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SERIES ON THE SAFETY OF MANUFACTURED NANOMATERIALS Number 4

MANUFACTURED NANOMATERIALS: WORK PROGRAMME 2006-2008

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No. 4

MANUFACTURED NANOMATERIALS: WORK PROGRAMME 2006-2008



INTER-ORGANISATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

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

Environment Directorate ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT Paris, 2008

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FOREWORD

In 2006, OECD's Chemicals Committee agreed to a Programme of Work on Manufactured Nanomaterials for 2006-2008 (Annex I). This Programme of Work is addressing human health and environmental safety aspects of manufactured nanomaterials. The Chemicals Committee also established a Working Party on Manufactured Nanomaterials (WPMN) to implement its programme of work. The Terms of Reference for the Working Party on Manufactured Nanomaterials are found in Annex II.

From the earliest discussions on nanomaterials in the Chemicals Committee, OECD member countries have consistently stressed the need for this work to be as open and transparent as possible. With this in mind, the Working Party on Manufactured Nanomaterials (WPMN) discussed a *Communication Strategy* at its 3rd meeting in November 2007. One of the outcomes of the discussion was the agreement that this document should be forwarded to OECD's Chemicals Committee with a recommendation that it be declassified and made publicly available.

Following the agreement of the Chemicals Committee, this document is being made available via OECD's nanosafety web site (http://www.oecd.org/env/nanosafety/). Since this Programme of Work was agreed, two additional projects have been developed by the WPMN. These projects are: i) The Role of Alternative Methods in Nano Toxicology; and ii) Exposure Measurement and Exposure Mitigation.

It should be noted that during 2006-2008, this Programme of Work has evolved considerably. Already, a new Programme of Work is under discussion for 2009-2012. This will be considered by OECD's Chemicals Committee in November 2008. If it is agreed, it will replace this document.

This document is published on the responsibility of the Chemicals Committee.

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INTRODUCTION

The 1st Meeting of the Working Party on Manufactured Nanomaterials (WPMN) was hosted by the UK Department of Environment, Food and Rural Affairs (DEFRA). It was held in London, 26th-27th October 2006.

The primary objective of this meeting was to agree a Programme of Work (2006-2008) for the WPMN to be approved by OECD's Chemicals Committee. The main aim of the programme is to promote international co-operation in human health and environmental safety related aspects of manufactured nanomaterials, in order to assist in the safe development of manufactured nanomaterials, while avoiding non-tariff barriers to trade.

BACKGROUND

The 38th Chemicals Committee held a Special Session (June 2005) on the Potential Implications of Manufactured Nanomaterials for Human Health and Environmental Safety. This was the first opportunity for OECD member countries, together with observers and invited experts, to begin to identify human health and environmental safety issues related to manufactured nanomaterials. The scope of this session was intended to address primarily the chemicals sector.

As a follow-up, the Chemicals Committee 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], the 39th meetings of the Chemicals Committee recommended that the OECD Council consider the establishment of a Working Party as a subsidiary body of the Chemicals Committee, to address the human health and environmental safety implications of manufactured nanomaterials.

ESTABLISHMENT OF THE WORKING PARTY ON MANUFACTURED NANOMATERIALS

The "*Creation of a Working Party on Manufactured Nanomaterials*" was discussed by the Executive Committee of the Council and it was forwarded subsequently to the OECD Council for agreement.

The OECD Council agreed to establish a Working Party on Manufactured Nanomaterials (WPMN) on 14th September 2006 as a subsidiary body of the Chemicals Committee, with Terms of Reference as in annex II of this document.

DRAFT PROGRAMME OF WORK 2006-2008

At its 1st meeting (October 2006), the Working Party on Manufactured Nanomaterials (WPMN) discussed and agreed the Draft Programme of Work 2006-2008 (Annex I), consistent with the Terms of Reference as agreed by the OECD Council.

