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No. 22

OECD PROGRAMME ON THE SAFETY OF MANUFACTURED NANOMATERIALS 2009-2012: OPERATIONAL PLANS OF THE PROJECTS

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OECD PROGRAMME ON THE SAFETY OF MANUFACTURED NANOMATERIALS 2009-2012: OPERATIONAL PLANS OF THE PROJECTS

IOMC
INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS
A cooperative agreement among UNEP, ILO, FAO, WHO, UNIDO, UNITAR and OECD

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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)*

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The Environment, Health and Safety Division publishes free-of-charge documents in ten different series: Testing and Assessment; Good Laboratory Practice and Compliance Monitoring; Pesticides and 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 the 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 (http://www.oecd.org/ehs).

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

The Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) was established in 1995 following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. The participating organisations are FAO, ILO, UNEP, UNIDO, UNITAR, WHO and OECD. The World Bank and UNDP are observers. 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.

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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 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. And as part of its programme of work, the WPMN has currently eight projects those are led by respective steering groups (SGs).

At the 6th meeting of WPMN in October 2009, draft version of the operational plans 2009-2012 for each project were presented and endorsed for the declassification. This document compiles the operational plans 2009-2012 for the eight projects of the WPMN and it is published on the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology of the OECD.

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THE WORKING PARTY ON MANUFACTURED NANOMATERIALS (WPMN)

The Working Party on Manufactured Nanomaterials[1] (WPMN) was established in 2006 to help member countries efficiently and effectively address the safety challenges of nanomaterials. OECD has a wealth of experience in developing methods for the safety testing and assessment of chemical products.

The Working Party brings together more than 100 experts from governments and other stakeholders from: a) OECD Countries; b) non-member economies such as Brazil, China, the Russian Federation, and Thailand; and c) observers and invited experts from UNEP, WHO, ISO, BIAC[2], TUAC[3], and environmental NGOs.

Although OECD member countries appreciate the many potential benefits from the use of nanomaterials, they wished to engage, at an early stage, in addressing the possible safety implications at the same time as research on new applications is being undertaken.

The Working Party is implementing its work through specific projects to further develop appropriate methods and strategies to help ensure human health and environmental safety:

- OECD Database on Manufactured Nanomaterials to Inform and Analyse EHS Research Activities;
- 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;
- Exposure Measurement and Exposure Mitigation; and
- Environmentally Sustainable Use of Nanotechnology.

Each project is being managed by a steering group, which comprises members of the WPMN, with support from the Secretariat. Each steering group implements its respective "operational plans", each with their specific objectives and timelines. The results of each project are then evaluated and endorsed by the entire WPMN.

[1] Updated information on the OECD's Programme on the Safety of Manufactured Nanomaterials is available at: www.oecd.org/env/nanosafety

[2] The Business and Industry Advisory Committee to the OECD

[3] Trade Union Advisory Committee to the OECD.

EXECUTIVE SUMMARY

The objective of the Working Party on Manufactured Nanomaterials (WPMN) is to address the international co-operation with respect to human health and environmental safety related aspects of manufactured nanomaterials. The WPMN is implementing its work through specific projects, which are led by respective steering groups (SGs).

At the 6th meeting of the WPMN (October 2009), the operational plans 2009-2012 for each project were proposed and discussed. This document compiles the operational plans, which include information on their respective objectives, expected outputs, and linkages with other OECD bodies and other activities. Below you will find an outline of the main objective of each project:

1. *OECD Database on Manufactured Nanomaterials to Inform and Analyse EHS Research Activities* [led by SG1/2] - this project developed a Database, which focuses on past, current and ongoing environmental and human safety (EHS) research on manufactured nanomaterials. The database allows to identify EHS research done, as well as highlighting those areas that still need to be addressed. In addition, it provides an opportunity for identifying scientists and research on similar fields, which could lead to collaboration and development of networks;

2. *Safety Testing of Representative Set of Manufactured Nanomaterials* [led by SG3] – the main output of this project is the Sponsorship Programme for Testing Manufactured Nanomaterials, which are or will soon enter into commerce. The first phase of the testing programme (2007-2010) will identify those physico-chemical properties relevant to EHS risk assessment. The second phase will address those cross-cutting issues or additional EHS testing needed on specific nanomaterials;

3. *Manufactured Nanomaterials and Test Guidelines* [led by SG4] – this project intends to develop the necessary guidance documents for the testing of manufactured nanomaterials. This work is done in co-ordination with the OECD Working Group on National Co-ordinators of Test Guidelines Programme (WNT); the main output of this work is to develop those guidance materials that will ensure that the methods used for testing manufactured nanomaterials (sponsorship programme) allow their rigorous safety evaluation;

4. *Co-operation on Voluntary Schemes and Regulatory Programmes* [led by SG5] – this project analyses the elements in current or proposed voluntary reporting schemes and regulatory programmes on manufactured nanomaterials. It provided considerations and recommendations, which should be considered in developing information gathering schemes. Through this project trends in commercial activity and legislative requirements will be identified;

5. *Co-operation on Risk Assessment* [led by SG6] – the overall objectives of this project are to evaluate risk assessment approaches for manufactured nanomaterials through information exchange and to identify opportunities to strengthen and enhance risk assessment capacity. A document identifying the critical issues when assessing manufactured nanomaterials, such as risk assessment strategies and methodologies, will be developed;

6. *The Role of Alternative Test Methods in Nanotoxicology* [led by SG7] – this project intends to harvest the experiences from general chemicals with the objective of exploring specific applications of alternative methods which can further the understanding of the properties of manufactured nanomaterials. An guidance document assessing the potential use of specific Integrated Testing Strategies is being developed under this project;

7. *Co-operation on Exposure Measurement and Exposure Mitigation* [led by SG8] – this project looks at exposure measurement and mitigation of manufactured nanomaterials from three standpoints: i) workplace, ii) consumer; and iii) environment. Specific projects on these three areas are being developed; in addition, case studies on specific nanomaterials (from the Sponsorship Programme) will be developed, to complement the set of information needed to assess and managed their risk; and

8. *Environmentally Sustainable Use of Manufactured Nanomaterials* [led by SG9] – the main focus of this project is to enhance the knowledge base about life cycle aspects of manufactured nanomaterials, as well as their potential positive and negative impacts on the safety of environment and health. It will focus on specific nano-enabled applications at their different stages of development. One of the first outputs will be a report on those applications, and their existing frameworks and tools for applying life-cycle considerations.

OECD DATABASE ON MANUFACTURED NANOMATERIALS TO INFORM AND ANALYSE EHS RESEARCH ACTIVITIES

TITLE

OECD database on manufactured nanomaterials to inform and analyse EHS research activities

BACKGROUND

This joint project builds on work undertaken by two separate OECD WPMN activities, former Project one *(Development of an OECD database on Human Health and Environmental Safety Research*) and former Project two (*EHS Research strategies on Manufactured Nanomaterials*) which were implemented under the Work Programme on Manufactured Nanomaterials 2006-2008.

These two projects were combined into a single project in March 2009, because the database contains information on available research projects that will facilitate a detailed analysis of current research efforts in order to determine urgent and medium/long term research needs regarding EHS aspects of manufactured nanomaterials.

OBJECTIVES

The objective of this project is to develop a global resource, which details research projects that address environmental, human health and safety (EHS) issues associated with manufactured nanomaterials and identify areas that require further research efforts to address human health and environmental safety issues. The Database will:

- assist those who want to identify research needs and avoid duplication.
- provide opportunities for researchers to identify scientists working in similar fields, and lead to collaboration and development of networks.
- provide critical information and support for several of the other WPMN projects.
- link to other relevant databases to form a global and comprehensive resource on EHS aspects of manufactured nanomaterials.

Research is defined in a broader sense in this context. Thus, not only experimental studies, but also projects relevant to EHS with regard to, comprehensive risk assessments of specific substances, risk mitigation measures as well as regulatory aspects and international standard setting and reports on the public dialogue are included.

An **application driven** (i.e. nanomaterials used in downstream processes and products) and **scientific** analysis of the information contained in the database will enable **identification and reporting** of urgent and medium/long-term research needs. It is important to note that this project will not develop a global research strategy nor coordinate existing or future research activities but rather identify and report on research needs linked to the OECD-WPMN-activities in its different SGs including its sponsorship programme.

