfoNano” is online and has been completely updated very recently. InfoNano provides information in German, French, Italian and English about the opportunities and risks associated with nanotechnology and synthetic nanomaterials. It is aimed at promoting the dialogue among stakeholders from industry, academia, society and administration. It presents all relevant governmental activities on nanotechnology and provide a structured entry into the world of nanotechnology. Among other topics, one can find international research highlights, safety of consumer products, regulatory activities of the ministries, and much more additional information.

Link: [www.infonano.ch](http://www.infonano.ch)

#### **Additional Information**

On an annual basis, the German speaking countries Principality of Liechtenstein, Austria, Germany, and Switzerland, and newly also Luxembourg, held a 2-days workshop on regulatory issues of nanomaterials. This year, the 10<sup>th</sup> workshop was hosted by Switzerland with the title: *Scientific evidence as basis for regulatory decision making*. The program consisted of four blocks: 1) Results from the national research programme “Chances and Risks of Nanomaterials”; 2) presentations of projects with relevance for regulation (NanoEHS Projects, Th.Kuhlbusch), OECD projects (B.Diderich), ProSafe (K.Steinhäuser), NanoReg (K.Höhener), 3) Perspectives from Industry and NGO, and 4) a workshop concluded the event, wherein the participants discussed about possible regulatory actions bearing in mind the latest research findings that were discussed previously. The next “Behördendialog” will be hosted by Austria in Spring 2017.

Link: <http://innovationsgesellschaft.ch/en/regulation-of-nanomaterials-at-the-10th-international-nano-authorities-dialogue-in-bern-ch/>

## THAILAND

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

### **Collaboration with Thailand Industrial Standard Institute (TISI)**

Completed 7 industrial standardization manuals related to nanotechnology:

1. Nanotechnologies Part 1: Guidance on specifying manufactured nanomaterials
2. Nanotechnologies Part 2: Guidance on material characterization for specifying manufactured nanomaterials
3. Nanotechnologies Part 3: Guidance on safe handling and disposal of nanomaterials
4. Nanotechnologies Part 4: Guidance on physio-chemical characterization for toxicologic assessment of manufactured nanomaterials
5. Nanotechnologies Part 5: Guidance on nanomaterial risk evaluation
6. Nanotechnologies Part 6: Particle size analysis using dynamic light scattering
7. Nanotechnologies Part 7: Health and safety practices in occupational setting relevant to nanomaterials (draft completed but no yet finalized)

5 of the 7 manuals have been officially announced. The 5 announced manuals are:

- **Guidance on specifying manufactured nanomaterials**
- **Guidance on material characterization for specifying manufactured nanomaterials**
- **Guidance on safe handling and disposal of nanomaterials**
- **Guidance on physio-chemical characterization for toxicologic assessment of manufactured nanomaterials**
- **Guidance on nanomaterial risk evaluation**

### **Developments related to voluntary or stewardship schemes;**

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.

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.

This year NANOTEC and other research agencies are participating in the NSTDA On-Line Learning Project (NOLP). NSTDA S&T courses are currently being VDO and taped for uploading to the Massive Open Online Courses (MOOC) network. A total of 16 on-line courses will be dedicated to nanotechnology of which 2 courses will focus on nanosafety of nano materials and products.

The 16 on-line S&T courses will be uploaded soon are:

- Wonders in Nanotechnology in nature
- Development of teaching communication and services.
- Water, roll on the lotus leaf .
- Inspired by nature, Nano textile
- Nanotechnology and the meaning of nanometers
- What is nanotechnology: size of nanometers .
- Why Nano?.
- The synthesis of nanoscale products: synthetic nanoparticles to test for lead .
- Why nano catalyst?
- Applications of Nanotechnology
- The camera and the benefits of AFM.
- The carbon nano: a structural model of Fullerenes .
- Carbon nano- structure: models diamond structure .
- Why Nano? optical properties of gold nanoparticles in solution .
- Gold nano- particle synthesis activity
- The safety of nano materials and products .

In May 2016, representatives from NANOTEC and the Chairman of NanoQ label participated as invited speakers at the 2 days' workshop on "Training and Capacity Building for the development of nanosafety pilot project in Vietnam". The workshop was organized by the Vietnamese Pollution Control Department (PCD) together with the Swiss Confederation and UNITAR.

Also on May 17-19 two NANOTEC representatives were invited to join the nano event in Iran to present report on Thailand nanosafety initiatives, policy, and labeling.

**Developments related to Integrated Testing Strategies and/or Alternative test methods (e.g. in-vitro and in-silico methods and high throughput methods)**

Construction of the National Advanced Nano-characterization Center (NANC) is completed and research activities have begun. The Nano Characterization Lab (NCL) is taking the leading role in setting up the center.

Since 2010 NANOTEC and National Institute of Metrology (NIMT) have collaborated to form the country's first research collaboration to build Thailand's capabilities in providing quality infrastructure in areas related to nano-scale measurement, calibration, and nanometrology. The collaboration was renewed on June 29.

