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Implementation of the Strategic Approach to International Chemicals Management: emerging policy issues

Background information in relation to the emerging policy issue of nanotechnology and manufactured nanomaterials

Note by the secretariat

1. The secretariat has the honour to circulate, in the annex to the present note, relevant background material on the emerging policy issue of nanotechnology and manufactured nanomaterials, as outlined in document SAICM/ICCM.2/10. The material is provided for the information of participants and has been reproduced as received without formal editing. The preparation of the material has been facilitated by Mr. Georg Karlaganis (Switzerland) and Mr. Jim Willis (United States of America).

2. The background material has been developed from the original submissions received on this issue from stakeholders ahead of the informal discussions held in Rome on 23 and 24 October 2008. The facilitators have followed the additional guidance developed by the informal Friends of the Secretariat planning group in preparing the document and have provided the opportunity for comment by Strategic Approach stakeholders by making drafts of the material available on the Strategic Approach website. The background material aims to set out how this issue meets the screening criteria for emerging policy issues developed during the informal discussions and to provide the rationale for the proposed cooperative actions on this issue contained in document SAICM/ICCM.2/10/Add.1.

3. There will be an opportunity for participants to discuss the background material at a technical briefing to be held on Sunday, 10 May 2009, from 9.30 a.m. to 1 p.m.

* Reissued for technical reasons.

** SAICM/ICCM.2/1.

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Annex

Background information in relation to the emerging policy issue of nanotechnology and manufactured nanomaterials

Introduction

1. Nanotechnology and manufactured nanomaterials was not yet an issue at the first session of the International Conference on Chemicals Management and the Strategic Approach for International Chemicals Management thus does not address nanotechnology. However, since 2006, the new technology has evolved rapidly and so the knowledge on potential environmental, health and safety risks.

2. This background document focuses on the human health and environmental safety considerations, potential environmental benefits as well as new social, economic and ethical challenges. The aim of the document is to raise awareness of the current state-of-the-art and proposes cooperative action for the future. The document includes a list of references of key documents for further reading. It is accompanied by a list of possible co-operative actions for the future.

3. Nanotechnology is an enabling technology that is expected to result in major changes in many economic sectors from medicine to energy. It will contribute to the production of many novel materials, devices and products. Depending on the area of application under consideration there are different timelines for the beginning of industrial prototyping and nanotechnology commercialization. First generation products are already on the market in products such as paints, coatings and cosmetics, medical appliances and diagnostics tools, clothing, household appliances, food packaging, plastics, fuel catalysts. More sophisticated products such as pharmaceuticals, diagnostics and applications in energy storage and production are under development.

4. In addition to other commercial uses, it is noted that manufactured nanomaterials are providing critical technological advances that have the potential to significantly reduce pollution, improve energy generation, storage, and use, and improve human and environmental health. Some of these technologies are already deployed, while others are currently undergoing commercial development. Examples include:

- Green energy generation through more efficient solar collectors using fullerenes and lighter and stronger wind turbines that incorporate carbon nanotubes;

- Improved batteries using nanoscale electrode materials like carbon nanotube and nanostructured membranes that are enabling development of improved hybrid and plug-in electric vehicles with faster recharging, longer charges, and more charge/discharge cycles, while reducing consumption of fossil fuels and generation of emissions. This advancement may also allow development of ‘smart’ electrical grids whereby green energy is stored using the plugged-in car batteries;

- Nanoscale iron metal can directly reduce environmental pollution, for example in remediating sites contaminated with organochlorine waste and application as self-cleaning surfaces to reduce urban NOx levels;

- Nanoclays can be used as a substitute for brominated flame retardants that have targeted for phase-out due to environmental and human health concerns;

- Cerium oxide can be used as a fuel additive to reduce particulate emissions and increase fuel efficiency;

- Nanoscale catalysts can reduce the waste generated and energy consumed from a wide range of industrial processes;

- A wide range of nanoscale materials can be used as coatings that provide alternatives to more toxic chemicals, while simultaneously improving the durability and functionality compared to older technologies; and,

- Nanomaterials can be used in the provision and management of clean water (this aspect is being addressed in the WPN project on Fostering Nanotechnology to address Global Challenges).

