For Official Use **ENV/CHEM/NANO(2015)25**

Organisation de Coopération et de Développement Économiques
Organisation for Economic Co-operation and Development **26-Oct-2015**

English - Or. English

ENVIRONMENT DIRECTORATE
CHEMICALS COMMITTEE

ENV/CHEM/NANO(2015)25
For Official Use

Working Party on Manufactured Nanomaterials

OECD WORK ON NANOTECHNOLOGIES AND NANOMATERIALS; REPORT FROM THE SECRETARIAT

15th Meeting of the Working Party on Manufactured Nanomaterials
4-6 November 2015
OECD Conference Centre, Paris, France

Mrs. Mar Gonzalez
Tel: +33 (0) 1 45 24 16 77; Email: mar.gonzalez@oecd.org

JT03385081

English - Or. English

This document summarises those activities, projects and events which are relevant to the work of the WPMN and have occurred since WPMN-14. It also includes information on the activities of other OECD bodies. The information in this document is intended as the secretariat contribution to the tour de table.

ACTION REQUIRED: ***The Working Party is invited to:***

(i) take note of the report; and

(ii) provide comments, as necessary.

TABLE OF CONTENTS

HIGLIGHTS OF DEVELOPMENTS FROM THE WPMN: ACTIVITIES / ACHIEVEMENTS SINCE WPMN-14

STAFF CHANGES AT THE OECD SECRETARIAT

1. Since WPMN-14, Asako Aoyagi has returned to Tokyo (METI). Her successor, Terumi Munekane, joined the secretariat in early August, 2015 and she will on maternity leave from November 2015 till March 2016. Hoseok Song will return to Seoul (MOE) towards the end of November following WPMN-15. During a period of three months following WPMN-14, the secretariat was joined by a short-term secondee, James Pitman, from the Department of Industry, Australia. James contributed to the activities of the WPMN by designing and launching the web site dedicated to the dissemination of the dossiers from the Testing Programme. During September, a short-term intern, Marine Perez, worked with the secretariat on the compilation of responses and other information related to the implementation of the Council Recommendation. The other members of the secretariat, Peter Kearns, Mar Gonzalez and Jihane El-Gaouzi, remain in place.

TESTING AND ASSESSMENT

Testing Programme

2. A dedicated public website was launched in June 2015 to communicate the results from the Testing Programme.

3. The Testing Programme involved the co-operation from 17 countries across the world, in addition to BIAC and the Nordic Council of Ministers. Each country appointed national research institutes for a total contribution of almost 100 organisations. The outcome of this Testing Programme has been a first of its kind collaboration between government, industry and academia in the generation of testing dossiers to inform the future uses and safety concerns of Manufactured Nanomaterials.

4. Eleven types of nanomaterials were chosen to be tested for their:

- Nanomaterial information/identification;
- Physical-chemical properties and material characterisation;
- Environmental fate;
- Toxicological and eco-toxicological effects;
- Environmental toxicology;
- Mammalian toxicology; and
- Material safety.

5. The tests have been analysed with respect to the use of using OECD Guidelines for the Testing of Chemicals, comprising up to 111 unique Endpoints (or effects measurements and observations) and over 780 studies on the specific properties of nanomaterials, one of the largest studies to date.

6. As an outcome of the Testing Programme, more than 160 dossier documents have been collated (main documents and annexes), organised and formatted in a IUCLID format style. Titanium dioxide by itself generated 120 documents. Several comments on the dossiers have been received upon the declassification request, integrated in the documents and published in the new Testing Programme of Manufactured Nanomaterials website.

7. At the time of writing, the following Dossiers are already available on the public site: Cerium oxide; Dendrimers; Fullerenes (C60); Gold nanoparticles; Multi-walled carbon nanotubes (MWCNTs); Nanoclays; Silicon dioxide; Silver nanoparticles; Single-walled carbon nanotubes (SWCNTs). In addition, Titanium dioxide (NM100-NM105) has already been declassified and available as OLIS documents and is progressively been posted on the public site. The last Dossier on Zinc oxide finalised its review process and has now been formatted for its declassification.

8. This website combines all the necessary information related to the Testing Programme and gives an overall view on the achieved work. The public site is available at: http://www.oecd.org/chemicalsafety/nanosafety/testing-programme-manufactured-nanomaterials.htm

Assessment of Data from the Testing Programme

9. The Netherlands volunteered to lead an evaluation of the applicability of the test methods applied to determine the physico-chemical properties of different types of nanomaterials in the Testing Programme. The Netherlands benefited from the inputs from experts from Canada (Environment Canada, Université de Montréal); Japan (JFE Techno-Research Co. and Japan's Chemical Industry Association); the Netherlands (IRVM, Utrecht University; and TNO); United States (US EPA); European Commission (ECHA and JRC); BIAC (Cabot Corporation, DuPont, Evonik Corporation, and NIA). The document was reviewed by SGTA, which provided further comments that were incorporated in document ENV/CHEM/NANO(2015)29[1]. The WPMN will be invited to provide further comments if any and agree the next steps for its declassification.

