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Working Party on Manufactured Nanomaterials

DRAFT OPERATIONAL PLAN FOR PROJECT ON RISK ASSESSMENT AND REGULATORY PROGRAMMES 2014-2016

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Secretariat: Ms. Asako AOYAGI
Tel:+33 (0)1 45 24 14 63; E-mail: asako.aoyagi@oecd.org

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The Working Party on Manufactured Nanomaterials (WPMN) is a subsidiary body of OECD's Chemicals Committee. Its programme of work contributes to the Special Programme on the Control of Chemicals (CHEM) which is Output Area 2.3.3 in OECD's Part II Programme of Work and Budget (PWB) for 2013-2014. The aim of its programme of work is to promote international co-operation with respect to human health and environmental safety related aspects of MNs.

It has been agreed that the re-organisation of Steering Groups (SG's) of the WPMN will take place against the background of the Mid-Term Evaluation of the work on nanosafety undertaken during 2012 by the WPMN and subsequently endorsed by the Chemicals Committee [ENV/JM(2012)2]. This document quotes particular recommendations or statements from the Mid-Term Evaluation where relevant. It also builds on subsequent discussions at WPMN-10 (27-29 June 2012) when it was decided to merge Steering Groups (SG's) 5 and 6 into a single Steering Group, *Risk Assessment and Regulatory Programmes*, to prevent redundancy of work, to strengthen regulatory issues of the programme, and to make best use of the available data and resources.

This document has been prepared by SGs 5 and 6 for consideration by the WPMN. It presents a Draft Operational Plan 2013-2016 including; i) Objectives; ii) Expected outputs; iii) Link to other WPMN Project; and iv) Deliverables and timelines.

ACTION REQUIRED: ***The Working Party is invited to approve the Draft Operational Plan of Risk Assessment and Regulatory Programmes for 2013-2016, amended as appropriate.***

[DRAFT] OPERATIONAL PLAN FOR THE PROJECT RISK ASSESSMENT AND REGULATORY PROGRAMMES (SG-AP)

OBJECTIVE

The Project on risk assessment and regulatory programmes[1] will support the OECD Council Recommendation which concluded that "..Members, to manage the risks of manufactured nanomaterials, apply the existing international and national chemical regulatory frameworks or other management systems, adapted to take into account the specific properties of manufactured nanomaterials." [C(2013)107] by focusing on risk assessment issues most relevant to regulatory regimes. Consequently, it will:

- Identify regulatory needs specific to the risk assessment and risk management of MN;
- Consider the applicability to MN of existing methodologies and supporting tools for the risk assessment and risk management of chemicals, by using the research information generated through the Testing Programme in the context of risk assessment;, provide feedback on the relevance of this information to the risk assessment of MN in general; but also its relevance to the development of methodologies, strategies and tools
  - Identify and prioritise gaps, and enhance methodologies and tools accordingly;
  - Develop new approaches to support nano-relevant risk assessment and risk management where current risk assessment and risk management approaches for chemicals do not suffice;
- **Make recommendations** to WPMN for addressing identified MN specific risk assessment needs in available methodology / tools.

EXPECTED OUTPUTS

In accordance with the conclusions of "*Regulated Nanomaterials: 2006-2009*" [ENV/JM/MONO(2011)52] and "*Co-Operation on Risk Assessment: Prioritisation of Important Issues on Risk Assessment of Manufactured Nanomaterials - Final Report*" [ENV/JM/MONO(2013)18], the steering group will be undertaking the activities described below, producing the following expected outcomes:

Draft recommendations for the WPMN on the need for developing guidance notes on risk assessment and risk management needs specific to Manufactured Nanomaterials

- In order to address priority issues identified by the report "*Important Issues on Risk Assessment of Manufactured Nanomaterials"* [ENV/JM/MONO(2012)8], there is a need for implementing additional projects[2] to those currently underway[3]. The scope of these projects will also be based on

[1] The use of the term 'risk assessment' in SG-AP is in a broad sense – i.e., it ranges from screening-level to detailed quantitative assessments. Risk assessment is based on experimental data including steps such as hazard identification, hazard characterisation and risk characterisation using exposure information, linking this project to the work of other WPMN projects. Thus, SG-AP will integrate outputs from other WPMN projects into an overall methodological framework in which the risks of MN are assessed.

[2] It is noted that the detailed project scopes can currently not be described as these are subject to development and will depend on the voluntary contribution of lead countries and contributing members.

the outcomes of the surveys on regulatory regimes[4] and the prioritisation exercise [ENV/JM/MONO(2013)18]. Outcomes of these projects are expected to allow SG-AP to develop specific recommendations for the WPMN.

