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MANUFACTURED NANOMATERIALS: WORK PROGRAMME 2009-2012

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**OECD Environment, Health and Safety Publications
Series on the Safety of Manufactured Nanomaterials**

No. 16

**MANUFACTURED NANOMATERIALS: WORK PROGRAMME
2009-2012**

IOMC

INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

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

**Environment Directorate
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT
Paris 2009**

Also published in the Series of Safety of Manufactured Nanomaterials:

- No. 1, *Report of the OECD Workshop on the Safety of Manufactured Nanomaterials: Building Co-operation, Co-ordination and Communication (2006)*
- No. 2, *Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 1st Meeting of the Working Party on Manufactured Nanomaterials (2006)*
- No. 3, *Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 2nd Meeting of the Working Party on Manufactured Nanomaterials (2007)*
- No. 4, *Manufactured Nanomaterials: Programme of Work 2006-2008 (2008)*
- No. 5, *Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 3rd Meeting of the Working Party on Manufactured Nanomaterials (2008)*
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- No. 13, *Report of an OECD Workshop on Exposure Assessment and Exposure Mitigation: Manufactured Nanomaterials (2009)*
- No. 14, *Guidance Manual for the Testing of Manufactured Nanomaterials: OECD Sponsorship Programme (2009)*
- No. 15, *Preliminary Review of OECD Test Guidelines for their Applicability to Manufactured Nanomaterials (2009)*
- No. 16, *Manufactured Nanomaterials: Work Programme 2009-2012 (2009)*

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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. In 2006, the OECD’s Chemicals Committee agreed to a Work Programme on Manufactured Nanomaterials for 2006-2008 [ENV/JM/MONO(2008)2]. This Programme of Work is addressing human health and environmental safety aspects of manufactured nanomaterials. The OECD Council established a Working Party on Manufactured Nanomaterials (WPMN) to implement its programme of work.

In 2008, the Working Party renewed its Work Programme for 2009-2012 which was approved by the Chemicals Committee during its 43rd Meeting (November 2008) together with an updated Terms of Reference. Recognising the importance of transparency and expectations from stakeholders as well as comforting to the custom of its Work Programme 2006-2008, the Working Party agreed, at its 5th meeting in March 2009 that this document should be forwarded to OECD’s Chemicals Committee with a recommendation that it be declassified and made publicly available.

It should be noted that the work of the WPMN evolves continuously as needs arise. Already, the Working Party decided to the merger of Project 1: *Development of an OECD Database on Human Health and Environmental Safety Research* and Project 2: *Research Strategies on Manufactured Nanomaterials*, due to the close linkage and the stage of both projects at its 5th meeting. Furthermore, the 5th WPMN agreed to a number of documents derived from the projects to be declassified. With that in mind, Annex III of this document highlights the current WPMN activities following the achievements at the 5th meeting with an intention to provide a “snapshot” of information on the WPMN activities. This “snapshot” is current in June 2009.

This document is published on the responsibility the OECD’s Joint Meeting of the Chemicals committee and the Working Party on chemicals, Pesticides, and biotechnology.

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MANUFACTURED NANOMATERIALS: 2009 -2012 WORK PROGRAMME

INTRODUCTION

1. This programme of work has been developed for 2009-2012. It builds on the achievements of the programme of work during 2006-2008 [ENV/JM/MONO(2008)2]. It takes into account the rapid progress made by the Working Party on Manufactured Nanomaterials (WPMN) in the short period since it was established in 2006. Furthermore, it has been developed for a four-year period to be consistent with the current cycle of the programme of work of its parental body, the Chemicals Committee.

PROPOSED PROGRAMME OF WORK 2009-2012

2. The objective of the Programme of Work is to promote international co-operation in addressing human health and environmental safety aspects of manufactured nanomaterials. This will assist in their safe development. The programme aims to develop methods to efficiently assess the safety of manufactured nanomaterials so as to avoid adverse effects in the short, medium and longer term. Accordingly, the programme concentrates on the human health and environmental safety implications of manufactured nanomaterials (limited mainly to the chemicals sector); and will ensure that the approach to hazard, exposure and risk assessment is science-based and of a high internationally harmonised standard.

3. Research and development on manufactured nanomaterials is proceeding rapidly, so the programme of work will remain flexible so that the Working Party is able to address emerging issues in a timely and resource efficient way. It may be necessary to take into account the lessons learned from the use of other types of novel materials.