Test Guidelines and Guidance Document for their applicability to nanomaterials

10. The Secretariat will provide a status report on the TG/DG revision underway, which will include a highlight on those issues that should be considered by the WPMN. Currently, eight SPSFs have been approved by the WNT. The WPMN will be invited to identify possibilities for leading pending projects previously identified [see ENV/CHEM/NANO(2015)31].

Table 1. List of current activities underway for the revision of Test Guidelines and Guidance Documents

Title of the Activity (SPSF)	**TG and/ or GD under review**	**Lead country(ies)**
Amendments to the Inhalation Test Guidelines and Guidance to Accommodate Nanomaterials	**Test Guidelines** **403** (Acute Inhalation) **436** (Acute Inhalation –Acute Toxic Class) **412** (Subacute Inhalation Toxicity) **413** (Subchronic Inhalation Toxicity **Guidance Documents under Review** Reviews on	**U.S.**
Guidance Document on Aquatic (and Sediment) Toxicology Testing of Nanomaterials	New GD	**U.S.** **Canada**
Test Guideline for the Dissolution Rate of Nanomaterials in the Aquatic Environment	New TG	**U.S.**
Guidance Document for Dispersion and Dissolution of Nanomaterials in Aquatic Media – Decision Tree	New GD	**Germany**

[1] Comments received are available as document ENV/CHEM/NANO/RD(2015)2.

Test Guideline for Agglomeration Behaviour of Nanomaterials in different Aquatic Media	New TG	**Germany**
Guidance Document on Assessing the Apparent Accumulation Potential of Nanomaterials	**305** (Bioaccumulation in Fish)	**U.K., Spain**
Development of a Draft Test Guideline for Nanomaterial Removal from Wastewater	New TG	**U.S.**
Guidance Document on the Adaptation of *In Vitro* Mammalian Cell Based Genotoxicity TGs for Testing of Manufactured Nanomaterials	**487** (*In Vitro* Mammalian Cell Micronucleus Test) **473** (*In Vitro* Mammalian Chromosomal Aberration Test) **476** (*In Vitro* Mammalian Cell Gene Mutation Tests)	**E.U.**

11. A number of expert meetings have been organized by lead countries to further discuss and implement the work needed as follows:

- WNT/WPMN meeting on the Test Guidelines development agglomeration behaviour of nanomaterials, 28 September 2015, at OECD Conference Centre (led by Germany);
- WNT/WPMN meeting on the Inhalation Test Guidelines and Guidance to Nanomaterials, 21-22 September 2015 in Washington. D.C.(led by the US); and
- Expert Workshop on the Development of OECD Test Guidelines and Guidance Documents for Nanomaterial agglomeration and dissolution behavior, 28th-29th January 2015, Dessau-Roßlau (Led by Germany).

Work Plan and next Programme of Work

12. SGTA has updated its ***Work Plan*** for discussion at the meeting it will be held on the 3rd November. As discussed at WPMN14, the purpose of the ***Work Plan*** is to provide an overview of the current projects under SGTA and to easily identify synergies, potential overlaps or areas that need further consideration. The ***Work Plan*** is an internal living document that is available on the password-protected site and updated as needed. The ***Work Plan*** is expected to assist the discussions to start refining the Operational Plan for the next Programme of Work 2017-2020.

SIAR-like documents

13. At WPMN14, four SIAR-like documents were presented on the three carbons (Fullerenes, SWCNT, and MWCNTs), and for SiO2. These documents were prepared by their respective lead countries, Japan and EC. Since WPMN14, Japan included some additional reviews to the carbons. The SIAR-like document's have been completed and prepared for discussion at the SGTA meeting (3rd November). SGTA will present some recommendations to the WPMN15 on the possible next steps [see document ENV/CHEM/NANO(2015)31].

RISK ASSESSMENT AND REGULATORY PROGRAMMES

14. The Steering Group on Risk Assessment and Regulatory Programmes has completed the review of a number of documents that have either been declassified or close to completion. During WPMN15 under **agenda item 9**, SGAP will present the outcomes from the face-to-face meeting to be held on the 3rd November, including information on the three remaining pilot projects:

- Approaches on nano equivalence/ grouping/ read-across concepts based on physical-chemical properties for regulatory regimes: results from the survey;

- Physical and Chemical Property Analysis for Read Across and Risk Assessment Guidance; and

- Different types of risk assessments and identifying different levels of uncertainties used to inform risk assessment outcomes and risk management measures in member countries.

