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**Open-ended Working Group of the International Conference
on Chemicals Management**

First meeting

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Item 5 (c) of the provisional agenda*

**Implementation of the Strategic Approach:
new and emerging policy issues**

Progress report on nanotechnologies and manufactured nanomaterials

Note by the secretariat

1. The following report was submitted by the United Nations Institute for Training and Research (UNITAR) and the Organization for Economic Cooperation and Development (OECD) in response to resolution II/4 E on nanotechnologies and manufactured nanomaterials of the International Conference on Chemicals Management at its second session.

2. In addition, the secretariat has the honour to present, in the annex to the present note, the executive summary of a report on the applications, implications and safety management of nanomaterials in the context of the Strategic Approach to International Chemicals Management, which was commissioned by the secretariat in response to resolution II/4 E. The complete report can be found in document SAICM/OEWG.1/INF/8. The executive summary has been reproduced without formal editing.

Background

3. UNITAR and OECD support the implementation of the Strategic Approach. In April 2006, the Board of Trustees of UNITAR officially endorsed the Strategic Approach,¹ while the OECD Council adopted a resolution in 2008 making the implementation of the Strategic Approach objectives an integral part of the OECD Chemicals Programme.² The follow-up to the resolution was carried out through joint meetings of the OECD Chemicals Committee and the OECD Working Party on Chemicals, Pesticides and Biotechnology.

4. On the basis of preparatory work undertaken ahead of the second session of the International Conference on Chemicals Management, nanotechnology and manufactured nanomaterials were one of four emerging policy issues considered by the Conference in detail to focus attention, call for appropriate action and forge consensus on each, in accordance with the functions of the Conference as set out in paragraph 24 (j) of the Overarching Policy Strategy of the Strategic Approach. In addition, the Government of Switzerland organized a side event at which OECD participated, along with others, to introduce the topic of nanotechnology and manufactured nanomaterials. Subsequently, the topic was accepted as a fifth emerging policy issue.

* SAICM/OEWG.1/1/Rev.1.

1 See www2.unitar.org/cwm/publications/event/saicm_2006/UNITAR_BOT_SAICM_Decision_Final.pdf.

2 See [www.oecd.org/officialdocuments/displaydocumentpdf/?cote=c\(2008\)32&doclanguage=en](http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=c(2008)32&doclanguage=en).

5. By its resolution II/4 E, the Conference encouraged Governments and other stakeholders to assist developing countries and countries with economies in transition to enhance their capacity to use and manage nanotechnologies and manufactured nanomaterials responsibly, to maximize potential benefits and to minimize potential risks. It also requested Governments and intergovernmental, international and non-governmental organizations, including the private sector, subject to available resources:

- (a) To facilitate access to relevant information, realizing the needs of different stakeholders;
- (b) To share new information as it became available;
- (c) To use upcoming regional, subregional, national and other meetings to further increase understanding of such information, for example through the use of workshops if appropriate.

6. In addition, it invited relevant international organizations, including OECD, other organizations participating in the Inter-Organization Programme for the Sound Management of Chemicals and the International Organization for Standardization, to engage in dialogue with stakeholders with a view to gaining further understanding of nanotechnologies and manufactured nanomaterials.

7. Subsequently, the participants at the forty-fourth joint meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, held in June 2009, discussed the resolutions on emerging policy issues adopted by the Conference, including resolution II/4 E. The joint meeting participants noted that the Working Party on Manufactured Nanomaterials had already generated a great deal of documentation that would be of value to other stakeholders, especially in developing countries, and requested the OECD secretariat to explore with UNITAR and other participating organizations of the Inter-Organization Programme for the Sound Management of Chemicals the possibility of working together on information exchange on nanotechnology targeted at developing countries and of possibly making resources available from the Quick Start Programme.

A. Contribution to the implementation of resolution II/4 E

8. As a contribution to the implementation of resolution II/4 E, OECD and UNITAR held the following regional workshops involving over 200 participants:

- (a) Asia and the Pacific: Beijing, 27 November 2009; 56 participants;
- (b) Central and Eastern Europe: Lodz, Poland, 11 December 2009; 21 participants;
- (c) Africa: Abidjan, Côte d'Ivoire, 25 and 26 January 2010; 63 participants;
- (d) Latin America and the Caribbean: Kingston, 12 March 2010; 37 participants;
- (e) Arab subregion: Alexandria, Egypt, 11–13 April 2010; 43 participants.