EXPECTED OUTPUTS FOR THE PERIOD 2009-2012

Expected outputs are:

- Ongoing population of the database by DPs with appropriate verification of data and content by DCPs.

- Evaluation of the database for data quality, usefulness to identify research priorities and gap analysis, appropriateness of "administrative rights" of DPs and DCPs.

- Extend functionality of the database by

  - Developing keywords for use in analysis of the database.

  - Linking to other relevant databases, including national and regional databases (e.g. CORDIS, DE Nanocare, EC Nanosafe).

  - Including other types of information, such as uses and applications of nanomaterials that will assist in exposure and hazard assessments of nanomaterials.

  - Including information on risk assessment approaches, risk mitigation and risk communication related to human health and environmental safety aspects of manufactured nanomaterials.

  - Including information on environmental, health and safety benefits of manufactured nanomaterials (e.g. energy conservation) [This item has lower priority and should first be discussed by the WPMN with co-ordination with the WPN]

- Development of a CBI policy, as required– a WPMN wide policy consistent with OECD policies and practices is envisaged.

- Evaluate feedback mechanisms associated with the database.

- Develop mechanisms to identify and update future research needs including the clarification of which nanomaterials are to be covered, to facilitate information exchange on relevant EHS research themes and to analyse gaps which should be filled from the perspective of regulatory needs.

- Elaborate and update the information sharing network for "hot spots" research areas for coordinating co-operative work to streamline resources and address knowledge gaps in an efficient way (avoid unnecessary overlaps and duplicative work). The network will be built on the current scheme under construction at the SG 1/2 section of the password-protected website and involve research communities which are participating in the database and may be of interest for research policy makers.

LINKS TO OTHER STEERING GROUPS

The database will serve as a suitable and easy to use resource to the work of the WPMN as a whole by providing:

- a mechanism to document outcomes of research undertaken through the OECD Sponsorship Programme;
- information on research outcomes that can inform the work of other steering groups under the WPMN.

SG 1/2 will discuss further coordination with other SGs for strategic use of the database.

Analysis of the research efforts to date will provide other steering groups an overview on the major activities of the member countries and facilitate co-operative international approaches to fill gaps in knowledge on research themes which are not covered sufficiently. The database may support a range of activities of the WPMN. It may especially help:

- SG3 to plan the phase 2 of Sponsorship Programme; and
- SG4, SG7 and SG8 to consider co-ordination with existing and planned research on testing methods and exposure assessment aspects.
- The new SG "benefits" to further develop its joint activities with OECD-WPN including the development of a risk-benefit analysis helping in maximising the benefits of nanomaterials and boosting innovation. [This item should first be discussed by the WPMN with co-ordination with the WPN]

However, this extension of the database should be realized stepwise with a priority on the EHS perspective.

OUTCOME FROM ACTIVITIES in 2006-2008

FORMER PROJECT 1 (Development of an OECD database on Human Health and Environmental Safety Research) (Phase 1):

Phase 1 established an OECD database of planned, underway and completed EHS research projects. The information to be included, as well as format and categorisation were determined in Phase 1. To ensuring the usefulness of the Database linkages to the work of other Steering Groups and organisations were also considered in determining these information requirements.

The database has been publicly available since 1st April 2009 at URL: www.oecd.org/env/nanosafety/database. All data transferred from the WWC database and new research projects entered by delegations were checked by Designated Contact Points within delegations. Each delegation was required to develop its own *modus operandi* for coordinating the activities of the Data Providers and Designated Contact Points. Guidance material, an information brochure and a power point presentation have been developed by SG1 to support the EHS database.

FORMER PROJECT 2 (EHS Research strategies on Manufactured Nanomaterials)

This project has developed a list of research themes relevant to human health and environmental safety aspects of nanomaterials and produced the comprehensive compilation document on completed, current or planned research activities as well as urgent and medium/long term research priorities. Based on these data, the project identified research themes which already have wide current coverage ("hot spots") and research themes less covered ("gaps"), and proposed possible research projects for international co-operation.

The outputs including: i) the List of EHS Research Themes Relevant to Nanomaterials and ii) Analysis of the Frequency of Entries in the List of Current/Completed as well as Planned Research Projects were declassified as document "*EHS Research Strategies on Manufactured Nanomaterials: Compilation of Outputs*" [ENV/JM/MONO(2009)10].

As for the establishment of a web-based information sharing network for the five identified "hot spot" research areas, the OECD Secretariat asked the WPMN delegations for their interests in setting up a network, only two delegations (Germany and the United States) expressed their interest. A template will be constructed for the purpose of such information sharing in the WPMN password protected website.

SAFETY TESTING OF REPRESENTATIVE SET OF MANUFACTURED NANOMATERIALS

OBJECTIVE 2007 to 2012

The objective of this Project Three undertaken by Steering Group (SG) 3 will be to agree on and test a representative set of manufactured nanomaterials in accordance with the guidance manual for sponsors.

This project will be in two stages, a project definition stage and an implementation stage. The project definition stage is now complete. The implementation stage is underway, and will test the substances selected through "Phase One" and "Phase Two" testing.

During the first stage (in 2007 and 2008), SG3 developed and agreed on a priority list of candidate nanomaterials and a set of exploratory endpoints for "Phase One" testing through a sponsorship programme. The first stage also included developing a guidance manual for sponsors and a working definition of nanomaterials for use by the WPMN. During the second stage (from 2009 to 2012), the sponsorship programme will be implemented and supported by Project Three participants, and dossiers will be developed. Project Three will also consider what further testing may be needed under "Phase Two" of the project, with an eye towards making recommendations on nanomaterials, endpoints, and approaches for generating data. Phase Two testing may begin during the 2011-2012 timeframe. Project Three will also develop a report summarizing the results of the Phase Two testing programme. Results of the SG3 sponsorship programme will be regularly reported to other WPMN SGs and other relevant OECD Working Parties to ensure broadest possible advantage of the generated data.

The use of a review committee to exchange ideas, address technical issues and facilitate consistency between the Dossier Development Plans (DDPs) was a successful and positive approach that was applied by SG3 preceding WPMN-5. On that basis, SG3 will apply a similar approach to the development of the dossiers themselves.

EXPECTED OUTPUTS AND LINKS WITH THE OTHER STEERING GROUPS:

Outputs of the first stage

- A working definition of "manufactured nanomaterials" (MN) for use by the working party.
- Description of the information on intrinsic properties relevant for exposure and effects assessment of different groups of nanomaterials [4] and the corresponding methods of measurements or tests.
- Identification of a representative set of manufactured nanomaterials[5].

[4] Relevant endpoints include physical/chemical properties, material characterization, environmental fate and behavior, and health and environmental effects.

[5] This was done by identification of some of the current major groups of nanomaterials and selection within those groups of some example materials. For the example materials, information will be gathered and relevant testing performed. This should also identify whether or not existing methods (used for traditional chemicals) are applicable to nanomaterials.

- Guidance Manual for Sponsors.

Outputs of the second stage

- Selection of principal nanomaterial(s) and, if appropriate, relevant alternate nanomaterial(s) for each dossier
- Analysis and presentation of summary of data already available for the principal nanomaterial and relevant alternate nanomaterials, and control materials[6].
- Complete and published Dossier Development Plans (DDPs) for the nanomaterials.
- Testing of the nanomaterials *in vitro* and *in vivo* using the foundation data set[7].
- Draft Dossiers on the substances reflecting the progress of the tests:

  (a) draft dossier containing all existing data

  (b) draft dossier containing (a) plus outcome of physico chemical characterization

  (c) draft dossier containing (b) plus outcome of short term (eco)tox testing

  (d) draft dossier containing (c) plus outcome of long term (eco)tox testing
- Identification of physico chemical properties that can have a major impact on adsorption, distribution, metabolism and excretion (ADME) of MN.
- Final dossiers on the substances
- A summary report of Phase One testing
- Agreement on Phase 2 testing, and initiation of such testing where appropriate
- An interim report of Phase Two testing
- Regular progress reports to the WPMN

In addition, during the process of generating the dossiers, it may be relevant to take up other issues either within the WPMN itself or within the OECD work on chemicals. For example, proposals for revising and refining the Guidance Manual for the Testing of Manufactured Nanomaterials[8] (GM) may be put forward and the Annex (Template for Reporting) should be integrated in the GM once it is agreed, as well as proposals for new or revised test guidelines, to be taken forward by SG 4.