4. It is recognized that there are many issues related to manufactured nanomaterials that need to be addressed in the short term. Therefore, as work continues on specific projects during 2009-2012, the Working Party will continue to set priorities amongst them.

5. The Working Party will continue to be open and transparent in its activities. Strengthening participation from non-member economies with experience in nanotechnology (especially OECD accession countries¹ and OECD enhanced engagement countries²) will be a priority for this programme of work. In addition, the Working Party encourages the participation of a range of stakeholders. The participation of non-member economies as well as other stakeholders will be agreed by the Working Party, in line with the outreach policy of the Chemicals Committee.

6. The Working Party will continue to communicate and co-ordinate with other intergovernmental organizations active in the area, as well as standardisation and nomenclature organisations, as specified in the Terms of Reference (Annex II). This effort will avoid duplication and help to ensure complementarities with other intergovernmental activities. The Working Party will facilitate links, as needed, to encourage the

¹ Chile, Estonia, Israel, the Russian Federation and Slovenia.

² Brazil, China, India, Indonesia and South Africa.

active collaboration at the national level between delegates to the WPMN and their national representatives to other international activities.

7. The Secretariat will also ensure internal co-ordination on issues related to nanotechnologies/nanomaterials amongst relevant OECD bodies, including other subsidiary bodies of the Chemicals Committee and the Working Party on Nanotechnology (WPN), which is a subsidiary body of OECD's Committee for Scientific and Technological Policy (CSTP).

WORK PROJECTS³

8. During the first two years of its work and in accordance with its Terms of Reference, the Working Party established eight projects, each with an operational plan which was agreed by the Working Party. The projects are as follows:

Project 1: Development of a Database on Human Health and Environmental Safety Research

- This project has developed a *Database of Research into the Safety of Manufactured Nanomaterials* as Phase 1 of its work. This database holds details of completed, current and planned research projects on safety, which are to be updated (electronically) by delegations. This database is also intended to be an inventory of information on research programmes to help the other projects of the WPMN by identifying relevant research projects or storing information derived from the projects of the WPMN, including the sponsorship programme on the testing of manufactured nanomaterials. The database will be launched towards the end of 2008 and will be publicly accessible via the OECD website.
- During 2009-2012, a Phase 2 of the project will be implemented, which may lead to extended, functionality and scope of information, as well as further linking with other databases relevant to the safety of nanomaterials. Before activities under Phase 2 are decided, an evaluation of the database will be carried out. Also quality aspects of the database will be analysed and addressed, as needed.

Project 2: Research Strategies on Manufactured Nanomaterials

- The aim of Project two is to develop a research strategy for human health and environmental safety issues associated with manufactured nanomaterials. The project has developed a comprehensive list of research themes. Based on data collection from the delegations, compilations of current/planned research projects have been compiled as well as urgent and medium/long term research priorities. As a result of an analysis, research themes which already have wide current coverage ("hot spots") and research themes less covered ("gaps") have been identified. As scientific research in the area of nanomaterials safety is rapidly evolving, a regular update will be necessary to continue to identify priorities, gaps and hot spots. It has been recognised that further analyses will depend on the implementation of Project one. Consequently, Project two will move forward in 2009-2012 with a more detailed analysis once the *Database of Research into the Safety of Manufactured Nanomaterials* is fully operational.

3 . The status of these projects at its 5th meeting of the WPMN (June 2009) and next steps are found in Annex III.

Project 3: Safety Testing of a Representative Set of Manufactured Nanomaterials

- The objective of this project is to agree and test a representative set of manufactured nanomaterials using appropriate test methods, preferably the OECD Test Guidelines. Accordingly, the project has developed: i) a general working definition of nanomaterials for use by the WPMN; ii) a list of manufactured nanomaterials for testing (based on materials which are in commerce or close to commercialisation); and iii) a specific set of endpoints or effects for which these nanomaterials should be tested.
- The project has launched the first phase of a “sponsorship programme” for testing the selected nanomaterials for the specific endpoints. In 2009-2012, this will produce Dossier Development Plans, prepared by sponsors, for each nanomaterial tested. This work is being supported by the development of a guidance manual for sponsors of the testing programme, which will be further elaborated during 2009-2012. A clearing house, prepared by the Secretariat on the password-protected web site, will be set up to facilitate the information exchange amongst sponsors, co-sponsors and contributors. This will include information on the material selection and the test methods to be used. In addition, it is expected that the testing programme will identify those cross-cutting issues or tests that will need further consideration for a second phase of testing. It is the aim that dossiers reporting the results from testing under the sponsorship programme will be published during the period 2009 - 2012. This project is closely linked to Project 4 by utilizing, where possible, OECD Test Guidelines in phase one of the sponsorship programme. It will consider validation issues where possible and when necessary.