The content of the draft Programme of Work is based on the results of the Washington Workshop, as well as subsequent discussions in the Chemicals Committee.

IMPLEMENTING THE DRAFT PROGRAMME OF WORK 2006-2008

The Programme of Work is structured in three work areas: i) Identification, Characterisation, Definitions, Terminology and Standards; ii) Testing Methods and Risk Assessment; and iii) Information Sharing, Co-operation and Dissemination.

The **work areas** are intended to describe, in general terms, the work needed by OECD to help ensure human health and environmental safety of manufactured nanomaterials.

As the Chemicals Committee decided to endorse the Programme of Work, the Working Party moved forward with its implementation. The Working Party decided that this could best be achieved initially through six specific projects listed as follows:

- Project: Development of an OECD Database on Human Health and Environmental Safety (EHS) Research.
- Project: EHS Research Strategies on Manufactured Nanomaterials.
- Project: Safety Testing of a Representative Set of Manufactured Nanomaterials.
- Project: Manufactured Nanomaterials and Test Guidelines.
- Project: Co-operation on Voluntary Schemes and Regulatory Programmes.
- Project: Co-operation on Risk Assessments.

These specific projects will further develop appropriate methods and strategies to help ensure human health and environmental safety. It should be note that each project may have a bearing on more than one of the **areas of work**. The order in which these projects are presented does not have any bearing on their priority. The timing of each project will vary.

Each project is managed by lead countries and steering groups (comprised of experts for delegates to the WPMN), which were identified at the 1st meeting of the WPMN.

Progress achieved within each project is presented and discussed at each meeting of the WPMN.

RESOURCES

The work on Manufactured Nanomaterials is an activity of OECD's Part II Chemicals Programme. In addition, extra-budgetary contributions to support this work have been made available (or will be made available) by Japan, the United Kingdom and the United States in 2006.

STAKEHOLDERS' PARTICIPATION

The Working Party spent some time discussing the participation of stakeholders. In summary, it was agreed that those observers and invited experts which normally participate in the work of the Chemicals Committee should also be encouraged to participate in the Working Party.

With respect to the participation of non-member economies, the Working Party identified the need to forge closer linkages with those non member economies with significant national efforts regarding nanotechnologies. In this context, it was recommended that China and India be invited to participate in its work. Both these countries had made contributions to the Washington Workshop (December 2005).

Similarly, it was recommended that Thailand also be invited based on its contribution to the 1st Meeting of the WPMN. The Secretariat was invited to determine, on the basis of readily available information, which other non-members it would be appropriate to invite. This will be considered by the Bureau of the WPMN.

The Working Party also foresees close links with activities of ISO Technical Committee 229 and recommends that it participates in its work.

CO-ORDINATION WITH OTHER INTERGOVERNMENTAL ORGANISATIONS

As agreed in the Terms of References (Annex II) the Working Party will co-ordinate with other relevant intergovernmental organisations, especially those of the Inter-Organisation Programme for the Sound Management of Chemicals (OECD is a member as well as UNEP, ILO, FAO, WHO, UNIDO and UNITAR) and possibly UNESCO. It will also work with standardisation organisations (e.g., ISO and IUPAC), and nomenclature organisations (e.g., CAS), so avoiding duplication and ensuring complementarity with other activities.

CURRENT AND FUTURE WORK ON NANOTECHNOLOGIES AT OECD

At the present time, activities related to nanotechnologies are also being discussed and planned by OECD's Committee for Scientific and Technological Policy (CSTP). The work of the CSTP aims to enhance economic growth and social welfare by fostering science and innovation. The proposed activities of the CSTP will therefore seek to achieve, amongst other things, a better understanding of how best to promote research, development and innovation of nanotechnologies and the possible uses and commercialisation of products from this research, which foster the policy making in this science and technology area in OECD member countries. A CSTP activity will therefore address the applications of these technologies taking into account public perception and societal concerns.