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6 The text uses the key terms as defined in the guidance manual for sponsors, version 2.1

7 May include use of existing data on specific MN instead of generating new data where appropriate. SG-3 has used the term foundation data set to mean both the data set resulting from testing as well as the tests to be conducted.

8 Published by OECD as: Guidance Manual for the Testing of Manufactured Nanomaterials: OECD's Sponsorship Programme [ENV/JM/MONO(2009)20], 2009.

Links to other WPMN Steering Groups[9]

- Link SG1/SG2 to information on EHS research being conducted on specific nanomaterials and endpoints and research strategies for addressing data gaps.
- Link to SG4 to identify and resolve test guideline issues and evaluation criteria.
- Link to SG1 to provide the public and other stakeholders access to SG-3 results.
- Link to SG6 to provide data that may be used to identify data sets or trends that can be utilized in risk assessment methodologies.
- Link to SG7 on alternative test methods.
- Link to SG8 on exposure assessment;

In addition to the links within the WPMN, the links to activities under ISO TC229 will also continue to be relevant.

SPONSORSHIP PROGRAMME

Deliverables for the two stages of the sponsorship programme and associated time horizons.

First stage (completed)

Short term (April 2007) [delivered]

- A working definition of "manufactured nanomaterials" in collaboration with SG4.
- BIAC invited to provide an indicative list of MNs already in commerce.
- DuPont and Environmental Defense invited to provide a list of possible endpoints.

Short/medium term (July 2007) [delivered]

- A list of MN where FDS-type data have been generated or which are undergoing FDS-type testing now or in the near future.
- Selection of set of candidate nanomaterials and a combination of criteria to be defined (quantity etc.) including proposals for a foundation data set for these substances. Includes input from SG2, SG4 and SG6
- Identification of an agreed representative set of nanomaterials. Input from SG4 and available public reports[10].

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9 May need to be further elaborated on the basis of other steering groups' activities.

10 For instance SCENIHR report to be used for current testing methods for MN, the two UK projects: 'An Assessment of Regulatory Testing Strategies and Methods for Characterising the Ecotoxicological Hazards of Nanomaterials' and 'Reference Materials for Engineered Nanoparticle Toxicology and Metrology' due in summer 2007 and other relevant information.

Medium term (end 2007) [delivered]

- Agreement on end points necessary for evaluation of the intrinsic properties of MN.
- Identification of an "initial data set" needed for the representative set of nanomaterials.

Longer term (end 2008) [delivered]

- Guidance Manual for Sponsors
- Sponsors identified for 9 of the 14 MNs selected
- Circulate a first draft of the DDPs
- Guidance on Sample Preparation and Dosimetry (from SG4)

Second Stage

Short term (July-2009):

- Identification of additional sponsors (ongoing)
- Completion of the DDPs for all sponsored MNs, following the Guidance Manual for Sponsors
- Where not already underway, begin measurement and testing program for sponsored MNs.

Short/Medium term (mid 2010):

- Progress report for each MN for the regular meetings of the WPMN.
- Updated DDPs and timelines, as relevant.
- Initial discussions on possible Phase Two testing

Medium term (mid 2011)

- Draft dossiers should be available for some MNs.
- First identification of physico chemical properties of MN which can influence adsorption, distribution, (metabolism) and excretion (ADME).
- Develop a plan and structure for summary report of Phase One testing
- Develop initial Phase Two testing recommendations

Long term (beyond mid 2011):

- Draft dossiers should be available on all MNs
- Develop summary report on the outcomes of Phase One testing

- Implement Phase Two testing programme.

Long term (2012 and beyond):

- Report on outcome of Phase Two testing programme

MANUFACTURED NANOMATERIALS AND TEST GUIDELINES

I. OBJECTIVES

The unique properties of manufactured nanomaterials (MNs) raise the question of whether current OECD Test Guidelines are adequate to appropriately address their characterisation and the assessment of their toxicological properties. Accordingly, a project named "Manufactured Nanomaterials and Test Guidelines" was established and undertaken by Steering Group 4 (SG4) created under the supervision of the OECD Working Party on Manufactured Nanomaterials (WPMN). The objectives of this project are to:

- Review existing OECD Test Guidelines for adequacy in addressing manufactured nanomaterials; and

- Identify the need for development of new or revision of existing test guidelines.

SG4 will coordinate with the OECD Working Group on National Co-ordinators of Test Guidelines Programme (WNT) on any concrete proposals for development/revision of test guidelines and/or guidance documents.[11] In developing these proposals, SG4 will collaborate closely with the other steering groups under the WPMN that deal with other aspects of manufactured nanomaterials and take into account available relevant information and results coming from the scientific community.

During the period of 2006-2008, the short and most of the medium term actions and deliverables described in the previous operational plan agreed by the 2nd WPMN [ENV/JM(2007)13] were accomplished. This operational plan (2009-2012) is intended to provide general guidance to SG4. Because there are many unknowns about the properties of nanomaterials and their effects, it makes sense to design a process that is able to adapt to new information. Each of the activities listed below is intended to serve as a point of departure for further discussion and clarification of specific tasks that are needed. The work of Project 4 relies on data and results of the other WPMN projects, particularly SG3, SG7 and SG8 thus some of the final outputs will probably become available only towards the end of the planning period. However, throughout the period of this operational plan, SG4 will use information as it becomes available to make progress on its objectives.

II. EXPECTED OUTPUTS FOR THE PERIOD 2009-2012

- Final Guidance Notes on Sample Preparation and Dosimetry (GNSPD).[12]
- Functioning Communities of Practice

[11] The fact that Guidance Documents are not binding under the OECD MAD agreement may be a factor to take into account when making these proposals.

[12] A first version of this document for declassification by the JM is expected by the end of 2009. Nevertheless it will have to be considered as a living document and several updates may be produced as both the OECD work and scientific knowledge advance. The definitive guidance should be produced towards the end of the planning period.

- Informed by the sponsorship program, as well as other information,SG4 will produce for WPMN consideration:
  - Document(s) evaluating the need for new Test Guidelines and/or Guidance Document(s) to address the specific properties of manufactured nanomaterials
  - A list of current TGs already suitable for manufactured nanomaterials (if any)
  - Within each test guideline area , a prioritised list of current Test Guidelines to be revised or for which additional guidance is needed to be applicable to manufactured nanomaterials
  - Within each test guideline area as above, a prioritised list of new TGs to be developed
  - A plan/proposal to update specific current guidelines, generates new guidelines, validate them and gain their acceptance by OECD.

III. ACTIVITIES FOR THE PERIOD 2009-2012

- **Finalize the Guidance Notes for Sample Preparation and Dosimetry.** Building on the current draft version a first "interim final version" will be released in autumn 2009. It is expected that this version will need several updates as results and issues arise from the Sponsorship Programme, as the work in SG 8 progresses and scientific knowledge advances. Updated versions will be delivered as/when appropriate and a final version will be released at the end of the reporting period with the aim to eventually become an OECD Guidance Document.

- **Set up communities of practice** for the four test guideline-related areas (i.e., Physical-chemical Properties (Materials Characterization); Effects on Biotic Systems; Degradation and Accumulation; and Health Effects) in order to facilitate discussion, resolution and, when appropriate, harmonisation of technical issues that arise during testing conducted in support of the sponsorship program. Discussion on best practices and integrated approaches to testing and assessment and, if necessary, harmonization between the several data generation programs could also take place here. On the other hand, further evaluation of appropriateness of assessment methodologies and subsequent gap analysis for the new information needs that may arise or be identified within the programme could also be addressed by this activity. Although the organisation of the communities of practice will be coordinated by SG4, as the central focal point, this is a common endeavour with SG3 and SG7. Members of such communities of practice will be drawn from across the WPMN and, if appropriate, even experts external to the WPMN program.

- **Develop a draft list of current guidelines already recommended for manufactured nanomaterials (if any)**

- **Develop a draft list of recommended changes to existing guidelines,** with particular consideration to novel MN specific endpoints or sub-endpoints that might be identified for manufactured nanomaterials

- **Develop a draft list of recommended new test guidelines to be developed,** with particular consideration to novel nanomaterial specific endpoints or sub-endpoints that might be identified for manufactured nanomaterials.