Project 4: Manufactured Nanomaterials and Test Guidelines

- This project is reviewing existing test guidelines [especially the OECD Test Guidelines (TGs)] with view to establishing whether they are suitable for manufactured nanomaterials (MNs). This project has developed considerations for evaluating test guidelines for use in the assessment of MNs and gathered existing information about the unique characteristics of MNs by reviewing “white papers” or published reports. Based on these activities, it has finalised a preliminary review of test guidelines related to physical chemical properties, effects on biotic system, degradation and accumulation, as well as health effects. This project supports Project 3 in identifying existing testing methods (including international and national standards) for those endpoints identified for phase 1 of the “sponsorship programme” (see project 3).
- During 2009-2012, this project will make proposals for revisions of existing guidelines or draft proposals for new test guidelines, and/or guidance documents, as needed. They will be forwarded to the OECD’s Working Group of National Coordinators of the Test Guidelines Programme (WNT)⁴ for their consideration. This might also include the elaboration of a testing/assessment strategy which will be either general for all nanomaterials and endpoints, or for particular classes of nanomaterials and/or specific endpoints. Because the work is closely related to the OECD Test Guidelines, as well as other international standards, there will be close co-ordination with OECD’s Test Guidelines Programme and international standardization activities such as those of ISO. Finally, the input from the testing programme under Project 3 will assist in the development of this project. Similarly, the outputs of this project will assist Project 3 in moving forward.

⁴ The OECD’s Working Group of National Coordinators of the Test Guidelines Programme (WNT) is the body responsible for implementing the OECD’s Test Guideline Programme.

- Finally, two guidance documents will be developed as a high priority: i) sample preparation and dosimetry; and ii) the use of pulmonary instillation studies and consideration of their advantages and disadvantages compared to studies using the inhalation route.

Project 5: Co-operation on Voluntary Schemes and Regulatory Programmes

- This project analysed national information gathering programmes, whether voluntary or not, to assess the safety of manufactured nanomaterials. This project has already: i) identified elements common to these initiatives; ii) prepared recommendations on approaches and elements to consider for information gathering initiatives; and iii) prepared a Questionnaire on Regulatory Regimes for Manufactured Nanomaterials. This questionnaire identifies various components of regulatory regimes which are or may be applicable to nanomaterials. The questionnaire will be circulated to the WPMN delegations for its completion.
- The objective during 2009-2012 will be to identify applicable (current and proposed) regulatory regimes and how they address information requirements, hazard identification, exposure mitigation, risk assessment and risk management measures for manufactured nanomaterials. In addition, the project will update any information derived through national reporting schemes through a Table of Comparison.
- As a “spin-off” from Project 5, the WPMN has sought possibilities for sharing and comparing the data on manufactured nanomaterials which has been received by delegations as part of their national reporting schemes. The intention is to provide summary information on manufactured nanomaterials including the name, brief description of composition, description of the nature of any further information held on the material, the reporting country as well as contact points for further information. This information will be held on the WPMN password protected website. The information will be updated by submissions from delegations to the Secretariat. Additional mechanisms for further information sharing will be explored during 2009-2012.

Project 6: Co-operation on Risk Assessment

- The objectives of this project are to: i) exchange, collate and synthesise information on risk assessment approaches for chemicals that may apply to manufactured nanomaterials; ii) undertake a gap analysis of current risk assessment approaches as these apply to manufactured nanomaterials; and iii) prepare recommendations for addressing and filling identified gaps. A report aiming to address the first and second objectives as well as supporting tools is under development. This includes information on the supporting tools and a white paper on problem formulation analysis for the sponsored MNs. The project will finalise the report and proceed to prepare recommendations to the Working Party for addressing and filling identified gaps. During 2009-2012, this activity will include considerations on the need for the provision of guidance on issues that should be addressed when undertaking risk assessments for manufactured nanomaterials, based on the outcomes of the first two objectives.

