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**FUTURE CHALLENGES RELATED TO THE SAFETY OF MANUFACTURED NANOMATERIALS:  
REPORT FROM THE SPECIAL SESSION**

**Series on the Safety of Manufactured Nanomaterials  
No. 75**

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**OECD Environment, Health and Safety Publications**

**Series on the Safety of Manufactured Nanomaterials**

**No. 75**

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MANUFACTURED NANOMATERIALS  
Report from the Special Session**

**IOMC**

**INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS**

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

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

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, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD. 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 avoid 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. This programme concentrates on human health and environmental safety implications of manufactured nanomaterials (limited mainly to the chemicals sector), and aims to ensure that the approach to hazard, exposure and risk assessment is of a high, science-based, and internationally harmonised standard. This programme promotes international co-operation on the human health and environmental safety of manufactured nanomaterials, and involves the safety testing and risk assessment of manufactured nanomaterials.

This document is published under the responsibility of the Joint Meeting of the Chemicals Committee and Working Party on Chemicals, pesticides and Biotechnology of the OECD.

## **Background and Objectives of the Special Session**

1. The purpose of the special session was to give delegations an opportunity to share their current and future priorities/challenges in their respective countries related to the safety of manufactured nanomaterials and their convergence with other technologies. The discussion was intended to facilitate better understanding of the issues facing delegations and also to identify areas of common concern, to ensure the effective development of the regulatory arrangements in their respective countries.
2. The session was also intended to identify areas of work that could be undertaken by the OECD's Working Party on Manufactured Nanomaterials (hereafter WPMN) in its future programme of work that would assist delegations with the regulation/management of manufactured nanomaterials. It has been recognised that delegations can work collaboratively to leverage the international expertise available to the WPMN to tackle those challenges. This will in turn ensure that the regulatory agendas of member countries move forward in a timely way.
3. This document presents the summary of the discussion.

## **Main Issues from Individual Presentations**

### ***Main regulatory challenges: conclusions and recommendations from the seminar on Risk Assessment and Regulatory Programmes***

*Presented by Yasir Sultan - Environment Canada/ Chair of the WPMN SG on Risk Assessment and Regulatory Programmes*

4. This presentation summarised the main outcomes of the discussion held during the WPMN seminar on *Risk Assessment and Regulatory Programmes*, which took place in November 2015. During this seminar, participants expressed their concern regarding the lack of:
  - *Valid methods for regulatory decisions.* For example, identifying key physicochemical properties to predict hazards, reliable Test Guidelines for use under the Mutual Acceptance of Data (MAD)<sup>1</sup>.
  - *Appropriate exposure data.* It is important to develop the type of exposure data required for regulatory risk assessments that will inform research needs. There is a need to strengthen links between programmes/ projects (for example, between the Task Force on Exposure Assessment and the WPMN work on exposure). This could be achieved perhaps via the validation of emission scenario documents for nanomaterials?
5. During the discussion, the WPMN noted the importance of developing Alternative Testing Strategies (ATS) and screening tests that focus on the identification of nano-specific considerations to improve decision making.
6. Another issue that was discussed was the dissimilarity amongst different information gathering approaches amongst OECD countries. Consistency between approaches would help, for example, to identify environmental fate, use of standardised organisms for specific endpoints.
7. Vis-à-vis risk assessment methodologies, the group recognised that regulatory risk assessment has been evolving based on experience and new research information. The WPMN saw the value in

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<sup>1</sup> See: <http://www.oecd.org/env/ehs/mutualacceptanceofdatamad.htm>

continuing to apply approaches used for conventional chemicals, and identifying and developing those nano-specificities needed. For example, how many physico-chemical properties are sufficient to identify nanomaterials? How can we use categorisation and read-across frameworks for identification, prioritisation and risk assessment?

8. In moving forward, participants saw value in learning from well-studied nanomaterials and to build frameworks based on those experiences. The strategy should be pragmatic -including *in vitro*, alternative methods, intelligent testing strategies, but complemented by *in vivo* studies where necessary - and data generated should inform multiple needs simultaneously.

### ***Regulatory uptake, implementation and mainstreaming within REACH context***

*Presented by Andrej Kobe- Head of Delegation to the European Union*

9. The EU informed on some of the challenges that will need to be overcome in the next five years such as: a) people and skills; b) tools and data; and c) market (public) perception. The EU is working to maintain adequate training of researchers since industry skills requirements will continue evolving over the next five years. Other challenges that need to be faced are public perception, transparency of decision making, and a growing need to move into "safe by design".