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

**Published Papers:**

Ultra-sensitive NO<sub>2</sub> sensor based on vertically aligned SnO<sub>2</sub> 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  $\gamma$ -oryanol-containing solid lipid Nanoparticles

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

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

(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

**Information on past, current or future activities on nanotechnologies that are being done in your respective countries in co-operation on a multilateral basis, including with non-OECD countries. Including the nature of the collaboration, and the expected outcomes.**

Collaboration with UNITAR

In 2011, NANOTEC and UNITAR signed a Collaborative Agreement to implement a Training and Capacity Building for the Development of the Nano-Safety Pilot project in Thailand (phase 1). The first training workshop was the Nano Inception/Awareness Raising Workshop which was held in 2012 in conjunction with NanoThailand 2012 conference. Since then several regional workshops have been initiated under this collaborative umbrella including the recent workshop being the Technical Workshop for the “Asia-Pacific Region on Nanotechnology and Manufactured Nanomaterials: Safety Issues” which was held on 10 & 11 September 2015 at Thailand Science Park in Pathumthani province, Thailand.

As a result of the above collaboration, NANOTEC will host 3-5 researchers from Dept of OHS and Dept of Chemical Engineering, Universitas Indonesia to do ecotox study (organic insecticide in powder form) at NANOTEC Safety and Risk Assessment Lab at Thailand Science Park.

Plans are in the work to invite representative from UNITAR to be a speaker at Nano Thailand 2016 which is scheduled for November 27-29 in Nakorn Rachasima, Thailand. The organizer of NanoThailand 2016 have identified topic of nanosafety as one of the highlight for this event.

## UNITED KINGDOM

### **National developments on human health and environmental safety**

Publication of guidance on “**Working Safely with Nanomaterials in Research & Development**” Second Edition, May 2016 which was developed by the The UK NanoSafety Group.

*<http://www.safenano.org/media/108929/UKNSG%20Guidance%20%20Working%20Safely%20with%20Nanomaterials%20-%202nd%20Edition.pdf>*

### **Developments related to voluntary or stewardship schemes**

The UK Environment Agency has collated information on active nano companies in the UK – not in the public domain

### **Developments related to good practice documents**

- A. The UK National Physical Laboratory (NPL) is leading the development of an ISO terminology standard on graphene and 2D material terminology. This is currently out for ballot and should be published 2016/early 2017 and provides the necessary terms and definitions for suppliers, manufacturers, characterisation labs and all other stakeholders to share a common language. NPL is also developing a draft ISO standard on graphene structural characterisation providing the framework and detailed methods for characterising graphene material.
- B. The UK Health and Safety Executive (HSE) as part of an advisory panel, including industry and a representative from the CLEAPSS (Consortium of Local Education Authorities for the Provision of Science Equipment) are developing a 3D printing Facts Sheet outlining good practice for their safe operation in schools and colleges.

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

#### **Project coordinators on the FP7 project: ITS Nano: Intelligent Testing Strategy for Engineered Nanomaterials**

Final Report can be found at: <http://nano.hw.ac.uk/research-projects/itsnano.html>

Editors: V. Stone, S. Pozzi-Mucelli and J.J. Scott-Fordsmand

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

- A. The Facility for Environmental Nanoscience Analysis and Characterisation (FENAC) is funded by the Natural Environment Research Council (NERC) to support environmental nanoscience and nanotoxicology research in the UK.  
Information can be found at: <http://www.birmingham.ac.uk/facilities/fenac/about.aspx>
- B. The UK Natural Environment Research Council has recently funded three project to conduct assessment of the pathways of release, fate and impact of engineered nanomaterials (including nanoplastics). Three consortium project were funded under this program:

- a) Tracking relevant nanomaterial transformations, exposure, uptake and effects in freshwater and soil systems (Lead Dr David Spurgeon, Centre for Ecology & Hydrology)
  - b) Distinguishing realistic environmental risks of nanoplastics by investigating fate and toxicology in real-world scenarios (Lead Dr Theodore Henry, Heriot-Watt University)
  - c) Multimodal characterisation of nanomaterials in the environment (Lead Dr Alexandra Porter, Imperial College London)
- C. The UK participated in the June 2016 EU-US “*Bridging NanoEHS Research Efforts*” workshop (under the auspice of the US National Nanotech Initiative and the EU commission).  
<http://us-eu.org/2016-us-eu-nanoehs-workshop/>

The purpose of the workshop was to further promote and deepen the U.S.-EU collaboration on nanosafety research.