5. In considering the commercial introduction of manufactured nanomaterials to achieve potential environmental benefits, countries should also give due consideration to potential health or environmental implications of such use of nanomaterials during their whole life cycle. This includes the potential effects of production of the nanoscale materials, as well as the disposition of nanomaterials that may, for example, require new hazard communication programs to recyclers or new concerns for disposal.

Background

6. The issue “nanotechnology and manufactured nanomaterials” was nominated by the Intergovernmental Forum on Chemical Safety (IFCS), the issue “manufactured nanomaterials” was nominated by the Inter-Organization Programme for the Sound Management of Chemicals (IOMC), and the issue “sound management of specific substances - nanomaterials” was nominated by Japan. In its submission IFCS referred to the new challenges, especially in health and safety, posed by rapidly emerging nanotechnological approaches and the need to understand, avoid, reduce and manage risks. IOMC referred to the challenges posed for assessing the safety of nanomaterials, the need to review the methods used for testing and assessing safety and the cooperative international work being undertaken in this regard. Japan referred to the wide use of nanomaterials and the lack of full assessment of health and environmental hazards.

7. Nanotechnology and manufactured nanomaterials are an important new and emerging issue. International activities to address this issue have so far been initiated within the OECD, though nanomaterials and nanotechnology are also broadly used in non-OECD countries. It is important to share this work of OECD with non-OECD countries. Moreover, additional activities, including international cooperation, may be desirable to help that nanotechnology and manufactured nanomaterials are used in a sustainable and beneficial manner. So far, while SAICM is aimed to providing the overarching policy framework for chemicals policy and sound chemicals management, it does not yet address this increasingly important area of chemicals management. SAICM consists of the Dubai Declaration, the Overarching Policy Strategy, and the Global Plan of Action (GPA). The GPA is a “voluntary toolkit” that outlines possible activities that countries can chose to undertake to address areas that they have identified as a priority. SAICM should provide a supportive international framework for GPA implementation, including by helping to support developing countries and countries with economies in transition to develop and implement concrete policies and activities. Including such activities in the GPA could thus help countries to address this issue, to develop and implement appropriate policies, and to access support for such policies. The ICCM may wish to consider whether and how to amend the GPA to address activities related to nanotechnology and manufactured nanomaterials.

Magnitude of the problem

Human health and ecological risks

8. Some of the same unique properties that make manufactured nanoparticles suitable for certain applications also raise questions about the impacts of nanoparticles on human health and the environment. Toxicity and fate of nanoparticles is affected by a variety of physicochemical properties such as size and shape, as well as surface properties such as charge, area, reactivity, and coating type on the particle. These factors also influence the uptake into and distribution within the human body of nanoparticles. As products made from nanoparticles become more numerous, and new uses are identified, the potential for human exposure and for release of nano-size particles into the environment may also increase depending on their stability and other characteristics. However, we are not starting from a blank sheet of paper. For instance, it has been known for many decades that inhaled particles cause damage to the lungs to the lining of arteries, and to the cardio-vascular system. How manufactured nanoparticles are the same as, or different from, natural or incidental nano-scale

particulates, as well as how they differ from their larger-scale counterparts, is the subject of current research. We are only just beginning to understand how nanomaterials impact human health and the environment.

9. We are beginning to learn that, in addition to the dose and the elemental composition of the nanoparticles, factors such as their surface area, the function of the surface, tendency to aggregate and agglomerate, the form and structure of the particles and their surface charge may affect their distribution through the body, and their possible toxicity. Still, for most nanoparticles as well for almost all chemicals it is not known whether and how they are taken up in the body, distributed, metabolised, accumulated and secreted. The levels of exposure that could have detrimental effects on the human body or the environment remain unknown. The development of kinetic models can help in the estimation of realistic doses of particles in target organs that could be affected. Another complication is that, in addition to particles themselves, the potential human health and ecological impacts of their breakdown products, as well as their interactions with other contaminants, also have to be considered.