Identify best practices for risk assessment of manufactured nanomaterials

- With Phase I of the Testing Programme completed, the information generated will be analysed in terms of its relevance to risk assessment and risk management, while recognizing that the Testing Programme focussed on test methods and hazard data. As discussed and agreed at the 12th WPMN meeting of the WPMN, a joint study group will be established involving SG-AP and SG-TA members to conduct case studies on the dossiers and identify gaps relevant to regulatory risk assessments. This study group will assess the relevance of information generated under the Testing Programme for risk assessments and risk management.

Guidance on Risk Assessment Methodologies

- The results of the projects on approaches to risk assessment may lead to the development of guidance notes that can assist risk assessors (see first output). In addition, the results generated in the projects will serve to assess the need for updating the report *Important Issues on Risk Assessment of Manufactured Nanomaterials*. Both of these documents, as well as other available information, may be used by member countries or other stakeholders to facilitate the development of regulatory specific guidance documents.

LINK TO OTHER WPMN PROJECTS

The activities of SG-AP are, to a large extent, based on the use and integration of outputs from other WPMN SGs.

- Link to SG-TA:
    - Obtain empirical data and basic data sets to inform the development of potential approaches and tools for risk assessment and risk management, as well as assisting in focussing the selection of conventional tests for use in a risk assessment.
    - Identify issues in risk assessment methodology that may be solved using alternative (in-vitro and/or in-vivo) test methods in conjunction with tiered approaches and/or integrated testing strategies (ITS). In particular, consider how results from *in vitro* testing can be used in a possible weight-of-evidence approach for supporting observed toxic effects, and if possible, provide guidance in the absence of effect.
    - Ensure close collaboration and inputs on the work on categorisation and read-across.
    - Provide inputs, as appropriate, in the different tasks of SG-TA, to disseminate project updates, priorities and needs, and ensure that work of the two projects is articulated.

[3] The projects underway are: i) *use of inter-species variability* (lead: Germany); ii) *approaches to dealing with nanoparticles dissolution* (lead: Canada); iii) *approaches for grouping, equivalence and read-across* (lead: Japan); and iv)*investigating the use of alternative testing strategies in risk assessments* (lead: Canada).

[4] See ENV/JM/MONO(2011)52 and ENV/JM/MONO(2011)53.

- Link to SG8:
    - Share information on exposure assessment and mitigation measures and discuss how this information can be used to address prioritised issues in risk assessment and risk assessment methodology.
- Link to SG9:
    - Follow-up on the work and provide inputs as appropriate, in particular on the LCA-guidance project.
    - Use data generated by the case studies as relevant for the evaluation and development of risk assessment methodology / strategies / tools.

Co-ordination with other international activities

Following the agreement of the WPMN-12 that the Tour de Table will include information regarding the relevant regulatory activities[5], SG-AP will use the information to keep abreast of regulatory developments.

- SG-AP will take into account the activities of non-governmental organisations, such as the Society for Risk Analysis (SRA), in order to exchange information and collaborate on the development of risk assessment methodologies and tools.

DELIVERABLES AND TIMELINES

Phase 2: From June 2014 to February 2015 (14th WPMN)

- Finalize three pilot projects[6] and produce draft final reports for discussion and endorsement by the WPMN.
    - These final reports will be published in the form of guidance notes by the WPMN to be used to support risk assessment activities.
- Identify volunteers to lead work on the priorities identified [ENV/JM/MONO(2013)18].
- Initiate a case-study project on evaluating a dossier from the Testing Programme to inform on the uncertainties outlined in the *Important Issues* document [ENV/JM/MONO(2012)8] and the information's impact on regulatory risk assessments.
- Engage in the workshop on Categorisation.
- Finalize the fourth pilot project[7] on alternative testing strategies.
- Complete Interim Report from new projects containing gap analysis.

[5] This was previously achieved through a survey.

[6] i) use of inter-species variability (lead: Germany); ii) approaches to dealing with nanoparticles dissolution (lead: Canada) ; and iii) approaches for grouping, equivalence and read-across (lead: Japan):

[7] Investigating the use of alternative testing strategies in risk assessments (lead: Canada).

- Provide a joint updated (with SG-TA) on the case-study dossier project at WPMN14.

- Initiate new projects including a new case-study project on dossiers (if relevant).

Phase 3: From 2015 to 2016 (15th Meeting of the WPMN)

- Prepare Interim report of projects underway, including recommendations on additional issues to be addressed for endorsement at WPMN-15.

- Present recommendations to WPMN-15 on the need for developing additional guidance related to the regulatory risk assessment needs for manufactured nanomaterials.