- D. The UK Public Health England (PHE) has an ongoing nanotoxicology programme, which is focussed on research into the effects of inhaled nanoparticles on public health. It includes in vivo and in vitro studies and associated biophysical investigations of interactions between nanomaterials and lung surfactant. Research is focussed on the deposition, clearance, biodistribution and biological effects of inhaled nanomaterials in normal and compromised (e.g. asthma) lungs. Nanomaterials currently being investigated include ceria, iron oxides, silver and carbon nanotubes. Some of the work is supported by external funding, including EU FP7 and UK NIHR (National Institute for Health Research). A study to explore individual exposures to engineered nanomaterials in consumer products is also currently being undertaken.
- E. The UK National Physical Laboratory (NPL) has number of ongoing work in this area:
- a) The NPL led an international VAMAS inter-laboratory study on the measurement of chemistry and thickness of nanoparticles’ coating using high vacuum techniques. Among other points, the study highlighted and resolved some of the challenges in nanoparticle sample preparation and relate data analysis. The outcomes will be summarized in a scientific publication and is informing relevant international standards (ISO) documentation currently under development.
  - (b) NPL is leading a project 14IND12 Innanopart of the European Metrology and Innovation Programme (EMPIR). This project’s aim is to develop accurate methods to measure concentration, agglomeration and surface properties of nanoparticles, with insight into how each property relates to the others. The project received significant industrial interest and support and is contributing to the area of nanomaterials’s characterisation not only providing novel accurate measurement methods, but also well characterised nanoparticle materials.
  - (c) Significant progress by NPL has recently been made in the development of methods for the quantitative analysis of nanoparticles’ coatings (thickness and chemistry) by using techniques in liquids as well as high vacuum techniques such as X-ray photoelectron spectroscopy (XPS). NPL has published a range of papers (see list) demonstrating the utility of these techniques to accurately measure the thickness of nanoparticle coatings in core/shell and core/shell/shell systems.
- A. Sikora, A.G. Shard and C. Minelli, *Size and  $\zeta$ -potential measurement of silica nanoparticles in serum using tunable resistive pulse sensing*, Langmuir 32 (2016) 2216-24.

<http://pubs.acs.org/doi/abs/10.1021/acs.langmuir.5b04160>

- D.J.H. Cant, Y.-C. Wang, D.G. Castner, A.G. Shard, *A technique for calculation of shell thicknesses for core-shell-shell nanoparticles from XPS data*, *Surface and Interface Analysis* 48 (2016) 274.

<http://onlinelibrary.wiley.com/doi/10.1002/sia.5923/abstract>

- N.A. Belsey, A.G. Shard and C. Minelli, *Analysis of protein coatings on gold nanoparticles by XPS and liquid-based particle sizing techniques*, *Biointerphases* 10 (2015) 019012.

<http://scitation.aip.org/content/avs/journal/bip/10/1/10.1116/1.4913566>

- C. Minelli, R. Garcia-Diez et al., *Characterization of IgG-protein-coated polymeric nanoparticles using complementary particle sizing techniques*, *Surface and Interface Analysis* 46 (2014) 663.

<http://onlinelibrary.wiley.com/doi/10.1002/sia.5381/abstract>

- N.C. Bell, C. Minelli and A.G. Shard, *Quantitation of IgG protein adsorption to gold nanoparticles using particle size measurement*, *Analytical Methods* 5 (2013) 4523.

<http://pubs.rsc.org/en/content/articlelanding/2013/ay/c3ay40771c#!divAbstract>

- A.G. Shard, *A Straightforward Method For Interpreting XPS Data From Core-Shell Nanoparticles*. *J of Phys Chem C* 116 (2012) 16806.

<http://pubs.acs.org/doi/abs/10.1021/jp305267d>

F. NPL is working on nanomaterial measurement challenges which include: i) concentration of nanoparticles, ii) average density of nanoparticles, ii) nanoparticle agglomeration and implications for their optical detection, iii) accurate description of nanoparticle surface chemistry, iv) characterisation of heterogeneous samples and v) nanoparticle detection and characterisation in complex media. NPL is exploring here the potentials of non-linear optic methods (such as photothermal effect, second harmonic generation and Raman-based methods) to address this challenge.

G. UK Plymouth University involved in several EU funded projects relating to ecotoxicity of ENMs and also bioaccumulation models: Nanosolutions (WP 7 leader), SUN, and NanoFase.

The University has published a significant critical review of the zebrafish test for nanomaterials (output of the EU MARINA project).

*Archives of Toxicology (Arch Toxicol)*; DOI 10.1007/s00204-016-1734-7;

ISSN 0340-5761

The University is also looking at human health and safety aspects of nanomaterials used in dentistry and medical implants.

*ACS NANO*, VOL. 9, NO.3, pages 2255–2289, (2015)

### **Public/ stakeholder consultations**

Publication on 26 May 2016 of the report *Public Dialogue to Understand Public Perceptions of Nanotechnologies*.

Through discussing specific nano products and applications, the objectives of this work were to:

- understand public aspirations and expectations for the development and application of new product
- ensure that transparency measures and potential communications are relevant and targeted; and
- promote mature and nuanced discussions between public and industry representatives.

The report is at

<http://sciencesearch.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&ProjectID=19488&FromSearch=Y&Publisher=1&SearchText=CB0486&SortString=ProjectCode&SortOrder=Asc&Paging=10#Description>

**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 National Physical Laboratory (NPL), UK is leading the development of a European standard on life cycle assessment of nanomaterials as part of EU mandate M/461 in CEN/ TC 352/ WG3. This draft CEN standard follows the structure of ISO 14044:2006 and includes three illustrative case studies covering inventory collection, environmental fate and impact assessment.