10. Understanding potential exposure and related toxicity of nanoparticles to biological systems is an important short-term research need and is already underway. For example, the lungs are the primary target site for inhaled nanoparticles. Lungs have an enormous exposed area, and some inhaled and deposited nanoparticles can get into the bloodstream through the air-blood-tissue barrier. We have yet to learn which airborne particles are actually capable of being inhaled as nano-scale particles, including due to such particles tendency to agglomerate or form aggregates. Equally but conversely, it is still unknown to what extent agglomerates will break down into smaller particles in the human body after inhalation or ingestion.

11. In addition to the lungs, the skin provides a potential uptake surface following dermal exposures (such as for cosmetics, sunscreens, and nanoparticle-impregnated clothing and in the workplace). Studies have demonstrated that the intact skin protects the body efficiently and effectively against nanoparticles (such as with TiO2 in sunscreens). However other particles might penetrate intact or broken dermal barriers, and a generic conclusion regarding skin penetration does not exist. However, if skin application of particles does result in exposure of living cells, we need to consider the hazard findings of preliminary studies using animals or cell cultures that have reported oxidative stress, inflammatory responses and cell membrane disruption through lipid peroxidation following nanoparticles exposure.

12. As with other exposure routes, oral ingestion of nanomaterials has not been adequately tested to date. Once ingested, some scientific studies report that nanoparticles are excreted efficiently through the intestine. For small particles (< 100 nm) increased uptake through the intestinal wall has been observed in rats.

13. Once in the bloodstream, studies have shown that nanoparticles can be transported around the body and are taken up by organs and tissues including the liver, spleen, kidneys, bone marrow and heart. Unlike larger particles, nanoparticles may also be taken up by structures within the cell including cell mitochondria and the cell nucleus. It is not known whether nanoparticles, under non-test conditions, are able to enter biological systems in forms that would allow them to move across the blood-brain, placental, or other barriers. However, placental transfer is supported by a recent study, which demonstrated the ability of some nanoparticles to transfer from pregnant mice into the brain and testes of their offspring. A number of studies have also demonstrated that some nanoparticles may be able to be transported directly from olfactory neurons into the central nervous system, by-passing the blood-brain barrier. Due to the fact that data on translocation between organs are based on different approaches and artificial test conditions, the findings largely have not been replicated. More research would therefore be needed in this respect in order to reach definitive conclusion.

14. Finally, a growing number of studies highlight the specific vulnerability of foetuses (through the pregnant mother) and infants to many types of toxics and chemicals, which may strongly impact their future health. More research into potential toxicity of nanoparticles on this vulnerable population should also be undertaken so as to avoid any disruption of this critical window of development.

15. At present, few studies have been carried out on the ecotoxicity and environmental behaviour (fate, transport, and transformation) of nanomaterials. However, existing studies are limited and should be considered preliminary. Despite considerable persisting knowledge gaps, information regarding the ecotoxic effects of nanoparticles is growing steadily. For some nanomaterials, toxic effects on environmental organisms have been demonstrated, as well as the potential to transfer across

environmental species, indicating a potential for bioaccumulation in species at the end of that part of the food chain[1].

16. There are not yet any reliable estimates of possible emissions into the environment that could occur during the production, use and disposal of nanomaterials or products containing nanomaterials. In particular there is a lack of suitable methods to measure nanomaterials in the environment. Similarly, few, if any, studies have been carried out on by-products and breakdown products of nanomaterials.