- **Elaborate work plan/proposal(s) for revising existing guidelines or develop new test guidelines** (including in vitro methods), validate them and gain acceptance by OECD. This might also include the

- **Elaboration of a testing/assessment strategy in collaboration with other SGs** either general for all nanomaterials and endpoints, or for particular classes of nanomaterials and/or concrete endpoints.

IV. COORDINATION.

SG4 will keep other groups informed of its work so that they might benefit from SG4's work and be aware of SG4's needs. In addition, SG4 will seek for active participation and coordination with other SGs' activities.

- **SG1/SG2**. SG4 can use the OECD database to find information on the state of the science for testing nanomaterials.

- **SG3.** WPMN sponsors can make use of initial information from SG4 in developing protocols for testing. SG3 and SG4 will work together (and with other SGs, in particular SG7) in an iterative manner since the testing and modification of test guidelines are so closely related. The results from the sponsorship program will inform SG4's work on modifying guidelines. The communities of practice established within the WPMN and coordinated by SG4 will be the main forum for information sharing, discussion and, when appropriate, harmonisation of best practices among the sponsors and partners of the Sponsorship Programme including the "alternative methods group", which addresses selected in vitro test methods for human health related effects.

- **SG5.** SG5 can provide information to SG4 from existing voluntary reporting schemes and regulatory programs concerning unique endpoints that have been identified and other information that could be useful in modifying guidelines. The results of SG4's work will be useful to SG5 in identifying relevant test guidelines and data needs.

- **SG6.** As one important use of testing is to provide data for hazard and risk assessment, it is important that SG4 communicate closely with SG6 on the implications of any possible modification to existing test guidelines or the creation of new guidelines.

- **SG7.** SG4 will closely co-ordinate with SG7 on the opportunities to use alternative test methods and testing strategies. Because alternative methods are an integral component of the sponsorship program, there will likely be implications of testing findings on guideline development. Integrated testing strategies incorporating both *in vitro* and *in silico* approaches (as well as other alternative methods and other relevant information sources) outlined in collaboration with this group should be recommended for implementation by SG3 within the sponsorship programme, mainly via the Communities of Practice.

- **SG8.** As the sponsorship program generate information that has implications for the accumulation/degradation Test guidelines, such implications may be of interest to the development of exposure scenarios and models. This may become particularly relevant as SG8's work during this period moves from the workplace to environmental and consumer exposure. One of the key coordination points is in what metric the doses/concentrations should be expressed (e.g. mass, size, size distribution, surface area, and particle number). In fact, there is a need that NOELs and/or other dose-response data resulting from testing are also comparable to how exposures could/should be measured and expressed. This implies a continued dialogue between SG 4 and SG 8 (as well as with all other groups) whose results will have to be incorporated in the GNSPD.

- **Other OECD Bodies and Other International Organisations.** It is essential to guarantee direct, prompt and clear communication between SG4 and OECD's WNT. If revisions are needed to current test guidelines or if new test guidelines are needed, SG4 will co-operate with WNT under the supervision of the Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology (JM). This will be ensured by the Secretariat, the co-chairs, and those participants who are common to both groups. Communication with the JM will be ensured via the WPMN bureau and secretariat. Also, particular attention should be given to coordination with the relevant ISO technical committees, especially ISO TC229 in order to ensure that the efforts OECD and ISO continue to be complementary.

CO-OPERATION ON VOLUNTARY SCHEMES AND REGULATORY PROGRAMMES

OBJECTIVES

This project will examine voluntary reporting schemes and regulatory programmes with five primary objectives.

- The first objective is to finalise a report on the current and proposed regulatory regimes which will summarise the information requirements, hazard identification, risk assessment and exposure mitigation/ risk management features present in these regimes.
- The second objective is to gather information on the lessons learned from jurisdictions which have completed information gathering initiatives, and summarize non-CBI information and statistics on nanomaterials reported, to provide insight of global market activity.
- The third objective is to gather information on the nanomaterials notified under the various regulatory regimes for the periods 2006-2009 and 2010-2011, to provide an indication of regulatory activity and trends over time.
- The fourth objective is to establish, on a pilot basis, a collaborative workspace to allow government delegations to exchange information on approaches, considerations, experiences and lessons learned in implementing voluntary or regulatory activities for manufactured nanomaterials.
- The fifth objective would be to secure substantial member participation in the Information Sharing database.

EXPECTED OUTPUTS AND LINKS TO OTHER STEERING GROUPS

Outputs

The following documents/workspaces/databases will be developed:

- A report on current and proposed regulatory regimes and how they address information requirements, hazard identification, risk assessment and exposure mitigation/ risk management of nanomaterials.
- A report summarising the information gathered and lessons learned from the various information gathering initiatives that have been completed.
- A report summarising the nanomaterials that have been notified under the various regulatory regimes for the periods 2006-2009 and 2010-2011.
- Establishment of a collaborative workspace for information exchange.
- An up-to-date Information Sharing database.

Links to other steering groups

- Information identifying the availability of regulatory notifications/submissions and risk assessments will provide input into Steering Group 6 (SG-6) as they pursue information on risk assessment practices.
- Understanding which materials are more common within the global marketplace can assist SG1/2 in pointing towards updated needs linked to the WPMN activities, as well as with identifying which nanomaterials should be identified in measurement studies under SG8.

CO-ORDINATION WITH OTHER OECD BODIES AND OTHER INTERNATIONAL ACTIVITIES

- Co-ordination with OECD Committee on Science and Technological Policy's Working Party on Nanotechnology.

ACTIVITIES

Short-Term Activities (current to summer 2010)

- Regulatory Regime Report
  - Finalise analysis and wording of report and submit to Working Party at its 6th meeting (October 2009).

- Follow-up to Information Gathering Initiatives Report
  - Canada to draft a follow-up questionnaire for review by Steering Group (September, 2009).

  - Submit to the Working Party at its 6th meeting (October 2009) with a call for comments by the end of November 2009 and permission to move forward with a call for responses by March 1 2010.

  - Canada to compile responses and prepare a report for review by the Steering Group (Summer 2010).

- Follow-up to the Regulatory Regime Report
  - Canada to draft an electronic survey for review by the Steering Group (January 2010).

  - Submit to the Working Party at the 7th meeting (July 2010) with a call for responses by the end of August 2010.

- Information Sharing Database
  - Secure input from various jurisdictions to populate the Information Sharing Database by summer 2010.

- Collaborative Workspace
  - Once technology is available (based on upgrades to OECD WPMN network), a call for participants will be made.

Medium-Term Activities (Summer 2010 to spring 2011)

- Follow-up to the Information Gathering Initiatives Report
  - Finalise the wording of the report and submit to Working Party for its 8th meeting (Fall 2010).

- Follow-up to the Regulatory Regime Report
  - Canada to compile responses and prepare a report for review by the Steering Group (Fall 2010-Winter 2011).
  - Finalise analysis and wording of report and submit to the Working Party at the 9th meeting (Spring 2011).

- Collaborative Workspace
  - Lead and participants to develop a workplan to develop the workspace.
  - Establishment of the Workspace with a plan to encourage and monitor participation.

Long-Term Activities (Spring 2011 and later)

- Follow-up to Regulatory Regimes Report
  - Canada to draft Part 2 of the electronic survey for review by the Steering Group (Winter 2011/2012).
  - Submit to the Working Party for its 10th meeting (Fall 2011) with a call for responses (Spring 2012).

- Information Sharing Database
  - Secure input from various jurisdictions to update the Information Sharing Database by summer 2011 with new data received since summer 2010.

- Collaborative Workspace
  - Continue to monitor participation and update as necessary.

ISSUES TO BE DISCUSSED WITHIN THE STEERING GROUP 5

- Scope of information to be collected for both follow-up surveys. What is the right level of details for the information that will be gathered and how to handle confidential business information?

- How best to secure input from various jurisdictions to the Information Sharing Database.

CO-OPERATION ON RISK ASSESSMENT

OBJECTIVES

The overall objectives of this project are to evaluate risk assessment approaches for manufactured nanomaterials through information exchange and to identify opportunities to strengthen and enhance risk assessment capacity.