Project 7: The role of Alternative Methods in Nanotoxicology

- This project was initiated relatively recently. It is looking into alternative test methods and will analyse how they might be used in an overall assessment plan for the testing of manufactured nanomaterials. This activity is closely related to the “sponsorship programme” of project 3.
- This project will assess available *in vitro* methods (including their validation/development status) and evaluate how they might be used and/or further developed in an overall assessment plan for

the testing of manufactured nanomaterials. It will then identify additional approaches to endpoints that could be addressed by the sponsorship programme (project 3). Consideration will be given to other alternative approaches and the broader issue of integrated testing strategies.

Project 8: Exposure Measurement and Exposure Mitigation

- This project was also recently initiated with the objective of exchanging information on guidance documents for exposure measurement and exposure mitigation and will develop recommendations on future work that needs to be undertaken. Specifically, the project aims to address: i) exposure in occupational settings; ii) exposure to humans resulting from contact with consumer products and environmental releases of manufactured nanomaterials; and iii) exposure to biota in the environment resulting from releases of manufactured nanomaterials, including releases from consumer products containing manufactured nanomaterials. The WPMN recognizes that information on exposure measurement and exposure mitigation developed for incidental nanoscale particles is highly relevant to this project and thus it will be considered.
- Recommendations for specific work needed on exposure measurement and exposure mitigation in occupational settings have been prepared. Specific projects related to occupational settings have been identified and will be developed, while the projects move forward in analysing the other two kinds of exposure (consumer products and environmental releases). Two projects have already commenced: (a) developing recommendations on measurement techniques and sampling protocols for inhalational and dermal exposures in the workplace; and (b) comparison of guidance on personal protective clothing, gloves and respirators.

9. Each of these eight projects is a key part of the programme of work and they will evolve over time, as needed.

10. Each project is being managed by a steering group which are implementing their respective operational plans. Each steering group is being led/ chaired by members of the WPMN, with support from the Secretariat. At the same time, the results of each project will continue to be evaluated and endorsed by the entire WPMN.

INFORMATION SHARING AND DISSEMINATION

11. The Working Party will continue to make available to the public (via the OECD web site) clear and concise information relevant to the human health and environmental safety of manufactured nanomaterials so as to promote the effectiveness of national efforts. In particular, the "Tour de table" documents prepared for each meeting of the WPMN provide a comprehensive overview of current activities related to the safety of nanomaterials in all delegations. These documents have been declassified and published following each meeting of the WPMN.

12. The Working Party aims to facilitate harmonisation of practices relevant to the chemicals regulatory area. Accordingly, the Working Party will act as a forum for sharing information on current or planned initiatives related to the safety of manufactured nanomaterials, for example on risk assessments, voluntary programmes and regulation. This will be an opportunity for delegations to describe the status and direction of national research programmes related to human health and environmental safety. Based on the approaches in member countries, industry, and other stakeholders, the Working Party will identify opportunities for co-operation and for harmonising approaches.

13. Consistent with the Terms of Reference (Annex II), the programme of work will involve the exchange of information on regulatory and risk management frameworks (limited mainly to the chemicals

sector) as well as environmental benefits. In 2009-2012, the Working Party will strengthen its work related to information exchange on environmental benefits. In this case, a specific link between the Working Party and the relevant projects of the Working Party on Nanotechnology (WPN) is important. The WPN is a subsidiary body of OECD's Committee of Scientific and Technological Policy (CSTP).

14. The WPMN has developed a communication strategy, which is intended to disseminate information on its work as widely as possible (see Annex I). The OECD website is updated on a regular basis with documents and announcements related to the work of the WPMN.

CO-ORDINATION

15. The WPMN believes it is important to build strong communication for identifying synergies and avoiding duplicative work with other related activities. Accordingly, the Secretariat will continue to work to co-ordinate its programme with other activities addressing nanotechnologies, both within OECD bodies⁵ and externally⁶.