At the CSTP Meeting, held 26th- 27th October, in Seoul, Korea, the CSTP agreed in principle to the establishment of a Working Party on Nanotechnology. A Workshop will be held in the Netherlands before the next meeting of the CSTP (to be held in March 2007) to develop the terms of reference for the new group. The CSTP will decide at its next meeting whether to propose to Council the creation of a new Working Party. The CSTP also stressed that close co-ordination will be kept with the Working Party on Manufactured Nanomaterials (WPMN). Similarly, the WPMN welcomed the co-ordination with activities of CSTP.

OECD INTERNAL CO-ORDINATION

The OECD Secretariat considers it essential to co-ordinate activities related to nanotechnologies and nanomaterials across the Organisation. This will avoid duplicative work and allow the identification of synergies, and when appropriate, identify potential joint activities across OECD Directorates and relevant Committees.

Furthermore, the importance of internal co-ordination has been stressed by the OECD Council and will be a priority for the Programme of Work on Manufactured Nanomaterials 2006-2008 (see Annex I).

ANNEX I PROGRAMME OF WORK ON MANUFACTURED NANOMATERIALS 2006 -2008

INTRODUCTION

This draft programme of work on *Manufactured Nanomaterials* was developed for 2006-2008 based on the results of the Workshop on the Safety of Manufactured Nanomaterials (7-9 December 2005). It has also taken into account the discussions held during the 39th Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology.

Initially, the specific areas of work that were considered by the Washington Workshop were: 1) definitions, nomenclature and characterisation; 2) environmental fate and effects (hazard identification, hazard, exposure and risk assessment methods); 3) human exposure and health effects (hazard identification, hazard, exposure and risk assessment methods); and 4) exchange of information on regulatory and risk management frameworks (limited mainly to the chemicals sector). These areas, and the recommendations identified within them, have been refined into the revised work areas identified below.

This document also includes the Terms of Reference for the Working Party on Manufactured Nanomaterials (Annex II) as agreed by the OECD Council.

PROPOSED PROGRAMME OF WORK 2006 – 2008

The objective of the Programme of Work is to promote international co-operation in health and environmental safety related aspects of manufactured nanomaterials, in order to assist in the safe development of manufactured nanomaterials.

The programme will concentrate on human health and environmental safety implications of manufactured nanomaterials (limited mainly to the chemicals sector), and will ensure that the approach to hazard, exposure and risk assessment is of a high, science-based, and internationally harmonised standard. It is 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.

Research and development on manufactured nanomaterials is proceeding rapidly, so it is important that the programme of work **remains flexible** so that the Working Party is able to address emerging issues in a timely and resource efficient fashion.

The Working Party will be open and transparent in its activities. Strengthening participation from **non-member economies** will be a priority for this programme of work. In addition, the Working Party should encourage the participation of a range of stakeholders. Participation of non-member economies as well as stakeholder participation will be agreed by the Working Party, in line with the policy of the Chemicals Committee.

It is recognized that there are many issues related to manufactured nanomaterials that need to be addressed in the short term. Therefore, when work begins on specific projects during the 2006-2008 programme of work, it may be necessary to devise a system to set priorities amongst them.

Co-ordination

In undertaking the programme of work, the Working Party will work to communicate and co-ordinate with other intergovernmental organizations active in the area, as well as standardisation and nomenclature organisations (for example, ISO), as specified in the Terms of Reference (Annex II). This effort will **avoid duplication** and **help to ensure complementarity** with other intergovernmental activities and other related organizations. The OECD will establish direct links as appropriate, and encourage the active collaboration at the national level between Working Party members and their national representatives to these activities.

The Secretariat will also ensure internal co-ordination on issues related to nanotechnologies/ nanomaterials with bodies within OECD.