9. The main aim of this first round of workshops involving government, industry and civil society representatives was to raise awareness of nanotechnology, its current and potential applications and the possible human health and environmental safety implications associated with the use of nanomaterials. An additional objective was to ensure that developing countries and economies in transition would be able to participate, in an informed way, in discussions at the third session of the International Conference on Chemicals Management.

10. The workshops involved the presentation of materials and documentation prepared, in part, by the OECD secretariat and derived from the activities of the OECD Working Party on Manufactured Nanomaterials. Working Party members also provided materials and made presentations. This round of workshops was supported by the Governments of Switzerland, Sweden, the United Kingdom of Great Britain and Northern Ireland and the United States of America.

11. Documentation was also made available on other intergovernmental activities with the assistance of the participating organizations of the Inter-Organization Programme for the Sound Management of Chemicals.³ The International Organization for Standardization assisted by providing information on its work. Other stakeholders, such as the OECD Business and Industry Advisory Committee, the OECD Trade Union Advisory Committee and environmental non-governmental organizations, also prepared and presented materials.

3 See www.who.int/iomc/en/.

12. The outcomes of this first round of regional workshops included:
- (a) Increased understanding on the part of the participants of the implications of nanomaterials for their daily work as general chemicals management specialists in their countries;
 - (b) Input from participants on what their countries would need to deal with nanomaterials as part of a sustainable general programme for the sound management of chemicals at the national level;
 - (c) Understanding of the outcomes of the second session of the International Conference on Chemicals Management as a first step towards deliberations on furthering the nanotechnology agenda at the third session of the Conference.
13. Subsequently, in 2011, UNITAR organized a second round of regional workshops, as follows:
- (a) Africa: Nairobi, 5 and 6 April 2011; 86 participants;
 - (b) Latin America and the Caribbean: Panama City, 31 May and 1 June 2011; 55 participants;
 - (c) Central and Eastern Europe: Lodz, 27 and 28 June 2011; 26 participants;
 - (d) Asia and the Pacific: Beijing, 6 and 7 September 2011; 66 participants.
14. The outcomes of this second round, which also involved over 200 participants and was supported by the Government of Switzerland, included:
- (a) Discussion among Governments and key stakeholders on the inclusion of nanotechnology and manufactured nanomaterials in the Global Plan of Action;
 - (b) Consideration of regional perspectives in preparation for further discussions on nanotechnology at the first meeting of the Open-ended Working Group and the third session of the International Conference on Chemicals Management;
 - (c) Additional and more detailed input provided by participants on nanotechnology use and initiatives in their countries and organizations.

B. Progress in action plan development or implementation in selected countries

15. Following the regional workshops, countries were encouraged to begin developing national policies on nanotechnology and nanomaterials. It is envisaged that systematic development of such policies will ensure an integrated approach and coordination between the Strategic Approach and the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade and the Stockholm Conventions on Persistent Organic Pollutants; encourage mainstreaming of nanotechnology issues into development planning; cover the full life cycle of nanomaterials and innovation; and involve a range of key stakeholders and ministry representatives, including those responsible for science and technology, trade, health, environment, labour, agriculture, industry, transport, Customs, foreign affairs, justice and planning.
16. Each country's central plan or policy would be intended to assist with identifying priority activities to build or strengthen capacities; linking to other areas of and tools for sound chemicals management (e.g., the Globally Harmonized System of Classification and Labelling of Chemicals, national nanotechnology profiles, Strategic Approach implementation plans); setting national policy at the core of national nanotechnology programmes; developing nanotechnology committees to direct and guide national nanotechnology programmes; ensuring that the main focus would be on environmental and health protection with regard to both risks and applications (promotion of applications); and undertaking monitoring and evaluation based on evolving nanotechnology priorities.
17. In 2011, UNITAR, with the support of the Government of Switzerland, initiated pilot projects to assist three developing countries and countries with economies in transition to develop programmatic capacities to tackle nanotechnology issues at the national level. Lessons learned from these projects will be considered by the International Conference on Chemicals Management at its third session, in 2012. UNITAR is developing guidance and training materials to ensure that the participating countries are aware of the current state of the nanotechnology field and possible actions that can be taken at the national level. To initiate the development of guidance, a draft outline of a national nanotechnology profile was developed and presented for comment at the regional workshops.