⁵ OECD's Chemicals Committee (i.e.: the Working Group of Test Guideline Coordinators (WNT); the Working Group on Chemical Accidents; the Task Force on Pollutant Release and Transfer Registers (PRTRs); the Task Force for the Safety of Novel Foods and Feeds; the Working Group on Pesticides; and the Task Force on Biocides); or other OECD bodies addressing nanotechnology (i.e.: the Working Party on Nanotechnology).

⁶ International organisations such as the IOMC participating organisations (i.e., UNEP, ILO, OECD, FAO, WHO, UNIDO and UNITAR); the Intergovernmental Forum on Chemical Safety (IFCS) and possibly NATO and UNESCO; standardisation organisations (e.g., ISO and IUPAC); and nomenclature organisations (e.g., CAS).

ANNEX I
ACHIEVEMENTS OF THE WORKING PARTY ON MANUFACTURED NANOMATERIALS
DURING THE PROGRAMME OF WORK 2006-2008

Published Documents

During the programme of work 2006-2008, six documents were published as part of the OECD Series on the Safety of Manufactured Nanomaterials:

- No. 1, Report of the OECD Workshop on the Safety of Manufactured Nanomaterials: Building Co-operation, Co-ordination and Communication (2006)
- No. 2, Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 1st Meeting of the Working Party on Manufactured Nanomaterials (2006)
- No. 3, Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 2nd Meeting of the Working Party on Manufactured Nanomaterials (2007)
- No. 4, Manufactured Nanomaterials: Programme of Work 2006-2008 (2008)
- No. 5, Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 3rd Meeting of the Working Party on Manufactured Nanomaterials (2008)
- No. 6, List of Manufactured Nanomaterials and list of Endpoints for Phase One of the OECD Testing Programme (2008)
- No. 7, Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 4th Meeting of the Working Party on Manufactured Nanomaterials (2008)

Other Significant Outputs

- Launch of the **OECD Sponsorship Programme for Testing a Representative Set of Nanomaterials** (2007)
- Launch of the **OECD database on Research into the Safety of Manufactured Nanomaterials** (2008)

Conferences, Workshops and Other Meetings

Meetings that led to the establishment of the Working Party on Manufactured Nanomaterials

- OECD Joint Meeting Special Session on the “potential implications of manufactured nanomaterials for human health and environmental safety” (June 2005)
- OECD Workshop on the Safety of Manufactured Nanomaterials (December 2005)

In addition to the regular meetings of the Working Party (at approximately 8-9 monthly intervals) the Working Party has also organised the following OECD Workshops and Meetings:

- OECD Meeting of Steering Groups 2, 3 and 4 (March 2007)
- OECD Meeting of Steering Groups 3 and 4 (October 2007)
- OECD Workshop on the Sponsorship Programme for the Testing of Manufactured Nanomaterials (April 2008)
- OECD Meeting of Steering Group 7 (September 2008)
- OECD Workshop on Exposure Assessment and Exposure Mitigation (October 2008)
- OECD Meetings of Steering Group 8 (October 2008)
- OECD Workshop on the Safety Testing of Manufactured Nanomaterials (November 2008)

Meetings (OECD) in co-ordination with other international activities related to nanomaterials

- Dialogue between Academia and Participants of OECD's WPMN (March 2007)
- The International Workshop on Documentary Standards for Measurement and Characterisation in Nanotechnologies (February 2008): ISO, IEC, NIST and the OECD
- International Symposium on the Risk Assessment of Manufactured Nanomaterials (April 2008): NEDO, Japan; AIST, Japan; and OECD

**ANNEX II
TERMS OF REFERENCE 2009-2012**

I. Objective

1. The objective of the Working Party on Manufactured Nanomaterials is to promote international co-operation in human health and environmental safety aspects of manufactured nanomaterials among member countries and certain non-member economies (in accordance with the outreach policy of the Chemicals Committee).