10. As for the approach to nanomaterials, the EU distinguishes between two strands: a) engineered nanomaterials; and b) legacy nanomaterials (those that have been in commerce for several years, and have undergone unintentional incremental improvements -refinement). This raises some questions on their adverse effects – can risk change with functionality?

11. After an EU regulatory review, it was concluded that REACH is appropriate for regulating nanomaterials. The EU is currently adapting provisions – and a definition (harmonised in EU) in order to allow the implementation of the necessary measurement standards. To this end, there is consistent and effective implementation based on the use of Test Guidelines required. Accordingly, the validation, revision, or development of OECD Test Guidelines<sup>2</sup> that are applicable to nanomaterials is seen as a priority to allow the implementation of REACH. In addition, there is a need for further developing relevant nano-specific tools such as alternative methods, grouping, and read-across approaches.

12. It was recognised that significant effort has been undertaken to obtain necessary information for the technical assessment. But this effort should be further strengthened and should be forward looking so as to address the next generation nanomaterials.

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<sup>2</sup> More information on the OECD Test Guideline Programme can be found at:  
<http://www.oecd.org/chemicalsafety/testing/oecd-guidelines-testing-chemicals-related-documents.htm>

***Perspective for a WPMN Programme of work 2017-2020***

*Presented by Carsten Kneuer, German delegation to the WPMN*

13. Carsten Kneuer laid out what Germany sees as the areas that should continue to be developed and where the focus of the WPMN should be:

A. *Methods for physicochemical characterisation, supporting NM identification*

14. There is an urgent need for reliable methods for physicochemical characterisation on nanomaterials. This is also a prerequisite to practically implement the legal nanomaterial definition(s), develop (Q)SARs, do an exposure/fate assessment, and ultimately move into "safe by design".

15. Further work is needed to identify the gaps and assess existing methods. Test Guidelines that are applicable to nanomaterials should continue to be supported, so as the Guidance Documents that will allow their implementation as well as interpretation of test results. It was also stressed that there is a need to implement a nanomaterial nomenclature system that is based on physico-chemical properties.

16. Integrated Testing Strategies (ITS) could be a tool to guide the selection of the most suitable test methods, taking into account the specific material properties and the assessment context.

B. *Dealing with NM diversity and novel developments*

17. OECD should continue the identification of main determinants of hazards (i.e. surface functionality, solubility, constituents). Furthermore, it should continue its efforts in adapting Test Guidelines, as well as adapting other methodologies for their application on nanomaterials. In particular, Adverse Outcomes Pathways (AOPs), and *in vitro*/ alternative testing strategies.

18. These activities should enhance governments' capacity to deal with novel materials, approach the discrimination of "discrete" forms of nanomaterials and the issue of read-across of data between materials, as well as to further define the physical-chemical data requirements to be implemented in legislations.

C. *Methods for detection, property characterisation and measurement of NM in and release from complex matrices including products*

19. This point is critical to supports the development of test methods and enforce regulation. It:

i) is a prerequisite for exposure assessment, which includes the generation of data for model development / validation and (bio) monitoring;

ii) informs hazard assessment on any relevant transformation products (i.e. size changes, changes in coatings) during the life cycle, relevant doses; and

iii) supports test method development, both for environment and human health.

D. *Assessment tools to support harmonised interpretation of data*

20. To support the members in the implementation of the OECD council recommendation, the activities on test guidelines should be flanked by development of guidance documents for harmonisation of data assessment, e.g. by setting criteria for acceptability and interpretation of test outcomes.

21. In addition, development of harmonised tools or calculation aids, e.g. for conversion / estimation of nanomaterial metrics or prediction of fate and environmental behaviour would be welcome and may be preferable to individual solutions.

22. The issues outlined above should be further strengthened considering the limited resources available. With this in mind there is a growing need to prioritise and focus on activities that allow the effective use of national and international research projects. The WPMN should continue discussion on how to improve its capacity to build on work of other initiatives. Furthermore, the WPMN should continue to adapt its structure to the above mentioned needs, as need arises.

### ***Enhancing International and intergovernmental activities***

*Presented by Brad Fisher, Canadian Head of Delegation to the WPMN*

23. The purpose of this presentation was to highlight the need for finding solutions to address the challenges posed by regulatory activities underway and the pressure to deliver results faster. One way to overcome this imbalance will be to identify potential partners and address any barriers to forming productive partnerships.

24. There is a growing potential for further fostering partnership with other OECD bodies, international organisations; and / or research groups and consortia. The WPMN should participate in other activities to leverage this potential. It was suggested that the next Programme of Work should include a strategy to develop partnerships for a long term gain. For 2017-2020, it was suggested to have a greater emphasis on partnerships to further disseminate the WPMN outputs, while informing others on the regulatory needs. The amount of resources needed to effectively communicate with partners should be seen as a short term investment in improving longer term effectiveness.