EXPOSURE MEASUREMENT AND EXPOSURE MITIGATION

15. The objective of this programme is to exchange information on (or develop) guidance for exposure measurement and mitigation. As part of this programme, the following projects are in various stages of development and will be considered at WPMN-15 and WPMN-16:

- *Exposure assessment of nanomaterials: case study on nano-gold*
- *The biodurability of nanomaterials and their surface ligands; and*
- *Consumer and environmental exposure next steps: Light analysis from the survey.*

16. A survey has been conducted to identify available information and data on consumer and environmental exposure assessment and mitigation measures with the aim to prioritize future work and research needs. The *light analysis of the survey* will be presented at WPMN-15 under **agenda item 11**.

ENVIRONMENTALLY SUSTAINABLE USE OF MANUFACTURED NANOMATERIALS

17. The Steering Group finalised the Guidance Manual towards the integration of risk assessment into life cycle assessment of nano-enabled applications. To discuss the possible next steps, SG9 organised a **Workshop on the Environmentally Sustainable Use of Manufactured Nanomaterials**. This meeting was held on the 20th January 2015. This workshop was preceded by a face-to-face meeting from the Steering Group. Both meetings were held in Zurich, Switzerland and were hosted by Empa and the Swiss Federal Office of Public Health. The outcomes of these two meetings, including recommendations on the possible next steps, will be presented for discussion at the WPMN15 under **Agenda Item 12**.

PUBLICATION OR DECLASSIFICATION

18. Since WPMN-14, the following documents have been declassified and made available on the public website (http://www.oecd.org/env/nanosafety):

- *Considerations for using dissolution as a function of surface chemistry to evaluate environmental behaviour of nanomaterials in risk assessments*
- *Developments on the safety of manufactured nanomaterials - 2014*
- *Developments on the safety of manufactured nanomaterials - 2013*
- *Developments on the safety of manufactured nanomaterials - 2012*
- *Preliminary guidance notes on Nanomaterials: Interspecies variability factors in human health risk assessment*
- *Guidance Manual towards the Integration of Risk Assessment into Life Cycle Assessment of Nano-Enabled Applications*
- *Analysis of the Survey on Available Methods and Models for Assessing Exposure to Manufactured Nanomaterials*
- *Nos. 44-54 - Dossiers from the Testing Programme*

19. Documents under Review:

- by the Joint Meeting
  - *Physical-Chemical Parameters: Measurements and Methods and Categorisation of nanomaterials*.
- by the WPMN
  - *Categorisation of manufactured nanomaterials*.

20. Pending documents:

- *Workshop on Toxicokinetics*
- *Exposure assessment of nanomaterials: case study on nano-gold*
- *Harmonized Tiered Approach to Measure and Assess the Potential Exposure to Airborne Emissions of Engineered Nano-Objects and their Agglomerates and Aggregates at Workplaces*

CO-ORDINATION WITH OTHER OECD BODIES

Working Group on Chemical Accidents

21. The Working Group on Chemical Accidents (WGCA) will discuss the final report on *Risk of Major Accidents involving Nanomaterials* before it is sent to the Joint Meeting for declassification. It is expected to be publicly available in early 2016.

Working Party on Resource Productivity and Waste (WPRPW)

18. As part of the work programme of the Working Party on Resource Productivity and Waste (WPRPW), a report on "***Nanomaterials in waste streams***" will be published in the 1st quarter of 2016. This report provides a literature review on four specific waste treatment processes (recycling, incineration, landfilling and wastewater treatment). While state-of-the-art waste treatment facilities may collect, divert or eliminate nanomaterials from these waste streams, the report concludes that knowledge gaps associated with their final disposal remain, underlining the need for further research in this area.

22. Furthermore, under the work programme of the WPRPW, an information exchange platform on waste containing nanomaterials (WCNMs) has been developed to update, compile and identify research and documents on WCNMs in waste treatment processes to promote knowledge sharing among relevant stakeholders concerned in nanotechnology and waste management. This is available on the WPRPW password restricted site. Access could be extended to members of the WPMN as necessary. This will be implemented as a trial until the 7th WPRPW meeting in December 2015, where further arrangements may be discussed.

Working Party on Biotechnology, Nanotechnology and Converging Technologies (BNCT)

23. The Working Party on Biotechnology, Nanotechnology and Converging Technologies (hereafter BNCT) held its inaugural meeting on 18- 19 May 2015, reminding delegates of the genesis and main goals of the BNCT, based on the mandate of the group and on CSTP discussions and decisions.

