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**Working Party on Manufactured Nanomaterials**

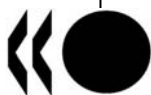
**CO-OPERATION BETWEEN SG6 AND OTHER STEERING GROUPS: A PROPOSAL FOR LIAISON**

**7th Meeting of the Working Party on Manufactured Nanomaterials taking place at OECD Conference Centre in Paris, France on 7-9 July 2010, starting at 10h00 on the first day.**

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The Working Party on Manufactured Nanomaterials (WPMN) is a subsidiary body of OECD's Chemicals Committee. The aim of its programme of work is to promote international co-operation on human health and environmental safety aspects of manufactured nanomaterials, in order to assist in their safe development.

As part of its programme of work, the WPMN currently has eight projects led by respective Steering Groups. At the 6<sup>th</sup> meeting of the WPMN in October 2009, each Steering Group presented their draft version of operational plans for 2009-2012, and those operational plans were endorsed by the WPMN and declassified [ENV/JM/MONO(2010)11].

The issue of "Linkage with other Steering Groups" is noted in each operational plan for 2009-2012; however, the processes for how individual Steering Groups establish liaisons should be pursued on a case-by-case basis. Based on the operational plan 2009-2012 of the Project 6, *Co-operation on Risk Assessment*, the Steering Group 6 (SG6) has taken the opportunity to discuss the development of liaison between SG6 and other Steering groups.

This document was prepared by the co-chairs of SG6, for the consideration by the WPMN. It includes an Annex with SG6 research priorities. It should be considered as a thought starter on how to better communicate and liaise between Steering Group 6 and the Steering Groups 3, 4, 7 and 8.

***ACTION REQUIRED: The WPMN is invited to take note.***

***The Chairs of SG3, SG4, SG7 and SG8 are invited to provide inputs as appropriate.***

## CO-OPERATION BETWEEN SG6 AND OTHER STEERING GROUPS: A PROPOSAL FOR LIAISON

### 1. Introduction

1. The 2009-2012 Operational Plan (OP) for Steering Group (SG) 6 was approved at the 6th meeting of the Working Party on Manufactured Nanomaterials (WPMN) in 2009. The OP included the development of liaisons with other SGs within the OECD WPMN. This report is a proposal, prepared by co-chairs of SG6, that should serve as a thought starter on how to organise the liaisons.

### 2. Purpose

2. The purpose of these liaisons is to establish formal communication between SG6 and other steering groups. By maintaining communication, SG6 can ensure that the data and/or guidance generated within each steering group: i) can be efficiently and timely used to develop the data for use in risk assessment; ii) identify which data elements are of utility for use in a risk assessment; and iii) generate information necessary for the development of risk assessment methodology.

### 3. Background

3. The OECD Workshop on Risk Assessment of Manufactured Nanomaterials in a Regulatory Context took place in September 2010. The Workshop objectives included the identification of the critical issues specific for the risk assessment of nanomaterials, and identification of issues which may be addressed through the Sponsorship Programme.

4. Participants at the Workshop noted the importance of having additional information on fate, transport, exposure, persistence and bioaccumulation, among other relevant data. There was also a need to understand which material properties are responsible for toxic effects, how different media in different test protocols impacts particle behaviour, and the need for more sensitive methodologies to measure and characterize nanoparticles. Another common theme emerging from the Workshop was the need for identifying appropriate metrics.

5. As a result of these identified needs and issues, SG6 noted the importance for strengthening communication with other SG, in particular SG3 (Sponsorship Programme); SG4 (Test Guidelines); SG7 (Alternative Test Methods); and SG8 (Exposure Monitoring and Exposure Mitigation). The objective of a liaison strategy is to ensure the data and guidance generated by these steering groups meets the needs for risk assessment in a regulatory context.

### 4. Objectives

6. The SG6 liaison exercise will involve prioritizing risk assessment data and methodology issues identified at the September, 2009 workshop, and to cooperate with SG 3, 4, 7 and 8 in the resolution of these issues. A number of key research areas identified are appended in Annex.