This Steering Group will serve to integrate outputs from other WPMN steering groups into an overall framework within which risks of manufactured nanomaterials are assessed, ensuring good practice across OECD.

There are three detailed objectives:

1. Consider risk assessment strategies, methodologies, and supporting tools that offer the potential to underpin risk assessment.

2. Identify and consider any unique issues that manufactured nanomaterials present for risk assessment.

3. Make recommendations to WPMN for addressing and filling identified gaps.

These recommendations will also consider the need for provision of guidance on key issues that should be considered when undertaking risk assessments for manufactured nanomaterials as well as development of empirical evidence to support this guidance.

EXPECTED OUTPUTS AND LINKS TO OTHER STEERING GROUPS:

Outputs

- Report on issues critical to risk assessment which includes current risk assessment strategies and methodologies for chemicals that may apply to manufactured nanomaterials.

- Report on the Workshop on Risk Assessment of Manufactured Nanomaterials in a Regulatory Context.

- Liaison groups to interact with Steering Groups 3, 4, 7 and 8 to address research related to risk assessment methodology principles and needs.

Links to other steering groups

SG 6 will serve to integrate outputs from other WPMN SGs within an overall consideration of the framework in which risks of manufactured nanomaterials are assessed.

- Link to SG1/2 to obtain information on EHS research relevant to risk assessment methodologies and tools; also to assist in identifying research gaps.

- Link to SG3 to obtain empirical data and base data sets to inform the development of potential approaches and tools for risk assessment.

- Link to SG4 to incorporate test guidelines identified as appropriate for nanomaterials into risk assessment methodologies.

- Link to SG5 to share information on risk assessments methodologies and approaches used by regulatory agencies.

- Link to SG7 to incorporate risk assessment approaches using alternative methods.

- Link to SG8 to share information on exposure assessment and mitigation measures.

Co-ordination with other international activities

- Co-ordination with ISO TC 229 on standards development which can be used in risk assessment methodologies.

- Co-ordination with the Society for Risk Analysis (SRA) and other relevant organisations to exchange information and collaborate on the development of risk assessment methodologies and tools.

ACTIVITIES

Phase 1: Until July 2010 (7th meeting of WPMN)

- Report on the Workshop on Risk Assessment of Manufactured Nanomaterials in a Regulatory Context

  - Workshop to take place in September 2009 in Washington D.C. hosted in conjunction with BIAC and the Society for Risk Analysis.

  - Workshop report to be prepared for public consumption and the workshop results to be disseminated as appropriate.

- Report on "Risk Assessment of Manufactured Nanomaterials – Critical Issues"

  - SG6 to revise the document taking into account the outcomes from the Workshop on Risk Assessment in a Regulatory Context (September 2009).

  - The document will be prepared for declassification as agreed at the 5th meeting of the WPMN (March 2009).

  - The report will include:

    - An overview of information on risk assessment approaches for chemicals that may apply to manufactured nanomaterials with a view to consider risk assessment strategies,

methodologies and those supporting tools that offer the potential to underpin risk assessment.

- A gap analysis of current risk assessment approaches as these apply to manufactured nanomaterials in order to identify and consider any unique issues that manufactured nanomaterials present for risk assessment.

- Recommendations to WPMN for addressing and filling identified gaps considering the need for provision of guidance on key issues when undertaking risk assessments for manufactured nanomaterials as well as development of empirical evidence to support this guidance.

- Establish liaison groups with Steering Groups 3, 4, 7, and 8 to address research related to risk assessment methodology issues

  - Develop strategy to link risk assessment methodology needs with ongoing research in the Sponsorship Programme

  - Examine use of a collaborative workspace and other IT options to facilitate exchange of information.

Phase 2: From July 2010 to early 2011 (8th meeting of WPMN)

- Continue liaison with Steering Groups 3, 4, 7 and 8 to obtain information in support of risk assessment approaches.

Phase 3: 2011 to 2012 (9th Meeting of the WPMN)

- Risk assessment workshop to exchange information and increase risk assessment capacity

  - Follow-up workshop to examine the state-of-the-science and lessons learned which can be applied to strengthen risk assessment methodologies and tools.

- Undertake an analysis of how research results can contribute to current risk assessment approaches

- Report on proposed risk assessment methodologies for manufactured nanomaterials.

THE ROLE OF ALTERNATIVE TEST METHODS IN NANOTOXICOLOGY

I. OBJECTIVES

The project called "Role of Alternative Test Methods in Nanotoxicology" was established and undertaken by Steering Group 7 (SG7) created under the supervision of the OECD Working Party on Manufactured Nanomaterials (WPMN).

The area of the development and use of integrated testing strategies using alternative test methods to test chemicals is a vast area which is quickly developing. This project therefore intends to harvest the experiences from general chemicals with the objective of exploring specific applications of alternative methods which can further the understanding of the properties of manufactured nanomaterials (MNs). The sponsorship programme (SG3) aims at providing information on the properties of specified MNs and SG4 aims at combining the experiences from the Test Guideline Programme (TGP) with the practical experience from SG3 to target MN-specific needs in the current Test Guidelines. SG6 has developed a number of case studies for substances in SG3 assessing the hazards and risks, which are further developed. SG7 aims at complementing SG3 and SG6 by developing, assessing and applying integrated testing strategies for specified MNs actively pursued in SG3 and for which case studies exist in SG6, thereby creating a basis for generalising and harmonizing testing approaches. This operational plan will be updated in light of progress and in particular if such generalisation is shown to be plausible.

The objectives of this project are to:

- Develop case studies of integrated testing strategies for selected MNs;
- Assess, based on the case studies, in how far generalisations are possible which could lead to the development of guidance on integrated testing strategies and use of alternative test methods specific for MNs;
- Develop a list of alternative test methods which can reliably be applied to MNs (or specified groups of MNs) providing relevant information for hazard and risk assessment;
- Provide support to the sponsorship programme with respect to use of alternative test methods and integrated testing strategies for MNs;

The work will focus and build on the work of SG3 and SG6 regarding carbon nanotubes (CNT), nano-silver as well as e.g. TiO_2. This will comprise review of alternative test methods other than OECD Test Guidelines for bulk chemicals, for purposes of establishing the reliability and relevance.

In order to ensure that the focus of SG3 remains that of developing information on the specified MNs, the *modus operandi* with SG3 will be one of providing advice on the use of alternative test methods and integrated testing strategies based on requests from SG3.

On the basis of the case studies an assessment will be carried out as to the possibility and feasibility of developing MN-specific guidance on integrated testing strategies. It should address identified needs for hazard and risk assessment. Proposed approaches for testing should emphasize on integrated and combined testing, which makes best use of information from different sources.

SG7 will also participate in the communities of practice. It will thereby work in co-operation with recognised scientists in MN-specific alternative test method development from both academia and industry and perform a dedicated Expert Consultation Meeting on the subject before the 7th meeting of the WPMN. The table will be regularly updated.

II. EXPECTED OUTPUTS FOR THE PERIOD 2009-2012

Informed by the sponsorship program, Project 7 aims at delivering:

- Report on the use of alternative test methods in the frame of the testing of representative MNs for CNT, nano-silver and e.g. TiO_2 for the 7th meeting (progress report) and for the 8th meeting of the WPMN.

- A compilation of actually used test methods (other than Test Guideline test methods as covered by SG4 and the related report) for MNs and the respective targeted effects/endpoints. The compilation will include an identification of where the test methods can and where they can not be used reliably for MN testing.

- An assessment report of the possibility and feasibility of developing a MN-specific Guidance Document on integrated testing strategies making best use of alternative test methods and in accordance with the 3R-principles will be drafted for the WPMN 9th meeting (GD-ITS).

III. ACTIVITIES FOR THE PERIOD 2009-2012

- **Provide advisory support to performance of testing on request by SG3** for selected MN including CNT and nano-silver.

- **Collaborate in setting up and participate in the communities of practice, in particular with respect to integrated testing strategies,** for the two related areas (i.e. Effects on Ecosystems and Health Effects) in order to facilitate discussion, resolution and, when appropriate, harmonisation of technical issues that arise during testing conducted in support of the sponsorship programme. Discussion on best practices and integrated approaches to testing and assessment and, if necessary, harmonization between the several data generation programs could also take place here.