**Past, current or future activities on nanotechnologies that are being done in your respective countries in co-operation on a multilateral basis.**

A. The UK supported the UK-US research programme Environmental Nanoscience Initiative.

A concluding event for the second phase of the Environmental Nanoscience Initiative was held on 10 December 2015 at The Royal Society in London. Delegates heard talks from each of the three UK-US consortia and a round-table discussion on future opportunities and challenges with nanomaterials.

Final brochure can be found at:

<http://www.nerc.ac.uk/research/funded/programmes/nanoscience/eni-phase2/>

B. On the 29 -30 November the National Physical Laboratory (NPL), UK is organising a 2 day meeting on the Differential Centrifugal Sedimentation technique for nanoparticle size and size distribution characterisation. The conference will feature 9 international speakers and discuss specific challenges and solutions in measurement, sample preparation, data analysis and applications.

## UNITED STATES

### **National developments on human health and environmental safety**

*EPA Regulatory Actions.* Since January 2005, the U.S. Environmental Protection Agency (EPA) has received and reviewed more than 180 new chemical notices for nanoscale materials under the Toxic Substance Control Act (TSCA) including fullerenes and carbon nanotubes. EPA has issued consent orders and significant new use rules (SNURs) regulating new chemical submissions of these nanoscale materials permitting manufacture under limited conditions. A manufacturer or processor wishing to engage in a designated significant new use identified in a SNUR must submit a Significant New Use Notice (SNUN) to EPA at least 90 days before engaging in the new use. A sanitized version (i.e., without confidential business information) of such a consent order is available. Because of confidential business information claims by submitters, EPA may not be allowed to reveal to the public the chemical substance as a nanoscale material in every new chemical SNUR it issues for nanoscale materials. EPA will continue to issue SNURs and consent orders for new chemical nanoscale materials in the coming year. On May 16, 2016 EPA issued a final SNUR on functionalized carbon nanotubes.

**New activities (e.g. regulatory changes, guidance, voluntary, etc.) been initiated to implement the OECD Council Recommendation<sup>19</sup>**

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

**Developments related to voluntary or stewardship schemes**

As part of its nanotechnology research agenda, the U.S. National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention created a team to conduct on-site assessments of potential occupational exposure to a variety of nanomaterials, and to evaluate methods to mitigate exposures (<https://www.cdc.gov/niosh/topics/nanotech/field.html>). The team establishes partnerships with companies that produce or use engineered nanomaterials to expand and share knowledge specific to the health and safety aspects of the research. A key element of these partnerships is the voluntary nature of the collaboration that provides opportunities for on-site investigations. The team works with partners to evaluate workplace processes, identify potential emissions and occupational exposures, and provide guidance on how to effectively control exposures. To date, the team has completed assessments at over 50 facilities covering a wide range of nanomaterial producers and users. A recent assessment by the team was published in: Sara A. Brenner MD, MPH, Nicole M. Neu-Baker MPH, Adrienne C. Eastlake MS, REHS/RS, Catherine C. Beaucham MPH, CIH & Charles L. Geraci PhD, CIH (2016): NIOSH Field Studies Team Assessment: Worker Exposure to Aerosolized Metal Oxide Nanoparticles in a Semiconductor Fabrication Facility, *Journal of Occupational and Environmental Hygiene*, DOI: 10.1080/15459624.2016.1183015

**Information on:**

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

EPA reviewed TSCA section 5 premanufacture notices for 7 carbon nanotubes, 4 quantum dots, and two metal oxides. Based on potential risk findings to human health and the environment, EPA issued consent orders and/or SNURs all of these materials. See details in #4b for risk management approaches and #6 for required testing.

On May 16, 2016 EPA issued a final SNUR on functionalized carbon nanotubes.

The U.S. National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention held a public meeting concerning public review and discussion of a draft document entitled *Draft Current Intelligence Bulletin: Health Effects of Occupational Exposure to Silver Nanomaterials* on March 23, 2016 in Cincinnati, Ohio. The purposes of this meeting was to provide a forum for discussion about the draft document, to request feedback and comments, and to allow stakeholders to make presentations to NIOSH. The draft document is available at [http://www.cdc.gov/niosh/docket/review/docket260a/pdfs/draft--niosh-cib-on-silver-nanomaterials-1\\_8\\_16.pdf](http://www.cdc.gov/niosh/docket/review/docket260a/pdfs/draft--niosh-cib-on-silver-nanomaterials-1_8_16.pdf).

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<sup>19</sup> [Recommendation of the Council on the Safety Testing and Assessment of Manufactured Nanomaterials](#)

**b. risk management approaches; and**

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

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

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

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

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

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

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

**Developments related to good practice documents**

The U.S. National Institute for Occupational Safety and Health (NIOSH) published a guidance for small and medium-sized enterprises in March 2016: *Building a Safety Program to Protect the Nanotechnology Workforce: A Guide for Small to Medium-Sized Enterprises*. The guide is available at <https://www.cdc.gov/niosh/docs/2016-102/>.