II. Tasks

2. The Working Party on Manufactured Nanomaterials, under the supervision of the Chemicals Committee, shall:

- i. implement a programme of work for 2009-2012, which will involve the exchange of information on regulatory and risk management frameworks (limited mainly to the industrial chemicals sector). It will also exchange information on environmental benefits. The main projects included in the programme of work include:
 - development of a Database on Human Health and Environmental Safety Research;
 - research Strategies on Manufactured Nanomaterials;
 - safety Testing of a Representative Set of Manufactured Nanomaterials;
 - manufactured Nanomaterials and Test Guidelines;
 - co-operation on Voluntary Schemes and Regulatory Programmes;
 - co-operation on Risk Assessment;
 - the role of Alternative Methods in Nanotoxicology; and
 - exposure Measurement and Exposure Mitigation.
- ii. advise the Chemicals Committee on priorities amongst the above projects which need to be addressed in the short, medium and longer-term within the context of the Chemicals Programme;
- iii. take a proactive approach in regard to co-operation on the health and environmental safety related aspects of manufactured nanomaterials by advising the Chemicals Committee on issues related to human health (*e.g.*, from both public and occupational exposures) and environmental impacts resulting from manufactured nanomaterials;
- iv. recommend the best means of undertaking the various projects, for example, through a lead country approach, small task groups or workshops;

- v. promote an understanding of the health, environmental and exposure implications of manufactured nanomaterials by:
 - tracking relevant scientific research efforts;
 - identifying relevant research needs; and
 - developing and promoting a strategy to meet identified needs.
- vi. co-ordinate with other subsidiary bodies of the Chemicals Committee and refer issues to them as appropriate, through the Chemicals Committee;
- vii. co-ordinate with other relevant groups within the OECD, especially the Working Party on Nanotechnology, a subsidiary body of the Committee for Scientific and technological Policy; and
- viii. co-ordinate with other relevant intergovernmental organisations, especially those of the Inter-Organisation Programme for the Sound Management of Chemicals (*i.e.*, UNEP, ILO, OECD, FAO, WHO, UNIDO and UNITAR); the Intergovernmental Forum on Chemical Safety (IFCS) and possibly NATO and UNESCO; standardisation organisations (*e.g.*, ISO and IUPAC); and nomenclature organisations (*e.g.*, CAS), so avoiding duplication and ensuring complementarity with other international activities;

III. Participation

3. The Working Party will be open and transparent in its activities. Accordingly the participation of stakeholders will be agreed by the Working Party, in line with the outreach policy of the Chemicals Committee;
4. The Working Party will elect a Chair and Vice-Chairs for a period of one year.

IV. Term

5. The Terms of Reference are established until 31 December 2012.

ANNEX III CURRENT STATUS AND NEXT STEPS OF WPMN ACTIVITIES

The Working Party on Manufactured Nanomaterials drafted its Work Programme for 2009-2012 in April 2009. Following the approval by the OECD's Chemicals Committee during its 43rd Meeting (November 2008), the Working Party agreed that the Work Programme including its Terms of Reference be publicly available at its 5th meeting of the WPMN (March 2009). Recognising the significant progress made at the 5th meeting, this annex has been prepared to highlight the current WPMN activities following the achievements at the 5th meeting with an intention to provide a "snapshot" of information on the WPMN activities. This "snapshot" is current in June 2009.

Activities of the Work Projects

Project 1: Development of an OECD Database on Human Health and Environmental Safety Research and Project 2: Research Strategies on Manufactured Nanomaterials

Due to the close linkage and current stage of both projects, the WPMN decided at its 5th meeting to merge Project 1 and 2 and their new operational plan will be prepared.

OECD Database on Human Health and Environmental Safety Research

This database holds details of completed, current and planned research on the safety of manufactured nanomaterials. This database helps identify research gaps and assists researchers in future collaborative efforts. The database also assists the WPMN projects as a resource of research information. Since October 2008, delegations have been populating the database with information from national research programmes through on-line interfaces.

The database became publicly available on 1st April 2009. The link to access the database is provided through the OECD website (www.oecd.org/env/nanosafety/database). At the present time, the database contains about 690 projects from 23 delegations including both OECD member and non-member economies and BIAC.

Research Strategies on Manufactured Nanomaterials

This project aims at developing a research strategy(ies) for safety issues related to manufactured nanomaterials. To date, it has reviewed current national research programmes and identified research themes which already have wide coverage ("hot spots") and those which are less well covered ("gaps"). This project will be further explored by investigating the entries of the OECD database in close collaboration with Project 1.

The document *EHS Research Strategies on Manufactured Nanomaterials: Compilation of Outputs* is expected to be publicly available in May.