- **Finalize the Feasibility Assessment of Developing MN-specific Guidance on Integrated Testing Strategies (GD-ITS).** Building on the current draft version a first "discussion version" will be released early 2010. It is expected that this version will need several updates on the basis of the results and problems likely to arise from the case studies elaborated in SG7 and the experiences gained in the work in SG3, SG4 and SG6 and the progress of scientific knowledge.

IV. CO-ORDINATION.

SG7 will keep other groups informed of its work so that they might benefit from SG7's work and be aware of SG7's needs, especially SG3, SG4, SG6 and SG8. SG7 will closely co-ordinate with SG4 on the opportunities to validate and use alternative test methods and integrated testing strategies with due regard to acceptance and the TGP.

- **SG1/SG2**. SG7 can use the OECD database to find information on the state of the science for testing MNs.

- **SG3.** WPMN sponsors can make use of SG7 as a resource of expertise on the application of alternative test methods and integrated testing strategies. The results from the sponsorship program will inform SG7's work on modifying test methods and possible setup of integrated testing strategies. The communities of practice established by SG4, in close cooperation with SG3 and SG7, will be the main forum for information sharing and discussion.

- **SG4.** SG4 addresses Test Guideline methods including validated alternative test methods. Because of the close relationship with alternative test methods and integrated approaches, SG7 can be used as a resource to the work of SG4.

- **SG5.** The relevance of the work of SG5 to SG7, and reversely, will be assessed as a result of the Feasibility work.

- **SG6.** SG6 is the origin of the case studies taken up in SG7 and hence a close collaboration is necessary. Furthermore, as one important use of testing is to provide data for hazard and risk assessment and risk management, it is important that SG7 communicate with SG6 on the implications for risk assessment/management of any possible test methods and integrated testing strategies, which contribute to the risk assessment process.

- **SG8.** The relevance of the work of SG8 is mainly through the case studies developed in SG6..

- **Other OECD Bodies and Other International Organisations.** It is essential to guarantee direct, prompt and clear communication between SG7, SG4 and OECD's Working Group of National Co-ordinators of the TGP (WNT) to make best use of alternative test methods and integrated testing approaches. This will be ensured by the Secretariat, the co-chairs, and those participants who are common to both groups. Also, particular attention should be given to coordination with the relevant ISO technical committees to avoid any potential duplication of efforts and gain maximum synergism and coherence of developments. Communication with the ISO will be ensured via the WPMN bureau and the Secretariat.

CO-OPERATION ON EXPOSURE MEASUREMENT AND EXPOSURE MITIGATION

OBJECTIVE 2007 to 2012:

The objective of this effort is to exchange information on guidance for exposure measurement (including sampling techniques and protocols) and exposure mitigation for manufactured nanomaterials and to develop suggestions for further steps to be undertaken by the WPMN. This will be achieved in three phases of work: 1) exposure in occupational settings; 2) exposure to humans resulting from contact with consumer products and environmental releases of manufactured nanomaterials; 3) exposure to environmental species (including compartments water, air, soil) resulting from environmental releases of manufactured nanomaterials, including releases from consumer products containing manufactured nanomaterials. It is recognized that exposure measurement and exposure mitigation information developed for unintentionally produced nanomaterials is highly relevant to this project and will be considered.[13] It is also recognized that in exposure measurement, it is often important to distinguish manufactured nanomaterials from background (both natural and unintentionally produced) nanomaterials.

- The **first phase** of work will focus on exposure in occupational settings. The objectives of this phase of work are:

  - To identify and compile guidance information for exposure measurement and exposure mitigation related to manufactured nanomaterials in occupational settings, including manufacture and use of products in industrial, institutional and commercial settings.

  - To analyse the compiled existing guidance information for adequacy in addressing exposure measurement and exposure mitigation related to manufactured nanomaterials in occupational settings, identify exposure and mitigation issues that are unique to manufactured nanomaterials in the workplace and prepare recommendations for next steps to be undertaken by the WPMN in relation to occupational exposure and mitigation.

- In the **second phase**, activities will be expanded to guidance for exposure measurement and exposure mitigation for human exposure resulting from contacts with consumer products and environmental releases of manufactured nanomaterials. The objectives of this phase of work are:

  - To identify and compile guidance information for exposure measurement and exposure mitigation related to manufactured nanomaterials for exposure of humans, if appropriate, from consumer products or via environmental releases.

  - To analyse the compiled existing guidance information for measurement and mitigation of human exposure via environmental releases and, if appropriate, consumer products for

[13] Consideration of data for incidental nanomaterials does not engender a change in scope of SG8 and the Working Party on Manufactured Nanomaterials, but rather signifies a recognition that such information may be of use in SG8 study of manufactured nanomaterials.

adequacy in addressing manufactured nanomaterials, and guidance information compiled during the first phase for its applicability to measurement and mitigation of exposures from environmental releases and consumer products containing manufactured nanomaterials, identify issues that are unique to manufactured nanomaterials and prepare recommendations for next steps to be undertaken by the WPMN in relation to human exposure via consumer products and environmental releases.

- In the **third phase**, activities will be expanded to guidance for exposure measurement and exposure mitigation involving exposure of environmental species (including compartments water, air, soil) as a result of releases of manufactured nanomaterials and consumer products containing manufactured nanomaterials. The objectives of this phase of work are:

  - To identify and compile guidance information for exposure measurement and exposure mitigation related to manufactured nanomaterials for exposure of the environment via environmental releases from the manufacturing processes and from consumer products.

  - To analyse the complied existing guidance information for measurement and mitigation of environment exposures via releases and consumer products for adequacy in addressing manufactured nanomaterials, and guidance information compiled during the first phase for its applicability to measurement and mitigation of exposures from environmental releases and consumer products containing manufactured nanomaterials, identify issues that are unique to manufactured nanomaterials and prepare recommendations for next steps to be undertaken by the WPMN in relation to environmental exposure.

EXPECTED OUTPUTS:

- Compilation and analysis of guidance information for exposure measurement for manufactured nanomaterials in occupational settings;

- Compilation and analysis of guidance information for exposure mitigation for manufactured nanomaterials in occupational settings;

- Compilation of and analysis of guidance information for the measurement of direct human exposure to manufactured nanomaterials from consumer products;

- Compilation of and analysis of guidance information for mitigation of direct human exposure to manufactured nanomaterials, if appropriate, from consumer products;

- Compilation and analysis of guidance information for measurement of human exposure to manufactured nanomaterials via environmental releases from industrial settings and consumer products;

- Compilation and analysis of guidance information for mitigation of human exposure to manufactured nanomaterials via environmental releases from industrial settings and consumer products;

- Compilation and analysis of guidance information for measurement of environmental exposures to manufactured nanomaterials via environmental releases from industrial settings and consumer products;

- Compilation and analysis of guidance information for mitigation of environmental exposure to manufactured nanomaterials via environmental releases from industrial settings and consumer products;

- Recommendations for next steps to be undertaken by the WPMN in the area of exposure measurement and mitigation for manufactured nanomaterials.

Key Inputs: Member countries and observers will be invited to exchange information on guidance for exposure measurement and exposure mitigation for manufactured nanomaterials.

TIMING:

2007-2008 [delivered]

- A summary and preliminary analysis of current exposure measurement and exposure mitigation guidance for occupational settings was developed by a preceding Drafting Group and was presented to the third Working Party meeting in November 2007.

- A prioritized list of potential phase 1 projects to be undertaken by the WPMN in the area of exposure measurement and mitigation for manufactured nanomaterials was presented to the fourth Working Party meeting in June 2008.

2009-2012 [ongoing]

Short term

- Prioritized lists of potential phase 2 and phase 3 projects to be undertaken by the WPMN in the area of exposure measurement and mitigation for manufactured nanomaterials will be presented to the 6th Working Party meeting in October 2009.

- A short term goal is to conduct a limited number of case studies for exposure assessment on a limited number of manufactured nanomaterials preferably chosen among 14 nanomaterials of the testing sponsorship program: 1) to obtain exposure data to enable risk assessment for specific nanomaterials; 2) to evaluate feasibility and necessity of developing a sponsorship program for exposure assessment; and 3) to facilitate strategic planning of SG8 activities in the area of exposure measurements for generation of data and guidance.

Medium term

- A medium term goal is to report on the outcomes of the case studies for exposure assessment and, if a sponsorship program for exposure assessment on representative nanomaterials, is found feasible and necessary to initiate such program.