17. Concerning risk assessment of nanomaterials SCENIHR[1] concludes in its recent opinion:

> "*While risk assessment methodologies for the evaluation of potential risks of substances and conventional materials to man and the environment are widely used and are generally applicable to nanomaterials, specific aspects related to nanomaterials still require further development. This will remain so until there is sufficient scientific information available to characterise the harmful effects of nanomaterials on humans and the environment. The methodology for both exposure estimations and hazard identification needs to be further developed, validated and standardised. The highest risk, and thus concern, is considered to be associated with the presence or occurrence of free (non bound) insoluble nanoparticles either in a liquid dispersion or airborne dusts.*"

Occupational safety and health

18. The workplace is of key importance when considering human safety and health with respect to manufactured nanomaterials. There is the potential for relatively high exposure in such settings. According to our present limited knowledge, worker exposure to nanoparticles occurs primarily through handling nanoparticles in the making of products, although the degree of exposure and possible effects are subjects for further study. Little if anything is known of worker exposure from the release of nanoparticles in the disposal and waste handling processes, in activities of workplace or equipment cleaning and during the packaging, handling and/or transport of products containing nanoparticles.

19. The specific physical and chemical properties of nanoparticles, compared with larger particles, can present unexpected safety risks. The most important material safety dangers are the risks of fire or explosion of oxidizable nanoparticles and of unexpectedly increased catalytic activity. In clouds of dust, the size of the particles and the related specific surface area are critical for explosion potential.

20. There have not yet been any epidemiological studies on the health risks of modern manufactured nanomaterials. Preliminary research demonstrates that forms of carbon nanotubes with the proper dimensions can cause granulomas. Whether this poses a risk for humans would depend on whether there is inhalation exposure to these specific types of carbon nanotubes.

21. Concentrations at the workplace have begun to be measured, and it is not clear whether the current models for local and temporal concentration profiles apply in the case of new nanomaterials. There is a growing level recognition that mass may be unsuitable for measuring nanoparticle exposure and that the surface area of particles, or the number of particles, may be more appropriate metrics. At present there are no international standards on methods for measuring nanoparticles and for estimating exposure to them. Until norms in this area become available, exchanges of experience between measuring engineers and scientists will be particularly important.

22. Proven strategies to reduce occupational exposure are being applied to nanomaterials in many workplaces. Appropriate protection measures are being evaluated and defined by specialists in occupational health and safety as part of international efforts to redress the significant knowledge gaps in this area.. It has been recommended that organisational protection measures should primarily be taken, supported by technical protection measures (such as closed systems) and the substitution of preparations that form powders. Personal protection equipment can occasionally supplement these measures, but in general it should not replace them. Studies show that correct use of technical protection systems and personal protection equipment are effective to product workers from some particle

1 SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), Risk assessment of products of nanotechnologies, 19 January 2009.

types[2345]. However, in many countries such protection equipment is not available or does not meet the necessary safety standards.

The relevance of the issue

23. Many studies have tried to estimate the economic prospects for the nanotechnology market. For example, it has been estimated that the area of nanoelectronics (semiconductors, ultra capacitors, nanostorage and nanosensors) will be worth around $450 billion in 2015. A similar estimate for the case of nanomaterials (particles, coatings and structures) has been made at $450 billion for 2010. Further generations of nano-enabled products based on active nanoscale structures and nanosystems will be developed in the future. Such developments will involve innovations with respect to processes of technical modernization and changes in the interface between humans and machines/products.

24. This foreseen growth prospect for the nanotechnology market is however dependant on the many uncertainties and potential new risks attached to this developing technology.

25. The current discussion on opportunities and challenges of nanotechnology and manufactured nanomaterials focuses, but should not be limited to 1st generation nanoproducts. It is incumbent on governments to develop and apply a policy framework which enables the responsible development of manufactured nanomaterials through science-based risk assessment and appropriate management of the risks. Governments and industry should ensure that nanomaterials are treated in a precautionary manner throughout their life cycle, with appropriate measures being taken to prevent or otherwise control human and environmental exposures until the risks can be better understood.

26. It is important to investigate thoroughly the potential risks as well as the opportunities associated with nanomaterials, and if necessary to take measures to protect humans and the environment. Investments in dangerous applications and the resulting costs to society and the economy, can thus be avoided.

The extent to which the issue is cross-cutting in nature

27. To ensure the safe use of manufactured nanomaterials, occupational safety, health and environmental protection needs to be addressed. Besides these issues there are also ethical and economic challenges posed by nanotechnology and questions about social utility of nanotechnology as for all innovations.