WORK AREAS

In accordance with the Terms of Reference, the programme of work will address **three work areas**, which are intended to describe, in general terms, the work needed by OECD to help ensure human health and environmental safety of manufactured nanomaterials. These work areas are:

- 1. Identification, Characterisation, Definitions, Terminology and Standards;
- 2. Testing Methods and Risk Assessment; and
- 3. Information sharing, Co-operation and Dissemination.

Within each work area, the Working Group will develop *specific projects*. These specific projects will be a key part of the programme of work and they will evolve over time. Six specific projects have already been identified.

Work Area One - Identification, Characterisation, Definitions, Terminology and Standards

This work area is important because it will provide the basis for establishing **criteria for the identification of nanomaterials**. Such identification is important for determining, inter alia, which specific nanomaterials could be notified and assessed by regulatory authorities.

The Working Party will develop a general working definition of nanomaterials within the context of human health and environmental safety for use by the Working Party. It will take into account the size range and other key characteristics of the manufactured nanomaterials as they relate to: biological and environmental fate; behaviour; toxicity and eco-toxicity.

This work area will also involve efforts to **harmonise standard reference materials and working definitions of manufactured nanomaterials of member countries**. There will be close collaboration with ISO in order to avoid an overlap of mandates and duplication of work, with ISO continuing to lead efforts towards international standards development through its Technical Committee 229. The Working Party also will institute an effort to develop a set of well characterized representative nanomaterials.

Work Area Two – Testing Methods and Risk Assessment

This work area will seek to harmonise methods for health and environmental testing of manufactured nanomaterials and seek to encourage co-operation and co-ordination in assessing their risks.

This work area will be an opportunity for the Working Party to assess whether or not existing test guidelines (used for traditional chemicals) are suitable for nanomaterials. It will also determine what information may be relevant to the safety assessment of manufactured nanomaterials, and what information might be needed to evaluate the appropriateness of various existing test guidelines for manufactured nanomaterials.

This work area will prioritize the need to evaluate existing standardized test methods and to adapt them to the testing of nanomaterials and/ or to develop new methods related to the assessment of the physicochemical properties, environmental fate, and toxicological and eco-toxicological effects of manufactured nanomaterials. This work area will also develop potential approaches for exposure measurement and detection of nanomaterials in the workplace and the environment. Methods to be examined should extend to those assessing, amongst other things, compartmentalisation properties, monitoring, measurement of exposure, fate and persistence. It will be important to specify the various contexts in which different test systems and levels of testing should be applied.

This work area will further seek to co-ordinate health and environmental safety research efforts and to consider developing an agreed OECD research "framework" based on those of member countries. It is recognised that research will be conducted by member countries; however, OECD will work to ensure that all work is "tracked" by the secretariat and that members have an appropriate forum to help ensure that the most critical research is undertaken and that duplication is avoided.

The progress in characterising nanomaterials as described in work area one will also help to understand appropriate testing methods. This will involve identifying priorities for reviewing, developing or modifying test methods for hazard assessment of nanomaterials.

Further consideration is needed to improve the understanding of exposure considerations in relation to nanomaterials. The **development and review of risk assessment approaches** has been agreed as important to this work area, including the need to share assessment reports, case studies, review the applications of risk assessment methodologies and consider pragmatic approaches such as control banding. In the meantime, it is noted that a number of members have already begun activities to assess manufactured nanomaterials, so information exchange, co-ordination and co-operation in this area would be valuable.

In summary, during the 2006-2008 programme of work, the Working Party will initiate specific projects related to safety testing of a representative set of manufactured nanomaterials, and manufactured nanomaterials and test guidelines. Steering groups have been established to move forward these projects.

Work Area Three-Information sharing, Co-operation and Dissemination

Amongst other things, this work area will seek to develop and make available to the public clear and concise information relevant to the human health and environmental safety of manufactured nanomaterials so as to promote the effectiveness of national efforts.

This work area will also help facilitate **harmonisation of regulatory practices in the chemicals regulatory area** by drawing up an inventory and comparing approaches by different member countries.