#### *Liaison with SG3*

7. The objective of the liaison with SG3 is to identify and prioritize risk assessment and risk assessment methodology issues (as described in Annex) relating to data gaps, and determine how SG3 can assist in resolution of these issues. This will involve further communication with respective researchers on how data currently under development can be focussed toward resolution of each issue. Liaison expertise would be required in the areas of human health effect and ecological fate and effects.

***Liaison with SG4***

8. The objective of the liaison with SG4 is to identify and prioritize risk assessment and risk assessment methodology issues relating to testing protocols, and determine how SG4 can assist in resolution of these issues. A second objective of this liaison is to provide a forum for discussing the modification of existing test guidelines and to ensure these methods provide for a robust and defensible risk assessment. Liaison expertise would be required in the areas of physical-chemical properties, human health effects and ecological fate and effects.

***Liaison with SG7***

9. The objective of the liaison with SG7 is to identify and prioritize risk assessment and risk assessment methodology issues relating to alternate test methods and determine how SG7 can assist in resolution of these issues. In particular, whether results from in-vitro testing can providing weight-of-evidence in terms of supporting observed toxic effects as well as assisting in focussing the selection of conventional tests for use in a risk assessment. The work may involve support to SG7 in extending the case studies presented at the Risk Assessment Workshop with the use of alternative methods. Liaison expertise would be required in the area of human health effects.

***Liaison with SG8***

10. The objective of the liaison with SG8 is to identify and prioritize risk assessment and risk assessment methodology issues relating to exposure measurement and determine how SG8 can assist in resolution of these issues. This work will include examining how exposure measurement can provide greater insight into the ability of nanomaterials interact with biological systems, to understand how materials will partition in the environment, as well as worker and consumer exposure, and determination of appropriate metrics. Liaison expertise would be required in the area of occupational, consumer and environmental exposure.

**5. Setting Contacts**

11. In order to maintain formal communication between the steering groups, it is proposed that individuals from these SGs are identified as liaison contacts. These liaison contacts will be responsible for communicating relevant information between the SG6 and the other steering groups to ensure the needs/issues identified in SG6 are communicated to the other steering group and taken into consideration when developing testing or guidance. It will also ensure that the latest data and guidance developed is incorporated into risk assessments and risk assessment methodology.

## ANNEX. SG6 RESEARCH PRIORITIES

12. This annex outlines the key research areas which were identified by SG6, in which coordination between SG6 and SG3, 4, 7 and 8 will be needed.

### Physical-chemical Characteristics and Media Considerations

- Consider the “particle nature” of the material, such as the surface properties and interactions, the relation of metrics used, the characteristic of the material, and the risk outcome and application to decisions;
- Assess and accommodate risk assessment approaches to the effects of test methods and exposure matrix (e.g., dispersion methods) on testing outcomes and inter-comparability of the data used in the assessment; and
- Include particular attention to the mixture nature of the material (e.g., variation in size, surface properties, and composition that create a heterogeneous range of particle types) and its interaction with environmental components and transport mechanisms in exposure and toxicity contexts.

### Human Health

- Focusing testing approaches and the building of databases on enabling and advancing modeling, QSAR, computational, etc. approaches that advance our ability to categorize and otherwise efficiently group materials for decision making. Key to this is linking material properties to effects;
- Understanding the particle nature of nanomaterials, and in particular, particle kinetics;
- Identifying whether there are nanoparticle-specific endpoints or nano-specific considerations for currently identified endpoints; and
- Advancing epidemiological approaches, including taking advantage of existing data and developing biomonitoring techniques.

### Ecological

- Comparison of acute to chronic data for all trophic levels;
- Toxicity as a function of size of the nanomaterial;

- Disposition of nanomaterials (ADME) in all trophic levels;
- Identification of the most sensitive species, potentially different from the current fish, daphnia, algae paradigm; and
- Mechanisms of bioaccumulation and determination of methods for predicting bioaccumulation.

#### **Exposure – Public, Occupational and Environment**

- Develop a database of published exposure information involving all routes of exposure and promote publication of exposure data from companies, etc. The database should be stratified by routes of exposure;
- The detection limit of conventional methods to measure particles in the environment may be limited. Therefore, it may be necessary to develop more sensitive methodologies to measure and characterize nanoparticles; and
- OECD in collaboration with ISO should define standardized exposure measurements for various media and exposure types that could be used to validate exposure metrics and instrumentation.