Ethical considerations

28. A number of prestigious reports (e.g. UK Royal Society[6]) and coalitions (labour, environmental, and civil society groups) have advocated to apply precaution to development and commercialization of manufactured nanomaterials. The concept of precaution is often discussed in ethical committees. Other issues also identified as priorities for ethics discussion include: agreement on socially acceptable or unacceptable risks, the application of nanotechnology and other technologies in the field of 'human enhancement', the social and global distribution of benefits, costs and risks, ownership/patent issues, health and safety risks to workers, the environment and the public, regulatory oversight and, public participation in decision making.

29. The United Nations Educational, Scientific and Cultural Organization (UNESCO) publication[7] presents a number of ethical issues that the international community will face in the near future. The report states that as the use of nanomaterials and nanoscale production processes is commercialized new

2 Hullmann A. Measuring and assessing the development of nanotechnology; Scientometrics 70(3): 739-758, 2007.

3 Nanosafe II.

4 Guidance for Handling and Use of Nanomaterials at the Worklace, BAUA, VCI, 2007, http://www.vci.de.

5 http://www.cdc.gov/niosh/updates/upd-02-13-09.html.

6 The Royal Society and the Royal Academy of Engineering: Nanoscience and nanotechnologies: opportunities and uncertainties; 2004, page 8.

7 http://unesdoc.unesco.org/images/0014/001459/145951e.pdf.

ethical and political issues can be generated and old ones will be activated. It further states that "nanotechnologists are hyper-aware of the need to study both potential uses and potential harms well in advance of their commercialization. This recognition and precautionary direction to corporate research is novel." It notes that the institutional and organizational framework for address the concerns across competing interests associated with creating and adoptions of standards and international best practices are not yet well developed. The report states that the ease of communication and access to information by experts in most countries would indicate that nanotechnology will be an international scientific project and the "knowledge divide" between countries may look different from the past with the possibility of the greatest divide within nations rather than between nations. Relevant to this is the question of how nanotechnology research that could benefit the poorest should be promoted, for example research on applications that could address the Millennium Development Goals.

30. A related question is the extent to which all nations will benefit equally from the new scientific knowledge – on nanotechnology and innovative research more generally. The report notes the issues of intellectual property rights and rewards, public scrutiny of scientific research, accountability of research and the use of scientific information in the context of antiterrorism efforts all may impact the kind and quality of science. The lack of the necessary infrastructure to manage good science may result in developing countries unable to obtain the best and most reliable scientific knowledge and practices.

Social utility of nanotechnology

31. The way in which we use available natural resources has effects on our health and the environment and is to a large part heavily influenced by cultural aspects, personal and economic choices. Natural resources are an important factor in the economy and an important element of our welfare. Proponents hope that technological innovations, including those resulting from nanosciences and nanotechnologies, can play a key role in the more efficient use of our resources.

32. Before the development or use of any application from nanotechnologies, the question of social utility should be asked. To answer that question the potential contribution of specific applications from nanotechnologies, alternative technologies or non-technology option, to solve a specific socially relevant problem such as climate change, water shortages and starvation should be known. Health and environmental risks and implications for society and economy should be taken into account as well as existing alternative solutions. The merits of particular options may be specific to particular countries or regions.

33. For the majority of developing countries, commodity production is the backbone of the economy[8]. Historically, advances in science and technology have also had profound impacts on commodity production and trade. There are concerns that nanotechnology will change the commodity markets, disrupt trade and eliminate jobs. Worker-displacement brought on by commodity obsolescence will hurt the poorest and most vulnerable, particularly those workers in the developing world who don’t have the economic flexibility to respond to sudden demands for new skills or different raw materials. Currently, nanotech innovations and intellectual property protection are being driven mainly from developed countries. The world’s largest transnational companies, leading academic laboratories nanotech start-ups are seeking intellectual property on novel materials, devices and manufacturing processes. Commodity dependent developing countries must gain a fuller understanding of the direction and impacts of nanotechnology-induced technological transformations, and participate in determining how emerging technologies could affect their futures.