C. Progress related to the programme on the environmental, health and safety considerations of manufactured nanomaterials

18. Governments and industry have invested significant resources in research into the environmental, health and safety considerations of manufactured nanomaterials. At the international level, these efforts are documented in the tour de table document published twice a year by OECD in conjunction with each meeting of the Working Party on Manufactured Nanomaterials. The latest tour de table is publicly available.⁴

19. One key OECD programme revolves around coordinated testing of a prioritized set of reference nanomaterials and is known as the sponsorship programme on the testing of manufactured nanomaterials. It consists of three components:

(a) *Safety testing of a representative set of manufactured nanomaterials*: This work coordinates investigations into reference nanomaterials for 59 endpoints of physical-chemical properties, mammalian toxicity, environmental fate, environmental toxicity and material safety. As at August 2011, some 20 member countries, in addition to some non-members and other stakeholders, had committed themselves to participating in this programme in various capacities in order to pool expertise and to fund the testing;

(b) *Manufactured nanomaterials and test guidelines*: This project examines whether existing OECD test guidelines are adequate for the assessment and characterization of the toxicological properties of manufactured nanomaterials, taking into consideration their unique properties;

(c) *Role of alternative methods in nanotoxicology*: This work considers the use of alternative methods and testing strategies for manufactured nanomaterials, including in vitro and in silico approaches, and matters relating to the revamping of traditional toxicological tests.

20. The first set of comprehensive results of the testing carried out under the sponsorship programme (phase one testing) is expected to be compiled by June 2012 and made publicly available shortly thereafter. A second phase is envisaged, but its exact nature will depend on the results and experience of the first phase. It is expected that the results of the first phase will feed into other work of the OECD programme on the safety of manufactured nanomaterials.

21. Currently, work is under way as part of the manufactured nanomaterials and test guidelines project to revise the preliminary guidance notes on sample preparation and dosimetry,⁵ a need that was deemed key in the light of new work arising out of the sponsorship programme. As additional information from the testing is released, OECD will begin updating additional test guidelines and/or developing new cross-cutting guidance documents.

22. An OECD database on manufactured nanomaterials to inform and analyse research into the environmental, health and safety considerations of manufactured nanomaterials was publicly launched on 1 April 2009.⁶ It provides details of completed, current and planned research on the safety of manufactured nanomaterials. It can be queried using the names of nanomaterials, OECD test guidelines and specific endpoints. As at August 2011, there were 800 projects listed in the database from OECD member countries and non-member countries and organizations.

23. Work under a project on cooperation on voluntary schemes and regulatory programmes is aimed at compiling and analysing national information-gathering schemes and regulatory programmes for assessing the safety of manufactured nanomaterials. To identify trends, an analysis of information-gathering schemes and a report on regulated nanomaterials from 2006 to 2009 were developed.⁷ In addition, as part of this project a collaborative workspace for sharing information and discussing issues on national voluntary or regulatory programmes between Governments was implemented. OECD will begin working on the various definitions of nanomaterials with a view to identifying regulatory challenges.

24. Work under a project on cooperation on risk assessment is aimed at evaluating risk assessment approaches for manufactured nanomaterials by exchanging information and identifying opportunities to strengthen and enhance risk assessment methodologies. As an outcome of the OECD workshop on

4 Available from: [www.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono\(2011\)12&doclanguage=en](http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono(2011)12&doclanguage=en).

5 Available from: [www.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono\(2010\)25&doclanguage=en](http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono(2010)25&doclanguage=en).

6 Available from: <http://webnet.oecd.org/NanoMaterials/>.

7 Available from: www.oecd.org/env/nanosafety.

risk assessment of manufactured nanomaterials in a regulatory context,⁸ work continues on issues critical to the assessment of risks posed by manufactured nanomaterials.

25. There is also a project on cooperation on exposure measurement and exposure mitigation. To date, this project has been largely focused on the exposure to nanomaterials in occupational settings. Countries have been exchanging information on guidance and research on exposure to manufactured nanomaterials in occupational settings and a number of documents have been published. For example, a compilation and comparison of guidelines related to exposure to nanomaterials in laboratories has recently been published as part of the project.⁹ In addition, future work is planned on the exposure of consumers to nanomaterials through products, in addition to exposure through the environment.

26. The newest project is on the environmentally sustainable use of manufactured nanomaterials. The aim is to enhance knowledge of life-cycle aspects of manufactured nanomaterials, in addition to positive and negative impacts on environment and health of some nanotechnology-enabled applications at various stages of development (from research to end-of-life). A report on national activities related to life-cycle assessment and nanotechnology will be publicly available at the end of 2011.