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

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

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

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

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

The U.S. National Institute for Occupational Safety and Health (NIOSH) maintains an active nanotechnology research program, which aims to address five strategic goals:

- Increase understanding of new hazards and related health risks to nanomaterial workers.
- Expand understanding of the initial hazard findings of engineered nanomaterials.
- Support the creation of guidance materials to inform nanomaterial workers, employers, health professionals, regulatory agencies, and decision-makers about hazards, risks, and risk management approaches.
- Support epidemiologic studies for nanomaterial workers, including medical, cross-sectional, prospective cohort, and exposure studies.
- Assess and promote national and international adherence with risk management guidance.

More information about the program can be found at <https://www.cdc.gov/niosh/topics/nanotech/>.

#### **Public/ stakeholder consultations**

The U.S. National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention held a public meeting concerning public review and discussion of a draft document entitled *Draft Current Intelligence Bulletin: Health Effects of Occupational Exposure to Silver Nanomaterials* on March 23, 2016 in Cincinnati, Ohio. The purposes of this meeting was to provide a forum for discussion about the draft document, to request feedback and comments, and to allow stakeholders to make presentations to NIOSH. The draft document is available at [http://www.cdc.gov/niosh/docket/review/docket260a/pdfs/draft--niosh-cib-on-silver-nanomaterials-1\\_8\\_16.pdf](http://www.cdc.gov/niosh/docket/review/docket260a/pdfs/draft--niosh-cib-on-silver-nanomaterials-1_8_16.pdf).

#### **Development related to exposure measurement and exposure mitigation.**

The National Institute for Occupational Safety and Health (NIOSH) published a guidance for small and medium-sized enterprises in March 2016: *Building a Safety Program to Protect the Nanotechnology Workforce: A Guide for Small to Medium-Sized Enterprises*. The guide is available at <https://www.cdc.gov/niosh/docs/2016-102/>.

As part of its nanotechnology research agenda, NIOSH created a team to conduct on-site assessments of potential occupational exposure to a variety of nanomaterials, and to evaluate methods to mitigate exposures (<https://www.cdc.gov/niosh/topics/nanotech/field.html>). The team establishes partnerships with companies that produce or use engineered nanomaterials to expand and share knowledge specific to the health and safety aspects of the research. A key element of these partnerships is the voluntary nature of the collaboration that provides opportunities for on-site investigations. The team works with partners to evaluate workplace processes, identify potential emissions and occupational exposures, and provide guidance on how to effectively control exposures. To date, the team has completed assessments at over 50 facilities covering a wide range of nanomaterial producers and users. A recent assessment by the team was published in: Sara A. Brenner MD, MPH, Nicole M. Neu-Baker MPH, Adrienne C. Eastlake MS, REHS/RS, Catherine C. Beaucham MPH, CIH & Charles L. Geraci PhD, CIH (2016): NIOSH Field Studies Team Assessment: Worker Exposure to Aerosolized Metal Oxide Nanoparticles in a Semiconductor Fabrication Facility, *Journal of Occupational and Environmental Hygiene*, DOI: 10.1080/15459624.2016.1183015

## THE EUROPEAN COMMISSION (EC)

### National developments on human health and environmental safety

ECHA has prepared 4 draft guidance documents which were submitted for external consultation in May 2016. These documents address guidance on registration of nanoforms, read-across and grouping of nanomaterials, environmental endpoints and human health endpoints, as discussed in previous NMWG meetings. Currently, the Partner Expert Groups (PEGs) are scheduled for September 2016, and the updated guidance will be applicable for registrants preparing registration dossiers for the 2018 registration deadline under REACH.

ECHA is pleased to note that the drafts have received a lot of attention and comments from the PEG members which will further help to shape and refine the guidance.

### **New activities (e.g. regulatory changes, guidance, voluntary, etc.) been initiated to implement the OECD Council Recommendation<sup>20</sup>**

ECHA has updated IUCLID 6 to include new fields in section 1.2 to report size, shape, surface area and surface chemistry of nanoforms.

Additionally, IUCLID 6 has fields to report both compositional information for the registered substance and legal entity specific compositions of the registered substance. This compositional information on the registered substance is reported as a “boundary composition of the substance” record in section 1.2 of the IUCLID dossier. In joint submissions, this information will be reported in the lead registrant dossier together with the jointly submitted Annex VII-XI data. All lead registrant dossiers submitted following the release of REACH-IT 3 will be required to report at least one “boundary composition of the substance” record in section 1.2 of their dossier. This will facilitate the structured reporting of the substance identity profile (SIP) which gives the scope of the registered substance.

Guidance on defining the substance identity profile (SIP) will be available as Appendix III to the Guidance on substance identification and data-sharing. The draft is current with the PEG for written consultation – for more information see <http://echa.europa.eu/support/guidance/consultation-procedure/ongoing-reach>

#### **Information on:**

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

#### **ECHA**

The ECHA Board of Appeal held an oral hearing on an ongoing appeal case addressing nanomaterials on June 7th

France has submitted a proposal for harmonised classification and labelling of titanium dioxide as a carcinogen (Carc. 1B). A public consultation is currently ongoing with a deadline of 15 July 2016 to submit comments.

#### **EFSA**

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<sup>20</sup> [Recommendation of the Council on the Safety Testing and Assessment of Manufactured Nanomaterials](#)

3 recent opinions from EFSA on food additives: Ag, FeO and Au. Particle-size distributions are required using EM techniques, for a better quantification of the nanofraction present.