The Working Party will act as a forum for sharing information on current or planned initiatives on risk assessments, voluntary programmes and regulation. This will be an opportunity for delegations to describe the status and direction of national programmes related to Human Health and Environmental Safety (EHS) Research issues for manufactured nanomaterials. The objective will be to identify opportunities for co-operation and for harmonising approaches.

This area of work will also include initiatives to co-operate and share information on **risk** assessments and exposure measurements, voluntary schemes programmes and EHS research strategies on manufactured nanomaterials to address human health and environmental safety issues associated with nanomaterials. The Working Party will, based on the approaches in member countries, industry, and other stakeholders, develop specific recommendations on research strategies for the short, medium and longer term; and identify potential opportunities for collaboration.

The Working Party will also further consider the development of an OECD **Database on Human Health and Environmental Safety (EHS) Research**. The objective is to develop and make available a global resource on studies on environmental and human health safety. A steering group has been established to move forward this project.

In summary, during the 2006-2008 programme of work, the Working Party will initiate specific projects related to human health and environmental safety research strategies on manufactured nanomaterials, co-operation on voluntary schemes and regulatory programmes and co-operation on risk assessments and exposure measurements. Steering groups have been established to move forward these projects.

Consistent with the Terms of Reference (Annex II), this work area will involve the exchange information on regulatory and risk management frameworks (limited mainly to the chemicals sector) as well as environmental benefits. It will take into account the work of CSTP.

ANNEX II TERMS OF REFERENCE FOR THE WORKING PARTY ON MANUFACTURED NANOMATERIALS

The Working Party on Manufactured Nanomaterials is a temporary subsidiary body of the Chemicals Committee. It has the following terms of reference:

1. To elaborate and implement a programme of work for 2006-2008, which aims to promote international co-operation in the health and environmental safety related aspects of manufactured nanomaterials among member countries and certain non-member economies (in accordance with the policy of the Chemicals Committee), the main topic areas to be included in the programme of work will include:

- Definitions, nomenclature and characterisation (physicochemical properties, uses) where not otherwise available.
- Environmental fate and effects (hazard identification, hazard, exposure and risk assessment methods).
- Human exposure and health effects (hazard identification, hazard, exposure and risk assessment methods).
- Exchange of information on regulatory and risk management frameworks (limited mainly to the chemicals sector) as well as environmental benefits.

2. To advise the Chemicals Committee on priorities amongst the above issues which need to be addressed in the short, medium and longer-term within the context of the Chemicals Programme.

3. To take a proactive approach in regard to co-operation on the health and environmental safety related aspects of manufactured nanomaterials by advising the Chemicals Committee on issues related to human health (*e.g.*, from both public and occupational exposures) and environmental impacts resulting from manufactured nanomaterials.

4. To recommend the best means of undertaking the various projects, for example, through a lead country approach, small task groups or workshops;

5. To promote an understanding of the health, environmental and exposure implications of manufactured nanomaterials by:

- Tracking relevant scientific research efforts.
- Identifying relevant research needs.
- Developing and promoting a strategy to meet identified needs.

6. To co-ordinate with other subsidiary bodies of the Chemicals Committee and refer issues to them as appropriate;

7. To co-ordinate with other relevant groups within the OECD;

8. To co-ordinate with other relevant intergovernmental organisations, especially those of the Inter-Organisation Programme for the Sound Management of Chemicals (*e.g.*, UNEP, ILO, FAO, WHO, UNIDO and UNITAR) and possibly UNESCO, standardisation organisations (*e.g.*, ISO and IUPAC), and nomenclature organisations (*e.g.*, CAS), so avoiding duplication and ensuring complementarity with other intergovernmental activities;

9. The Working Party will be open and transparent in its activities. Accordingly the participation of stakeholders will be decided by the Working Party, in line with the policy of the Joint Meeting;

10. The Working Party will elect a Chair and Vice-Chairs for a period of one year.