The BNCT is focused on policy issues in emerging technology fields related to biotechnology, nanotechnology and converging technologies. It aims to contribute original policy analysis and messages to the global community, and to make ground-breaking proposals to policy makers. The 1st BNCT Meeting emphasised the nature of convergence between classical scientific disciplines and agreed to reflect this in a number of case studies on 'Cross-Cutting Topics'; the BNCT's work programme for the next two years will focus on the following project areas:

- Statistics & Indicators of Biotechnology and Nanotechnology: this project will review indicators for the two enabling technologies and collate statistical data for time series and convergence analysis, with a view to identifying the increasing convergence of technologies.
- Impact Assessment of Biotechnology and Nanotechnology: this project will commence with a national inventory of science, technology and innovation policies that cover biotechnology and nanotechnology (either directly or indirectly).
- Emerging Technologies and the Brain: this project will analyse and evaluate emerging technologies, innovations and policies in neurological medicine; it is envisaged that numerous nanotechnology, nanobiotechnology and nanomedicine applications play a large role in this area. The project furthermore plans to look at Responsible Research and Innovation governance with regard to its applicability to the case of neurology.
- Bio-Production for a Bioeconomy: this project will investigate the following three themes:
    - Replacing the Oil Barrel
    - Biomass Sustainability
    - Biorefinery Models & Policy
- Better Food for Better Health: this project will investigate the following themes:
    - Better Food
    - Better Resources

THE STRATEGIC APPROACH TO INTERNATIONAL CHEMICALS MANAGEMENT (SAICM)

24. Since 2009, OECD and UNITAR have collaborated to implement the Resolution III/2E of the International Conference on Chemicals Management (ICCM3) in particular in "….enhanc[ing] stakeholder capacity for the sound management of nanotechnologies and manufactured nanomaterials."

25. In 2015, the OECD Secretariat participated in two regional technical workshops:

- *Nanosafety Technical Regional Workshop for the Latin American and Caribbean Region, held in Bogota, Colombia, 22 to 24 June 2015; and*

- *Nanosafety Technical Regional Workshop for the Asia-Pacific Region, held in Bangkok, Thailand on 10-11 September 2015.*

26. Furthermore, side-events were co-organised with UNITAR during the Nano-Side-event at SAICM's Open-ended Working Group (15 December 2014) and at the fourth session of the International Conference on Chemicals Management (ICCM4) on 28th September 2015.

27. These events have been extremely valuable to promote the work of the WPMN.

CO-ORDINATION AND OUTREACH

28. The WPMN has worked to co-ordinate its programme with other activities addressing nanotechnologies. The amount of work under the current resources has limited the coverage vis-à-vis the work of other organisations.

29. It will be important for the WPMN to discuss and agree on possible mechanisms to improve information sharing, identification of synergies, and in particular, avoid duplicative work.

30. On the other hand, the mechanisms to ensure synergies with other bodies, in particular with organisation, require particular attention to ensure the linkages are sustainable.

Co-ordination with activities undertaken within OECD

31. The Secretariat continues to co-ordinate internally work that could interest different bodies of the Chemicals Programme of Work. Presentations are systematically done within those groups that are interested in the latest development and where there is a potential for collaboration (i.e. the Task Force on Hazard Assessment), or where an updated is needed on specific projects (i.e. information on nano-silver to the Working Group on Pesticides). On the other hand, specific collaborative mechanism have been established within the Secretariat, to ensure close communication for projects that are common, such as those related to the Test Guidelines and Guidance Documents development.

32. At the same time, The Task Force on Hazard Assessment, the Working Group on Pesticides, the Task Force on Pollutant Release and Transfer Registers (PRTRs), the Task Force for the Safety of Novel Foods and Feeds have all expressed interest in aspects of the work of the WPMN. The Secretariat has given an update of the work of the WPMN to these groups at their most recent meetings.

Co-ordination with other organisations

OECD continues to work closely with other intergovernmental organisations related to its work on manufactured nanomaterials. OECD is a Participating Organisation (PO) of the Inter-Organization Programme for the Sound Management of Chemicals (IOMC), in particular with WHO and UNITAR. The OECD secretariat has kept these other organisations up to date with the work of the WPMN through the IOMC.

International Standard Organisation (ISO)

33. It has been noted that the collaboration with other organisation, such as ISTO TC 229, will be beneficial for identifying synergies or areas of common interest. Due to resources constraints the Secretariat has been unable to follow the activities of ISO and has relied on those delegates, who participate in both bodies, for example, by identifuyng current activities that are of common interest.