Nanowaste

27. The OECD Working Party on Resource Productivity and Waste recently discussed a draft scoping paper on nanowaste. The report highlights many potential sources of current and future nanowaste in addition to some complex definitional and jurisdictional issues surrounding the topic. The Working Party is coordinating with the Working Party on Manufactured Nanomaterials on next steps for this work. At the same time, via the project on the cooperation on exposure mitigation and exposure assessment, OECD has begun coordinating projects relating to the assessment of exposure to nanomaterials; these projects include investigations into unbound nanomaterials and nanomaterials bonded in a matrix. Currently, a review of available information, including research activities, related to disposal and treatment technologies for manufactured nanomaterials, is being prepared.

8 Available from:
[www.oecd.org/officialdocuments/displaydocumentpdf?cote=env/jm/mono\(2010\)10&doclanguage=en](http://www.oecd.org/officialdocuments/displaydocumentpdf?cote=env/jm/mono(2010)10&doclanguage=en).

9 Available from:
[www.oecd.org/officialdocuments/displaydocumentpdf?cote=env/jm/mono\(2010\)47&doclanguage=en](http://www.oecd.org/officialdocuments/displaydocumentpdf?cote=env/jm/mono(2010)47&doclanguage=en).

Annex

NANOMATERIALS: APPLICATIONS, IMPLICATIONS AND SAFETY MANAGEMENT IN THE SAICM CONTEXT

EXECUTIVE SUMMARY

This report has been prepared for the SAICM Secretariat and uses the inputs which the Secretariat received from stakeholders. It has been drafted by Rob Visser in co-operation with Georg Karlaganis, Vladimir Murashov and Seonghee Seo.

Nanomaterials: Applications, Implications and Safety Management in the SAICM context

Executive summary

Background

Nanomaterials have special characteristics which mean that they can be used in various new applications, some of which have already been marketed for decades. Much research on new uses for nanomaterials is ongoing and, while currently the production volumes for them are not very large compared to traditional chemicals, many other applications are foreseen in the near future and production volumes are expected to increase significantly over the coming decade.

These special characteristics of nanomaterials can, however, also be a challenge, because these materials might have different implications for human health or the environment than the traditional chemicals. At this point in time it is not yet determined to what extent the classical testing and assessment approaches used in toxicology, which are the basis for the safety management decisions regarding traditional chemicals, will apply to nanomaterials. Also in this field research programmes are ongoing.

SAICM pays attention to nanotechnologies and manufactured nanomaterials as an emerging issue with respect to chemical safety. The Resolution II/4-E of ICCM2, in its section 9, "Invites Governments and other stakeholders to develop a report that focuses on nanotechnologies and manufactured nanomaterials including, in particular, issues of relevance to developing countries and economies in transition, and to make the report available to the Open-ended Working Group at its first meeting and to the International Conference on Chemicals Management at its third session". This report has been prepared to address this invitation. Inputs from thirteen stakeholders have contributed to the report. Recommendations made at Regional SAICM meetings for the content of the report, based on an outline, have been taken into account.

Introduction

The report gives a brief overview of the current market situation, and of expected developments. It describes possible applications of manufactured nanomaterials for industrial and consumer uses, but also addresses their beneficial uses for health and the environment, and gives special attention to the situation in developing countries and economies in transition. The report then describes the state of knowledge regarding risk assessment and risk management. It describes where science is with regard to material characterization, human health (including worker related aspects), the environment, information management and risk management. The report also highlights uncertainties in the science and on which issues more research is needed.

Risk assessment and risk management

One of the conclusions regarding this subject is that on the one hand much knowledge is available regarding possible health and environmental effects of traditional chemicals and exposures, but that, on the other hand, such knowledge cannot all be transposed directly to nanomaterials. In many cases, however, the robust methods applied to and frameworks used for traditional chemicals, will provide an adequate basis for dealing with manufactured nanomaterials. A widely applied policy is to use available provisions as far as possible and follow a precautionary approach. At the moment therefore often a case-by-case evaluation has to be relied upon, and qualitative outcomes have to be used when risk quantification is not possible. Precaution is then applied in those cases where an unacceptable level of uncertainty or concern is identified. In this context issues related to waste management, specifically in developing countries and economies in transition, require special attention.

Policy Making

Currently no countries have specific legislation in place to deal with the safety of nanomaterials. Meanwhile existing legislations requiring a duty of care are used to cover nanomaterials. Several specific suggestions have been made for better addressing nanomaterials, such as the inclusion of nano-aspects in Safety Data Sheets, establishment of a government register for products including nanomaterials, a provision by industry of information about potential risks of nanomaterials and integrating a chapter about the management of nanomaterials in National Profiles for chemicals management.