- The Steering Group will also continue phase 1 projects and to initiate phase 2 and phase 3 projects. Specifically, project on "Comparison on exposure mitigation guidance for laboratories" led by Germany will be completed.

Long term

- Long term deliverables include completion of phase 1, phase 2 and phase 3 projects and will be determined by further discussions within WPMN based upon recommendations developed by this effort.

LINKAGES

This Steering Group will exchange information with other WPMN Steering Groups (SGs) about activities undertaken within WPMN to ensure that this effort can benefit from the activities of other SGs and SGs are aware of the needs of this effort. This will especially include the essential aspect of the selection of the exposure metric. In addition, this effort will establish more active mutually beneficial interactions as follows:

Within OECD Steering Group

Project 1/2 *Development of an OECD database on EHS research* and *EHS Research strategies on Manufactured Nanomaterials* can provide information about research activities taking place around exposure measurement and mitigation techniques and can be informed about the further research needs for the development of exposure measurement and mitigation guidelines for manufactured nanomaterials.

Project 3 *Safety Testing of Representative Set of Manufactured Nanomaterials* is conducting testing on a set of 14 nanomaterials through sponsorship programme. SG8 could help advance risk assessment for these nanomaterials by coordinating collection of exposure data.

Project 4 *Manufactured Nanomaterials and Test Guidelines* is reviewing and providing recommendations for revisions of OECD Test guidelines. It is critical that both groups coordinate their efforts to ensure that metrics and magnitude of dose used in toxicity studies are harmonized with exposure measurement guidance developed by SG8.

Project 5 *Co-operation on Voluntary Schemes and Regulatory Programmes* focuses on examination of voluntary reporting schemes and regulatory programs including those for exposure mitigation. Project 8 *Co-operation on Exposure Measurement and Exposure Mitigation* will continue working with Project 5 in exposure mitigation area.

Project 6 *Co-operation on Risk Assessment* is collecting information on exposure assessment techniques as part of its focus on risk assessment methodologies for nanomaterials. Project 8 could help with identifying available exposure data and provide suggestions on appropriate exposure measurement techniques.

With other International Organisations

International Labor Organization (ILO) is developing the 5th edition of the ILO Encyclopaedia of Occupational Safety and Health, which will contain a section on nanotechnology. Information exchange between ILO and Steering Group 8 will be mutually beneficial to ensure global harmonization of approaches for exposure measurement and mitigation in the workplace.

World Health Organization (WHO) Global Network of Collaborating Centers for Occupational Health in its program of work for 2006-2010 has five nanotechnology projects under the Communication and Networking Activity Area looking at developing guidelines for working with nanomaterials (http://www.who.int/occupational_health/network/ 2006compendium/en/) which could feed into the OECD effort. Information exchange between WHO's and OECD's efforts could also help avoid duplications and improve impact of both activities.

International Organization for Standardization (ISO) Technical Committee 229 (Nanotechnologies) created Working Group 3 looking at Health, Safety and the Environment implications of nanotechnologies (http://www.iso.org/tc229). Among other projects, ISO TC229 WG3 is actively involved in developing guidance on exposure measurements and exposure mitigation. Linkage with this group will facilitate exchange of information in the form of 1) updates on guidance development within ISO TC229, which

could be evaluated by the OECD drafting group and 2) the OECD analysis of adequacy of existing schemes for exposure measurements and mitigation, which could inform ISO about needs for standards development.

IMPLEMENTATION:

The Steering Group will summarise and develop analyses of guidance information collected for exposure measurement and exposure mitigation through volunteer member and observer activities.

To facilitate a more concentrated and effective analysis of compiled guidance information for exposure measurement and exposure mitigation for manufactured nanomaterials, identification of issues that are unique to manufactured nanomaterials and preparation of recommendations for next steps to be undertaken by the WPMN, the Steering Group could organize workshop(s) and face-to-face meetings. Volunteers will be invited to host such workshop(s) and meetings.

ADDITIONAL INFORMATION:

- To date (June 2009) SG8 published the following documents as part of OECD Series of Safety of Manufactured Nanomaterials:

  - *No.8, Preliminary Analysis of Exposure Measurement and Exposure Mitigation in Occupational Settings: Manufactured Nanomaterials (2009).*

  - *No.10, Identification, Compilation and Analysis of Guidance Information for Exposure Measurement and Exposure Mitigation: Manufactured Nanomaterials (2009).*

  - *No.11, Emission Assessment for the Identification of Sources and Release of Airborne Manufactured Nanomaterials in the Workplace: Compilation of Existing Guidance (2009).*

  - *No.12, Comparison of Guidance on Selection of Skin Protective Equipment and Respirators for Use in the Workplace: Manufactured Nanomaterials (2009).*

  - *No. 13, Report of an OECD Workshop on Exposure Assessment and Exposure Mitigation: Manufactured Nanomaterials (2009).*

- SG8 held the following workshop in 2008:

  - *OECD Workshop on Exposure Assessment and Exposure Mitigation for Nanomaterials in the Workplace*. This workshop was held on 20th October 2008 in Frankfurt, Germany. It was sponsored by the German Federal Institute of Occupational Safety and Health (BAuA) and the Business and Industry Advisory Committee to the OECD (BIAC).

THE ENVIRONMENTALLY SUSTAINABLE USE OF MANUFACTURED NANOMATERIALS

The 5th WPMN (4-6 March 2009) agreed to establish a new Steering Group (SG9) to look into the potential of *applications based on the use of manufactured nanomaterials* [14] to address major environmental challenges such as climate change, pollution of water, soil, and air, and natural resource depletion, as well as the potential negative impacts that such new technologies may have on environment and health.

The OECD Conference held 15-17 July 2009 in Paris on the "*Potential Environmental Benefits of Nanotechnology – Fostering Safe Innovation-Led Growth"* generated a number of ideas that could be continued at the OECD level. This draft operational plan outlines concrete tasks from the conference that fit within WPMN's mandate and that are proposed to be carried as WPMN SG9 activities.

PROJECT OBJECTIVES

The main focus of this project will be to enhance the knowledge base about life cycle aspects of manufactured nanomaterials, as well as positive and negative impacts on environment and health of certain nano-enabled applications at their different stages of development.

Tools and frameworks based on *life cycle considerations*[15] will be developed and applied to selected cases of nano-enabled applications. The tools or frameworks should systematically provide information on potential positive contributions and unwished negative impacts on environment and health to support decision making in various situations; from research, innovation, product development, scaling-up of production, marketing, and end-of-life as well as regulatory decisions. In particular, integrating life cycle considerations into the research and innovation stages will help inform decision makers early in the process on how novel applications could be exploited in a safe and sustainable manner, where potential negative impacts could be addressed upfront.

[14] For this project, these applications will be called *nano-enabled applications* (to indicate that manufactured nanomaterials are used for some performance improvement in applications).

[15] *Lifecycle considerations* take into account the potential positive and negative health and environmental impacts (these impacts can include greenhouse gas effects, acidification, smog, ozone layer depletion, eutrophication, eco- and human-health toxicity, habitat destruction, desertification, land use as well as depletion of rare minerals and fossil fuels) of a nano-enabled application throughout the lifecycle of the material from its extraction to its disposal/recycling. The considerations include identifying potential physical impacts at various stages (research, innovation, product development, scaling-up of production, marketing, and end-of-life, and regulatory decisions) before a concrete product, service, or process is in place. This approach does not exclude the possibility of full lifecycle assessment (LCA) being undertaken; LCA being comparative approach where a product, service, or process already exists.

The applications selected for case studies may directly address an environmental problem (like water purification) or indirectly contribute to environmental objectives by being more energy or resource efficient.

As the project progresses, options for a broader initiative focusing on maximising environmental benefits and minimizing risks of nano-enabled applications will be pursued together with OECD partners.

DELIVERABLES

The work will be carried out in three phases.

The first phase of work will focus on the *screening and selection of case studies*[16] with the following specific activities:

- Listing of existing key nano-enabled applications that demonstrate potential to reduce environmental, health, and safety impacts as a basis for selecting cases for further study.