34. There are concerns as well that developed countries will benefit more from nanotechnology and that developing countries will suffer more from potential risks (e.g occupational health and safety standards may be lower, waste management and waste disposal infrastructure may not be adequate for nanomaterials and nano-enabled products). This is one element in the range of aspects that need to be fully considered. The potential for nanotechnology to widen existing economic inequities is a significant issue. This underscores the importance of evaluating nanotechnology’s potential social and economic ‘costs’, alongside potential ‘benefits’.

8 The Potential Impacts of Nano-Scale Technologies on Commodity Markets: The Implications for Commodity Dependent Developing Countries; Research Papers 4; ETC Group, South Center, November 2005.

The level of knowledge about the issue

35. Both developed and emerging countries are devoting increasing resources to promoting nanoscience and nanotechnologies in an effort aimed at gaining a leading position in the field and reaping the benefits promised, often without adequately addressing the potential risks.

36. However, the belief is also becoming widely shared that the hopes pinned on this emerging technology will fully materialise only if its development will take place responsibly. The level of attention directed towards the environmental, health and safety (EHS) implications and ethical, legal and social issues (ELSI) deriving from nanotechnology and its applications has increased considerably in recent years. Addressing these issues properly and responsibly will be of paramount importance for the success of nanotechnology.

37. Most of the countries with an interest in nanotechnology and supranational organisations giving high priority to ensuring the responsible development of this technology. Governments, regulatory and standards-setting agencies/bodies have started to develop expertise and technical background to cope with the related regulatory issues. Many countries and the European Commission have adopted action plans how to deal with EHS and ELSI issues.

The extent to which the issue is being addressed by other bodies

38. In 2006 OECD established a Working Party on Manufactured Nanomaterials (WPMN) as a subsidiary body of its Chemicals Committee. The objective of the WPMN is to promote international co-operation in human health and environmental safety aspects of manufactured nanomaterials among member and non-member countries, NGOs, industry and IGOs. Currently, the following areas are covered by the work plan of the WPMN:

- Development of an OECD Database on Human Health and Environmental Safety (EHS) Research
- EHS Research Strategies on Manufactured Nanomaterials (including Occupational Health and Safety)
- Safety Testing of a Representative Set of Manufactured Nanomaterials
- Manufactured Nanomaterials and Test Guidelines.
- Co-operation on Voluntary Schemes and Regulatory Programmes
- Co-operation on Risk Assessment
- The Role of Alternative Methods in Nano Toxicology
- Exposure Measurement and Exposure Mitigation

39. Since the establishment of the WPMN, much progress has been achieved. Most noticeably, a Sponsorship Programme for testing manufactured nanomaterials for human health and environmental safety endpoints was launched in November 2007.

40. In addition, in 2007 OECD’s Committee for Scientific and Technological Policy established a Working Party on Nanotechnology (WPN). The aim of this programme is to address Science and Technology (S&T) Policy issues related to the responsible development and use of nanotechnology and the potential benefits nanotechnology can bring to society, taking into account public perceptions related to advances in nanotechnology and its convergence with other technologies, without forgetting legal, social and ethical issues. The following projects are in the work plan of the WPN:

- Statistical framework for nanotechnology
- Monitoring and benchmarking nanotechnology developments
- Addressing challenges in the business environment specific to nanotechnology
- Fostering nanotechnology to address global challenges
- Fostering international scientific co-operation in nanotechnology
- Policy roundtables on key policy issues related to nanotechnology

41. The project areas of the WPN, mentioned above, are based on work undertaken during 2007-2008. This work has resulted in several forthcoming reports which address the following issues: nanotechnology developments and impacts based on available indicators and statistics; impacts of nanotechnology on companies and business environments based on a large number of company case

studies; identification of S&T infrastructures and co-operation opportunities across countries; outreach and public engagement; policy developments and responses across countries; opportunities and barriers for nanotechnology to mitigate the global challenge of clean water. In addition, the WPN has facilitated policy discussions between participating countries in numerous workshops.