The conclusions for risk assessment are for the bulk materials authorised as food additives. The presence of the nanofraction might be inconclusive (due to lack of data) or negative on the basis of low solubility (e.g. of Au).

On food packaging, some recent submissions to EFSA:

Request for the evaluation of Zinc oxide nano particles	<b>Finished 2016</b>
Request for safety evaluation of zinc oxide, nano particles for use as an additive in plastics	<b>Finished 2015</b>
Request for safety evaluation of Nano-Hexadecyltrimethylammonium Bromide modified Montmorillonite Organoclay for use as additive in plastics	<b>Additional data requested</b>
Request for the evaluation of additive : copolymer in Nanoform of methacrylic acid, ethyl acrylate, n-butyl acrylate, methyl acrylate, butadiene	<b>Finished 2015</b>

### **Updates, including proposals, or modifications to previous regulatory decisions**

#### **SCCS**

In 2016, a revision of the opinion on Hydroxyapatite (nano) has been adopted: opinion

SCCS was requested to give its opinion on the safety of the nanomaterial Hydroxyapatite when used in oral cosmetics products including toothpastes, tooth whiteners and mouth washes with a maximum concentration limit of 10%, taking into account the reasonably foreseeable exposure conditions. The SCCS has concluded that the evidence, both that provided in the submission and that available in the scientific literature, is insufficient to allow drawing a conclusion on the safety of nano-hydroxyapatite when used in oral cosmetic products. In addition, it stated that nano-hydroxyapatite in needle-shaped form (one of the materials submitted had such structure) is of concern in relation to potential toxicity and should not be used in cosmetic products.

#### **New regulatory challenge(s) with respect to any action for nanomaterials**

#### **ECHA, JRC**

A framework for read-across between nanoforms - Elements to consider by Eric A.J. Bleeker, Fleur van Broekhuizen, Agnes G. Oomen, Niklas Andersson, Anu Kapanen, Abdelqader Sumrein, Kirsten Rasmussen, Juan Riego Sintes, Jenny Holmqvist.

Under ECHA's lead, a new publication entitled "Usage of (eco)toxicological data for bridging data gaps between and grouping of nanoforms of the same substance: elements to consider", drafted in collaboration with RIVM and JRC, has been published on the ECHA website. The report can be downloaded from the following link [http://echa.europa.eu/documents/10162/13630/eco\\_toxicological\\_for\\_bridging\\_grouping\\_nanoforms\\_en.pdf](http://echa.europa.eu/documents/10162/13630/eco_toxicological_for_bridging_grouping_nanoforms_en.pdf)

This work was a cornerstone in the Commission funded OECD workshop on read-across and grouping of NMs took place on 13-14 April 2016 to discuss grouping and read-across for nanomaterials. It will also feed into the ECHA's guidance development on the topic.

The JRC and RIVM co-chaired the SETAC Europe, 26<sup>th</sup> annual meeting in Nantes, France, 22-26 May 2016, session on Ecotoxicology and risk assessment of nanomaterials - Grouping and read-across.

The JRC, ECHA and others co-authored the following platform presentations at SETAC Europe 2016:

1) A framework for read-across between nanoforms - Elements to consider by Eric A.J. Bleeker, Fleur van Broekhuizen, Agnes G. Oomen, Niklas Andersson, Anu Kapanen, Abdelqader Sumrein, Kirsten Rasmussen, Juan Riego Sintes, Jenny Holmqvist.

2) Preliminary outcomes of the OECD Expert Meeting on "Grouping and read-across for the hazard assessment of manufactured nanomaterials", Juan Riego Sintes, Kirsten Rasmussen, Stefania Gottardo, Agnieszka Mech, Andrew Worth, Andrej Kobe, Jenny Holmqvist, Mar González, Peter Kearns.

The feedback on the developed framework for read across for nanoforms raised an interest among the SETAC participants and was considered an important step forward on the assessment of the environmental hazard and fate of nanomaterials in regulatory context. Providing practical case examples on the applicability of the developed framework for different type of nanomaterials was seen as an important next step.

### **Developments related to good practice documents**

#### **JRC**

Publication by JRC of the NANoREG harmonised terminology for environmental health and safety assessment of nanomaterials, EUR 27808, DOI: 10.2788/71213

Publication by JRC and others "Review of Achievements of the OECD Working Party on Manufactured Nanomaterials' Testing and Assessment Programme. From Exploratory Testing to Test Guidelines" in Regulatory Toxicology and Pharmacology. Volume 74, 2016, Pages 147–160. Authors: Kirsten Rasmussen, Mar González, Peter Kearns, Juan Riego Sintes, François Rossi, and Phil Sayre.

Publication by JRC and others "A comparison of techniques for size measurement of nanoparticles in cell culture medium" in Analytical Methods, 2016,8, 5272-5282. Authors: Christian Gollwitzer, Dorota Bartczak, Heidi Goennaga Infante, Vikram Kestens, Michael Krumrey, Caterina Minelli, Marcell Palmai, Yannic Ramaye, Gert Roebben, Aneta Sikora and Zoltan VARGA. DOI: 10.1039/c6ay00419a

Publication by JRC "Nanomaterials as a potential environmental pollutant: Overview of existing risk assessment methodologies" in Human and Ecological Risk Assessment, Vol. 22 , Iss. 2,2016. Authors: Iria M. Rio-Echevarria, David G. Rickerby and Andreas N. Skouloudis.