Project 3: Safety Testing of a Representative Set of Manufactured Nanomaterials

The main outcome of this project was to launch a "Sponsorship Programme for Testing Manufactured Nanomaterials". This project was launched in November 2007 when delegations agreed to fund and

manage the testing of 14 nanomaterials for endpoints relevant to human health and environmental safety. Since that time, delegations have been “signing up” to this work. By the end of the 5th WPMN, 15 member countries, the EC, the Nordic Council of Ministers, China and BIAC have committed to this programme as either “lead sponsors”, “co-sponsors” or “contributors”. A summary of the latest arrangements is found in Annex I and also available on the OECD web site.

During the meeting, it was possible to review and comment on “Dossier Development Plans (DDPs)” for ten of these nanomaterials. Amongst other things, each DDP identifies who is doing the testing of a specific nanomaterial, as well as when and where. In addition, they explain which test methods will be used for specific endpoints. It was noted that work has already begun on the testing of some of these nanomaterials, notably, fullerenes, single-wall carbon nanotubes and multi-wall carbon nanotubes.

As part of the “sponsorship” programme, a drafting group had prepared the document “Guidance Manual for the Testing of Manufactured Nanomaterials”, which is mainly intended to assist sponsors in their testing work. Nevertheless, it is believed of value for other stakeholders who are working on the testing of nanomaterials but that are not necessarily engaged in the OECD work. The first version of the “Guidance Manual” is expected to be publicly available in July. It is expected that subsequent versions of this Manual will be prepared in light of the experience gained with the sponsorship programme.

Project 4: Manufactured Nanomaterials and Test Guidelines

The WPMN has undertaken a Preliminary Review of 115 OECD test guidelines (designed for the safety assessment of chemicals) to assess whether or not they are suitable for nanomaterials. This review also benefited from input from the OECD’s Working Group of National Coordinators of the Test Guidelines Programme (WNT). It addresses Guidelines related to: i) physical chemical properties; ii) effects on biotic systems; iii) degradation and accumulation; and iv) health effects. The preliminary review is currently under consideration for its declassification.

This Review raised the need for preparing *Guidance Notes on Sample Preparation and Dosimetry*. This is because nanomaterials have distinct properties which may be affected by the test medium in which they are used. The WPMN reviewed the first draft and forwarded it to the WNT with a request for inputs. The guidance notes will be evolved based on the experience gained through both the testing programme (Project 3) and other efforts under the WPMN.

Finally, the WPMN is also preparing a document on *Non-inhalation Exposure Methods for Studies on the Pulmonary Toxicology of Nanoparticles*.

Project 5: Co-operation on Voluntary Schemes and Regulatory Programmes

This project has analysed national information gathering programmes, whether voluntary or part of an existing regulatory framework, to assess the safety of manufactured nanomaterials. By doing this, it has: i) identified common elements to these initiatives; ii) prepared recommendations on approaches and elements to consider for information gathering initiatives; iii) identified current and proposed regulatory regimes and how they address information requirements; and iv) prepared a Questionnaire on Regulatory Regimes for Manufactured Nanomaterials, to identify various components of regulatory regimes which are or may be applicable to nanomaterials.

The document *Analysis of Information Gathering Initiatives*, which includes the *Table of Comparison of Information Gathering Schemes*, is expected to be publicly available in August.

Project 6: Co-operation on Risk Assessment

The 5th WPMN agreed to hold a workshop on risk assessment of manufactured nanomaterials in a regulatory context in September 2009. The Steering Group for this project organises this workshop in co-ordination with BIAC. The workshop is expected to provide substantial inputs to a report drafted as a result of this project in 2008, entitled *Critical Issues in the Risk Assessment of Manufactured Nanomaterials* which is expected to be declassified as a result of input from the workshop.

Project 7: The Role of Alternative Methods in Nanotoxicology

This project focuses on alternative test methods and aims to analyse how they might be used in an overall assessment plan for hazard testing of manufactured nanomaterials. This activity is closely related to that of project 3.

Project 8: Exposure Measurement and Exposure Mitigation

In the early stages of this work, the focus of this project has been on the analysis of national guidance documents for exposure measurement and exposure mitigation. The aim has been to consider the merit of such documentation when considering nanomaterials in occupational settings. For example, work has been underway to consider recommendations on measurement techniques and sampling protocols for inhalation and dermal exposures in the workplace. This project is now extending its work so as to address consumer and environmental exposure.