Clearly, however, more research is needed to get a better insight into those aspects for which the methodology has to be adapted for nanomaterials risk management, and into the possibilities to quantify the risks. In general, civil society organizations are rather critical about the way the risks of nanomaterials are currently being managed.

Economic, social and ethical matters

The report also discusses the economic, social and ethical aspects of the introduction of nanotechnology, how public dialogue on this issue is being progressing and the work of international and intergovernmental organizations.

Capacity Building

The report further addresses the issues of learning, training and capacity building in relation to nanotechnology and defines in this respect two related, but distinct elements. One is ensuring that all countries have the capacity to undertake research in order to use nanotechnologies to help them to possibly better address a number of the societal challenges. Concerns that developed countries will benefit more from nanotechnology and that developing countries will suffer more from potential risks are highlighted and the need that this issue has to be fully considered in order to avoid that a nano-divide will be created, is emphasized. The establishment of research partnerships is mentioned as a way forward here. The second element is that all countries should have a capacity to assess the health and environmental safety aspects of manufactured nanomaterials in order to be able to make well founded and effective decisions on the use of these materials in their countries, while the science regarding nanomaterial safety assessment methods is evolving. It is crucial to strengthen the capacities in this field in developing countries and in economies in transition. Suitable means to achieve this should be made available.

Recommendations on nanomaterials' safe management

The report concludes with a number of suggestions for actions which could be taken up in the SAICM context.

1. Facilitation of information exchange on nanotechnologies and manufactured nanomaterials in order to improve global transparency and allow better decision making processes. Such information exchange could involve several aspects. For example it could be recommended that, possibly through the IOMC and its participating organizations:
 - an international "nano-portal" for safety information be set up;
 - a clearinghouse of ongoing research activities be set up;
 - a mechanism be established for sharing technical, legal and institutional information;
 - awareness raising activities in the SAICM regions be continued and deepened.
2. Development of internationally applicable technical and legal guidance and training material for the sound management of manufactured nanomaterials, possibly through the IOMC and its participating organizations. This could involve:
 - guidance material on the assessment and management of the safety of nanotechnologies and manufactured nanomaterials;
 - guidance material on the integration of nanomaterial safety in existing national chemical safety programmes, including the updating of National Profiles;
 - guidance material on the adaptation of national legal frameworks to include the sound management of manufactured nanomaterials;
 - training materials based on the guidance;
 - training activities;
 - pilot projects which could also be used to test the guidance material;
 - education materials for the public.

3. Supporting the development of Regional SAICM strategies concerning manufactured nanomaterials, which could include arrangements for cooperation on research and on risk assessment and risk management issues.
 4. Facilitation of technology transfer, in particular related to applications which are beneficial for health and environmental protection. This could include various types of partnerships which should be financially supported in order to achieve their objectives. Partnerships could be among:
 - developing countries and/or economies in transition and developed countries;
 - public and private institutions in a country or region, including civil society organizations as they could contribute in various ways, for example by providing expertise, review and insights.
 5. Updating the Global Plan of Action with a specific work area which includes activities on nanotechnologies and manufactured nanomaterials.
 6. Including the possibility of financing projects related to nanomaterial safety in any possible future SAICM financing mechanisms in order to enhance the preparedness of countries to deal with the safety issues when larger volumes of products containing nanomaterials will reach the market.
 7. Inviting industry to step up their stewardship role and responsibilities in relation to nanotechnologies and manufactured nanomaterials, and to participate, including in financial terms, in supporting awareness raising, information exchange and training activities, as well as in public dialogue by providing, without major conditions, monetary contributions for such international work.
 8. Recommending to the UN Committees of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals the urgent preparation of a work plan for the adaptation or development of GHS criteria to address the safety of manufactured nanomaterials.
 9. Recommending to the Conferences of Parties of the Rotterdam, Stockholm and Basel Conventions to consider specifically addressing if it would be useful (and if so how) to consider applications and implications of manufactured nanomaterials which could fall under their respective mandates.
 10. Continuing to support the public dialogues on all aspects of nanotechnologies and manufactured nanomaterials, for example by holding Seminars or a Global Conference with participation of all stakeholders in order to discuss progress on addressing issues related to manufactured nanomaterials which are of wide public interest.
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