In Print: JRC scientific and technical reports

\* "Measurement of volume specific surface area of selected particulate materials in the frame of the EC nanomaterial definition".

\* "Measurement of particle size distributions of selected particulate materials in the frame of the EC nanomaterial definition".

## EFSA

The 2011 guidance (focused on the oral route of exposure) will be updated during 2016-2018. This will involve a multidisciplinary working group of experts; a supporting data collection of existing studies to inform about best practice; and public consultations on the draft guidance at the beginning of 2018.

The current EFSA guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain, does not include environmental hazard evaluation. The new working group under the EFSA Scientific Committee will develop in 2018 a de novo guidance for environmental risk assessment for nanomaterials in agri/food/feed products.

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

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

1. Funded under the call "*NMBP-29-2015: Increasing the capacity to perform nano-safety assessment*"

- **SmartNanoTox**: "Smart Tools for Gauging Nano Hazards"
- **HISENTS**: "High level Integrated SEnsor for NanoToxicity Screening"

2. Funded under the call "*NMBP-30-2015: Next generation tools for risk governance of nanomaterials*":

- **Calibrate**: "Performance testing, calibration and implementation of a next generation system-of-systems Risk Governance Framework for nanomaterials"

b. Three projects have been selected under the Horizon 2020 Research Framework Programme (H2020) and currently in grant preparation:

3. Selected 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"

4. Selected 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"

c. Horizon 2020 calls for research proposals for 2017 (submission deadline: 27 October 2016):

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 here:  
[https://ec.europa.eu/programmes/horizon2020/sites/horizon2020/files/05ii.%20LEIT%20NMBP\\_2016-2017\\_pre-publication.pdf](https://ec.europa.eu/programmes/horizon2020/sites/horizon2020/files/05ii.%20LEIT%20NMBP_2016-2017_pre-publication.pdf)

d. Other:

1. The ProSafe project organises, jointly with OECD-WPMN, a Conference on “*Science based support for regulation of Manufactured Nanomaterials*”. Paris, 29/11/2016 to 01/12/2016.
2. DG RTD NMP initiative EU Nanosafety cluster also continues their activities. More details at: [www.nanosafetycluster.eu](http://www.nanosafetycluster.eu). The 2016 edition of the "Compendium of Projects in the European NanoSafety Cluster" is available: [http://www.nanosafetycluster.eu/uploads/files/pdf/2015\\_NSC\\_Compendium.pdf](http://www.nanosafetycluster.eu/uploads/files/pdf/2015_NSC_Compendium.pdf).
3. The nanosafety cluster published the “Closer to the market research roadmap”: <http://www.nanosafetycluster.eu/news/189/66/Closer-to-the-market-Roadmap-CTTM.html>.
4. 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 fifth workshop was held in Washington 6-7 June 2016.

### **Information on public/ stakeholder consultations**

As the final stage of the review of the EUREcommendation on the definition of nanomaterial EC/2011/696, a public consultation is envisioned in autumn 2016. It is planned to include considerations for the minor revision of the current recommendation.

### **Past, current or future activities on nanotechnologies that are being done in your respective countries in co-operation on a multilateral basis, including with non-OECD countries.**

Scientific organisation and chairing of the OECD WPMN expert meeting on Grouping and Read-across for the Hazard Assessment of Manufactured Nanomaterials, Brussels 13-14 April 2016.

### **Additional Information**

#### **ECHA**

The European Commission has entrusted ECHA as the future host of an EU wide nanomaterials observatory. Internal preparation have started and the implementation is foreseen to be in three steps where the first phase is planned to go live towards the end of 2016 or alternatively early 2017. An important input in these preparation was the Commission organised workshop on April 25th where stakeholders, industry and member states attended to discuss the scope and content of such an observatory.

**THE INTERNATIONAL COUNCIL ON ANIMAL PROTECTION IN OECD PROGRAMMES (ICAPO)****Information on any developments related to Integrated Testing Strategies and/or Alternative test methods**