Four documents developed by this project: 1) *Report of the Workshop on Exposure Assessment and Exposure Mitigation: Manufactured Nanomaterials*; 2) *Identification and Compilation and Analysis of Guidance Information for Exposure Measurement and Exposure Mitigation: Manufactured Nanomaterials*; 3) *Emission Assessment for Identification of Sources and Release of Airborne Manufactured Nanomaterials in the Workplace – Compilation of Existing Guidance*; and 4) *Comparison of Guidance on Selection of Skin Protective Equipment and Respirators for Nanotechnology Workplace: Manufactured Nanomaterials* are expected to be publicly available in June.

OECD Conference on Potential Environmental Benefits of Nanotechnology: Fostering Safe Innovation-Led Growth

This conference is organized by the OECD Working Party on Manufactured Nanomaterials (WPMN) and the OECD Working Party on Nanotechnology (WPN). This event will take place 15-17 July 2009 at OECD's Conference Centre in Paris, France. The conference will cover both the opportunities and the challenges of the use of nanotechnologies for the potential benefits for the environment. The main objective is to learn from international expertise and to identify ways in which to promptly improve policies which could potentially enhance short term as well as long-term growth. The more information will be found at the OECD website (www.oecd.org/nanobenefits).

Programme on the Safety of Manufactured Nanomaterials: A Road Map for Activities during 2009 and 2010

The Programme on the Safety of Manufactured Nanomaterials has multiple activities and events associated with it. For this reason, the 5th meeting of the WPMN began work on a “road map” which will identify the expected outputs and events during (primarily) the coming two years. As a result, a document was prepared for its parent body “the Chemicals Committee”, which meeting will be held on June 10-11 2009. The purpose of the document is two-fold. First, it presents a brief description of the ways in which the WPMN contributes to the overall objectives of the Environment, Health and Safety Programme (EHS),

and the OECD as a whole. Second, it describes the key expected deliverables of the WPMN with an approximate timing of when the Chemicals Committee might be expected to review them.

Forthcoming Events

- **OECD Conference on Potential Environmental Benefits of Nanotechnology: Fostering Safe Innovation-Led Growth**, 15-17 July, 2009, OECD Conference Centre, Paris, France
- **OECD Workshop on Risk Assessment in a Regulatory Context**, 16-18 September 2009, Washington DC, the United States
- **6th Meeting** of the Working Party on Manufactured Nanomaterials, 28-30 October 2009, OECD Headquarters, Paris, France
- **7th Meeting** of the Working Party on Manufactured Nanomaterials, 26-28 May 2010, OECD Headquarters, Paris, France

Publications of the OECD's Series on the Safety of Manufactured Nanomaterials

Recent Publications

- 📖 Preliminary Analysis of Exposure Measurement and Exposure Mitigation in Occupational Settings: Manufactured Nanomaterials [[http://www.oalis.oecd.org/oalis/2009doc.nsf/linkto/env-jm-mono\(2009\)6](http://www.oalis.oecd.org/oalis/2009doc.nsf/linkto/env-jm-mono(2009)6)]
- 📖 EHS Research Strategies on Manufactured Nanomaterials: Compilation of Outputs [[http://www.oalis.oecd.org/oalis/2009doc.nsf/linkto/env-jm-mono\(2009\)10](http://www.oalis.oecd.org/oalis/2009doc.nsf/linkto/env-jm-mono(2009)10)]

Upcoming Publications

- 📖 Report of the Workshop on Exposure Assessment and Exposure Mitigation: Manufactured Nanomaterials
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- 📖 Emission Assessment for Identification of Sources and Release of Airborne Manufactured Nanomaterials in the Workplace – Compilation of Existing Guidance
- 📖 Comparison of Guidance on Selection of Skin Protective Equipment and Respirators for Nanotechnology Workplace: Manufactured Nanomaterials
- 📖 Guidance Manual for the Testing of Manufactured Nanomaterials: OECD Sponsorship Programme
- 📖 Analysis of Information Gathering Initiatives and Table of Comparison on Information Gathering Schemes: Manufactured Nanomaterials
- 📖 Preliminary Review of OECD Test Guidelines for Applicability to Nanomaterials
- 📖 Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 5th Meeting of the Working Party on Manufactured Nanomaterials (March 2009)
- 📖 Work Programme on Manufactured Nanomaterials 2009-2012