- Identification and assessment of existing frameworks and tools for applying life-cycle considerations to the above nano-enabled applications. Frameworks and tools to be investigated should aim to facilitate decision-making by streamlining analysis of positive and negative impacts on environment and health at different decision points (research, innovation, scaling-up of production, marketing, end-of-life and regulatory decisions). The work should result in the identification of key parameters on positive and negative impacts and ways to measure them.

- Selection of cases from the list of nano-enabled applications (individual applications or application areas with several types of nano-enabled applications). Particular focus will be given to case studies that are enabled by the WPMN representative set of MNs and contribute to the knowledge bases being developed by other SGs in the WPMN.

- Gathering of available background data relating to the applications being considered in the case studies, e.g. technology, impacts, geographical and/or socio-economic aspects, to put the case study work in context (dossier development).

- In collaboration with SG1/2, propose extensions of the database in to include life cycle consideration data (if feasible).

The second phase of work will focus on the *application of life cycle considerations to case studies* with the following activities:

- Application of appropriate frameworks and tools to the selected case studies. As the selected cases are likely to be for different types of applications and may be at different (or several) stages of development (from research to end-of-life), it is not clear from the out-set if different frameworks will be needed. – a "family" of frameworks and process flow diagrams may be needed to ensure that the key environmental, health, and safety parameters are considered for each case.

[16] See the Annex for examples.

- For each case,
  - Population of the framework with readily available or generic data on key positive and negative environmental, health, and safety impacts, including energy use and use of natural resources, throughout the life cycle at different decision points.
  - Identification and assessment of data gaps for key decision parameters
  - Engagement in an iterative process to refine the initial frameworks and tools while prioritising data gaps.
- Comparison of the results of case studies dossiers. To analyse the differences or similarities in approaches and to evaluate the extent that generic and simplified frameworks can be developed (covering several application types or stages in the application development).
- Harmonisation and streamlining the user-friendliness of the frameworks and tools with the aim of developing one (or more) frameworks or tools applicable to all of the cases
- Validation and refinement of the framework and/or tools developed in this project utilizing, where available, a full LCA. For some of the cases, a full life cycle assessment using ISO standard 14040 could also be conducted as part of the project.
- As appropriate, and where resources allow, comparisons with non technological/traditional solutions, commonly used technologies and/or technologies that can utilise bulk versions of the same chemicals as the case studies by applying the framework and/or tools developed in this project could be carried out.

The third phase of work will focus on the *evaluation and reporting of results* with the following activities:

- Evaluation of results and assessment of the frameworks and/or tools in terms of their feasibility and usefulness in guiding decision makers at the different decision points.
- Sharing findings with relevant stakeholders (Governments, business, NGOs, other international organisations, other OECD groups etc.), via meetings and a final report:
- Overall evaluation of the project and decision about any further activities at WPMN in light of its goals and work programme.

EXPECTED OUTPUTS:

- As a basis to select the case studies, a list of existing key nano-enabled applications that might demonstrate potential to reduce environmental, health, and safety impacts;
- List of applicable existing frameworks and tools for making life cycle considerations;
- Findings from case studies based on life cycle considerations;
- Evaluation of results and assessment of the framework(s) and/or tool(s) created;

- Possible comparisons between the nano case studies and LCA outcomes, existing technologies, traditional/non technological solutions, or use of bulk chemicals;

- Compilation and analysis of existing data sources for incorporation into life cycle considerations and assessments.

- An expansion of the OECD WPMN SG1/2 database (if feasible) with information about such activities.

KEY INPUTS:

Member countries and observers will be invited to work on one or several case studies (if preferred, in collaboration with other delegations), exchange of information on guidance on life cycle consideration approaches and data related to life cycle considerations (environmental health and safety data, production processes, energy consumption, sources of raw material, ultimate disposal, etc.). Some delegations may wish to carry out more in-depth studies and comparisons with existing technologies.

TIMING:

Before the 7th WPMN meeting

- To finalize the Operational Plan 2009-2012

7th WPMN meeting (July 2010)

- Present list of existing nano-enabled applications (Phase One)

- Present existing frameworks and tools for applying life-cycle considerations to the above nano-enabled applications (Phase One)

8th WPMN meeting (March 2011)

- Remaining objectives of phase 1, such as a proposal to extend the database in SG1 to include life cycle consideration data.

- Present work to date

Long term deliverables from Phases Two and Three to be decided from further discussions.

LINKAGES AND COLLABORATIONS:

There are linkages between this Project and the OECD initiatives on “Innovation” and the “Green Growth”. There are also a variety of LCA initiatives at the national and global levels, e.g. the "Life Cycle Initiative" that is coordinated by the United Nations Environment Programme (UNEP) and the Society for Environmental Toxicology and Chemistry (SETAC). This initiative focuses on both the specific LCA tools as well as broader thinking on life cycle and management (LCM).

The work of SG9 will establish links and collaborations with national initiatives in OECD member countries, OECD non-member countries, Working Party on Nanotechnology (WPN), Intergovernmental

organisations (IOMC) and other international organisations (e.g. ISO). Within the WPMN, SG 9 will interact with other WPMN SGs, in particular:

- SG 1/2 to exchange information about research activities taking place generating data for the project; possible extension of the database to include information about life cycle consideration issues.

- SG 3 to generate information about environment and health impacts, and SG9 about their function and uses in nano-enabled applications.

- SG 6 to exchange information about risk assessment for certain applications of nanomaterials.

- SG8 to help identifying available exposure data or specific scenarios throughout the life cycle. Vice versa, knowledge about environment applications (that are often tested in pilot cases) could generate information about exposures.

IMPLEMENTATION:

The WPMN Steering Group 9 (SG9) will be formed with interested delegations with the EC and US delegations as co-chairs. With the OECD secretariat, regular teleconferences will be organised to discuss progress in preparations of the regular WPMN meeting. Actions will as far as possible be split on subgroups that can work in between meetings. Communication channels with the WPN regarding potential coordinated efforts will be established. The SG9 will identify and nominate policy and technical experts to participate in ad hoc groups for subprojects. SG9 will also organise meetings to facilitate the subprojects. A workshop to review the results of the 2nd phase subprojects will be held (tentatively late autumn 2010).

ADDITIONAL INFORMATION:

- Rationale for an Innovation Strategy (http://www.oecd.org/dataoecd/2/31/39374789.pdf)

- Green Growth Declaration (http://www.olis.oecd.org/olis/2009doc.nsf/LinkTo/NT00004886/$FILE/JT03267277.PDF)

- ISO 14040 Standard (http://www.iso.org/iso/catalogue_detail?csnumber=37456)

- Conference on the Potential Environmental Benefits of Nanotechnology: Fostering Safe, Innovation-Led Growth (http://www.oecd.org/nanobenefits)

ANNEX: EXAMPLES OF POTENTIAL CASE STUDIES

This annex presents some examples of potential case studies to be addressed as part of phase 1. These examples were extracted from the OECD Conference "Potential Environmental Benefits of Nanotechnology – Fostering Safe Innovation-Led Growth".

Theme	Sub-Theme	Case Study	Manufactured Nanomaterials
1) Applications	Catalysis	Diesel fuel additives	Cerium oxide
		Reductions of car emissions	
	Catalysis and Coatings and Treatments	Self-cleaning surfaces	Titanium dioxide
	Coatings and Treatments	Biocides	Nanosilver
		Corrosion protection	
		Flame retardants	Nanoclays; CNTs
	Energy	Batteries	Nano-structured Lithium; Carbon nanotubes
		Hydrogen generation	
		Hydrogen storage	
		Insulation	
		Photovoltaics	Fullerenes
		Thermoelectrics	Silicon nanowires, nanostructured metals and metal oxides
		Lighting	Quantum dots;
	Photocatalysis	Water treatment and purification	Titanium dioxide; Polymers
		Green products through nanotechnology - reduced use of chemicals and materials	
		Strengthing/reducing materials in building structures	Nanoclays; CNTs
2) Cleaner production	Catalysis	Nanoscale materials as catalysts	Titanium dioxide;
		Synthesis of nanoscale materials	Cellulose nano fibres
		Green chemistry	
		Processing of nanoscale materials	
		Using nanoscale materials to reduce pollution from processing	Titanium dioxide;
3) Other benefits	Environmental remediation	Reduction, Photodegradation, Encapsulation, Filtration, Adsorption	Iron
		Environmental sensing	Dendrimers
		Reduction of agricultural pollution	