- The PETA International Science Consortium Ltd. [member of The International Council for Animal Protection in OECD Programmes (ICAPO)] organized an international workshop in 2015, attended by representatives from industry, government, academia, and NGOs with expertise in *in vivo* and *in vitro* (lung) systems, respiratory toxicology, nanotoxicology, and human health risk analysis. The goal of the workshop was to review the state-of-the-science and determine the technical needs to develop an *in vitro* system that is predictive of pulmonary fibrosis. The discussions from the workshop (Clippinger et al. 2016) and two reviews (Polk et al. 2016 and Sharma et al. 2016), have been published in three separate reports in peer-reviewed journals. Based on the approach developed at the workshop, the PETA Science Consortium is currently funding Professor Dr. Barbara Rothen-Rutishauser of the Adolphe Merkle Institute at the University of Fribourg, Switzerland to develop a nonanimal system to predict the development of lung fibrosis in humans following exposure to nanomaterials. The Science Consortium is also funding MatTek Corporation to develop a three-dimensional reconstructed human alveolar tissue model to be used in Professor Rothen-Rutishauser's work. The results of this work are expected to be submitted for publication at the end of 2016.
- The PETA International Science Consortium Ltd. [through the International Council for Animal Protection in OECD Programmes (ICAPO)] is working with Health Canada on the development of an adverse outcome pathway (AOP) for lung fibrosis. The AOP proposal titled 'Secretion of inflammatory cytokines leading to lung fibrosis' was accepted by the OECD's Extended Advisory Group on Molecular Screening and Toxicogenomics (EAGMST) for further development in 2015. This AOP encompasses a variety of pro-fibrotic materials, including nanomaterials, which share the key events leading to lung fibrosis.
- As part of a collaborative effort between the European Commission's Joint Research Centre, the U.S. Environmental Protection Agency, and the OECD, an AOP-Wiki has been created to provide an interactive and virtual platform for AOP development. Working with the organizers of the AOP-Wiki, the PETA International Science Consortium has launched a data challenge to encourage new contributors to add to the AOP-Wiki using available data. Both the number and merit of contributions will be judged by a panel, including scientists participating in the OECD's EAGMST, and prizes totalling up to \$8,000 will be awarded to the winner(s).
- The PETA International Science Consortium is working with the U.S. NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) to host a 6-part webinar series addressing current practices for acute inhalation toxicity testing, aiming to develop and implement alternative approaches to reduce and replace acute inhalation testing in animals for both regulatory and non-regulatory purposes (including for nanomaterial testing). The series includes presentations from The Dow Chemical Company, the U.S. Environmental Protection Agency, British American Tobacco, and other research institutions. See [www.piscltd.org.uk/acute-inhalation-toxicity/](http://www.piscltd.org.uk/acute-inhalation-toxicity/) for details.

## **UNITAR**

### Recent activities

1. The third round of UNITAR's e-Learning course - "Introduction to nanomaterial safety" – took place between October and December 2015. The course was run in collaboration with three expert tutors, and attracted seven participants.
2. The fourth round of UNITAR's e-Learning course - "Introduction to nanomaterial safety" – was open for registrations from 14 September 2016, and will run from 17 October to 4 December 2016.
3. In late 2013, UNITAR started a second phase of pilot projects at the national level, in Armenia, Jordan and Viet Nam, building on the first pilot projects. Viet Nam has now finished all main activities and UNITAR is in the process of closing the project. The project developed a proposal for activities for 2016-2020 and a national vision up to 2025, provided a review of activities and ongoing research in Viet Nam, and assessed national nanosafety priorities. Armenia is close to finalising the main project activities, with a new nanosafety policy at the final drafting stage and a nanosafety chapter set to be added to the national profile on chemicals management. Jordan is continuing its work and the final workshop and final deliverables are expected around the end of 2016.
4. A major outcome from the 2015 nanosafety regional workshops was to enhance networking and collaboration among nano stakeholders. UNITAR has initiated the design and development of a nano-related exchange platform, with elements of a contacts' database, a document repository, and an area dedicated to forums. The IT framework has been developed (building on other UNITAR platforms) and it is ready for data input. It is hoped that this will be fully ready by the end 2016.

### Call for support

5. UNITAR also made a call for support, both financial and non-financial, for its activities. The representative (Mr. Oliver Wootton, [oliver.wootton@unitar.org](mailto:oliver.wootton@unitar.org)) invited stakeholders to contact him to discuss options for support. Example areas included: financial support for the 2017/2018 regional workshops and future national policy development projects; and in-kind support to provide information to the nano online platform, submission of examples and case studies for activities between 2006 and 2016, and updates on proposed activities up to 2020.

## **ENVIRONMENTAL NGOS**

Following the report from the OECD working Party on Resource productivity and Waste calling for further research and precaution in addressing the question of nanomaterials in waste stream, CIEL, ECOS and the Oeko Institute (three organisation members of the NGO delegation to the WPMN), organized a workshop focusing on the lifecycle perspective for nanomaterials (brief report is available online). This workshop resulted in a Declaration on Waste Containing Nanomaterials calling for the implementation of preventive measures by governments, producers, waste managers and research organizations to minimize possible hazards of manufactured nanomaterials in waste streams. The declaration is available in English, French, Spanish, Portuguese, and Japanese and has been supported by over 120 organizations and individuals around the world: from environmental organisations, consumer groups, occupational health experts, and three Goldman Prize for the Environment winners.

The NGO delegation to the WPMN has commissioned IOM Singapore to prepare an analysis of the OECD Sponsorship Programme data looking in particular at the usefulness of the information for the regulatory risk management of MNMs, focusing especially on the human health aspects.

The conclusions from this analysis will be released on December 7<sup>th</sup>, during a conference organized in Brussels before being made public on both CIEL and ECOS websites.

For any questions relating to the ongoing analysis or the conference, please contact Doreen Fedrigo or David Azoulay.