### ***Mainstreaming regulatory decision making for nanomaterials***

*Presented by Maria Doa, USA Head of Delegation to the WPMN*

25. The greatest challenges ahead will be to assess a broader range of nanoscale materials. This creates a need to develop more sophisticated tools to assess them. i.e., tools for screening, testing and assessment – Different tools are also needed for different levels of assessment (in the US the level of information to support a finding is higher for existing than new chemicals).

26. Intermediate goals include developing more robust data, developing a road map or decision framework for material characterisation, and further refining worker protection tools. OECD test guidelines and guidance related to inhalation, aquatic toxicity, and wastewater, for example, will also be helpful for assessing nanomaterials. Long term goals include better characterisation for consumer and environmental exposure, and further developing a categorisation approach.

27. Some of the factors proposed by EPA to distinguish nanoscale materials of the same chemicals are:

- Each chemical substance with a different morphology;
- Each chemical substance with a different coating;
- And reporting if there is:
  - Change in process to affect a change in size and a change in other properties

- Measured change in at least one of the following properties: zeta potential, specific surface area, dispersion stability, or surface reactivity.

### ***Strengthening innovation for the leverage of EHS research resources***

*Presented by Tom Van Teunenbroek, the Netherlands Head of Delegation to the WPMN*

28. This presentation highlighted the need to have reliable safety data, both on environment and safety research that in turn strengthens innovation.

29. A large proportion of current research is not addressing regulatory needs. Furthermore, the research has no standardised methods that allow reporting and exchanging data results, which hampers its use for regulatory purposes. From a regulatory point of view, the relevance of the data is questionable (not comparable due to different methods, materials, operating practice)

30. The WPMN should also further work on exposure. For example, there is a need to develop realistic, worst case exposure scenarios.

31. The challenge remains the need for providing regulators with a set of tools for risk assessment and decision making instruments for the short to medium term, by gathering data and performing pilot risk assessment, including exposure monitoring and control, for a selected number of nanomaterials used in products. Develop for the long term, new characterization and testing strategies adapted to a high number of nanomaterials where many factors can affect their environmental and health impact, and establish a close collaboration among authorities and industry with regards to the knowledge required for appropriate risk management, and create the basis for common approaches, mutually acceptable datasets and risk management practices.

### **Summary**

32. The challenges for the regulation of nanomaterials identified by delegations were generally consistent. These were supported by the discussions that followed the presentations. Specific challenges that remain were:

- **Applicability of OECD Test Guidelines**
  - The applicability of OECD Test Guidelines addressing nanomaterials remains one of the main priorities of the work of the WPMN (in collaboration with the WNT), including the issue of validation. Special attention is required for guidelines related to physico-chemical properties (although further prioritisation within this group is required), as well as inhalation toxicity, environmental fate, aquatic toxicity and *in-vitro* test methods.
- **Assessment methodologies and tools**
  - The group recognised the need to further explore work on equivalence, grouping and read-across approaches as well as alternative testing strategies and adverse outcome pathways. The need for guidance materials to address these topics was also identified.

- **Exposure data**
  - The lack of appropriate exposure data for risk assessment of NM was acknowledged, in particular in consumer and environmental sectors. Need to progress exposure modelling.
- **Guidance materials to assist with the interpretation of data**
  - This was identified as critical. It was proposed to develop, for example, i) a (harmonised) core set of test data required for regulatory risk assessments; ii) criteria for acceptance/ non-acceptance of tests (data); and iii) Calculation aids (to assist with conversion of metrics).

33. Some delegations stressed that the WPMN should continue supporting the work on Test Guidelines as this is one of the corner stones of the work. However, it was also recognised that the programme on the Safety of Manufactured Nanomaterials is broader than that and delegations were encourage to further support work on: (a) alternative methods; (b) exposure; and (c) and risk assessment. The programme of the WPMN should have a good balance between these project areas.

34. The WPMN further recognised the importance of enhancing interactions with relevant OECD bodies, international research consortia, standardisation organisations, in order to leverage the work those groups undertake and minimise duplication of effort. While existing limitations were recognised due to different priorities between organisations, the WPMN agreed that a strategy should be sought during the next programme of work to find ways to leverage the expertise available in areas that are of interest for OECD and non-OECD bodies alike. This was particularly important for physico-chemical properties as a topic of immediate interest.

35. Taking into account the impact of limited resources within countries and the secretariat – the WPMN agreed that the areas of work (as identified above), should be reviewed with the aim of prioritising critical issues for action within the constraints of available resources.