42. Detail information and publications of OECD's work on manufactured nanomaterials and nanotechnology, are available at free download from http://www.oecd.org/env/nanosafety and www.oecd.org/sti/nano,

43. ISO has established Technical Committee 229 – Nanotechnologies. Currently the following 4 working groups have been established: Terminology and nomenclature; Measurement and characterization; Health, Safety and Environmental Aspects of Nanotechnologies; and Material specifications. The following two documents have been published: ISO/TR 12885:2008 Nanotechnologies -- Health and safety practices in occupational settings relevant to nanotechnologies; and: ISO/TS 27687:2008 Nanotechnologies -- Terminology and definitions for nano-objects -- Nanoparticle, nanofibre and nanoplate. About 30 work items are currently in development by the four working groups.

44. OECD WPMN and WPN and ISO/TC229 have been routinely co-ordinating through both Secretariats as well as national representatives.

45. The UNESCO Ethics of Science and Technology Programme was created in 1998 with the establishment of the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) to give an ethical reflection on science and technology and its applications. This programme aims to promote consideration of science and technology in an ethical framework by initiating and supporting the process of democratic norm building. This approach is founded upon UNESCO's ideal of "true dialogue, based upon respect for commonly shared values and the dignity of each civilization and culture". Awareness raising, capacity building and standard-setting are therefore the key thrusts of UNESCO's strategy in this and all other areas.

46. UNESCO has invited well-known experts in nanotechnology to discuss the state of the art of nanotechnology, examine the controversy surrounding its definition and explore related ethical and political issues. A 2006 report "The Ethics and Politics of Nanotechnology" "outlines what the science of nanotechnology is, and presents some of the ethical, legal and political issues that face the international community in the near future." UNESCO has recently published a book on "Nanotechnologies, Ethics and Politics. The aim of the book is to inform the general public, the scientific community, special interest groups and policy-makers of the ethical issues that are salient in current thinking about nanotechnologies and to stimulate a fruitful interdisciplinary dialogue about nanoscale technologies among these stakeholders.

47. A plenary session was held on nanotechnology and manufactured nanomaterials during the sixth session of the Intergovernmental Forum on Chemical Safety (IFCS Forum VI, 15-19 September 2008, Dakar, Senegal). The objective was to exchange information in order to help raise the awareness of participants to the potential new opportunities, the new challenges and the new risks posed by manufactured nanomaterials. The Forum VI adopted unanimously the Dakar Statement consisting of 21 recommendations for further actions and recommended that these be considered at ICCM2.[9]

48. FAO and WHO have planned to convene a joint Expert Meeting which aims to identify knowledge gaps including issues on food safety, review current risk assessment procedures, consequently support further food safety research and develop global guidance on adequate and accurate methodologies to assess potential food safety risks that may arise from nanoparticles. Joint FAO/WHO Expert Meeting on the Application of Nanotechnologies in the Food and Agriculture Sectors: Potential Food Safety Implications is to be held on 1-5 June 2009, at FAO Headquarters, Rome, Italy. FAO/WHO has called for experts and information for the meeting.

49. For many years, intergovernmental organisations have collaborated on chemical safety through the Inter-Organization Programme for the Sound Management of Chemicals (IOMC). The IOMC has discussed the safety of nanomaterials on a number of occasions.

9 The Dakar recommendations on manufactured nanomaterials are contained in document SAICM/ICCM2/INF/5.

The feasibility of the action proposed

50. Products containing nanomaterials are already on the market. The existing knowledge and methodological gaps do not allow a comprehensive assessment of health and environmental risks. Therefore, it is crucial to strengthen safety research and the development of the necessary methodological tools and data for safety evaluations. Until this is done, it would be premature to implement a science-based regulatory approach. Under these circumstances governance models should be worked out ensuring the safe use and handling of nanomaterials based on precaution.

51. There is a range of activities underway related to the safety of manufactured nanomaterials. These activities range from academic studies, through to national governments as well as regional and international studies. Other stakeholders also have activities which have a bearing on the issue. Information on these activities should be made available as possible in a digestible form to encourage the raising of awareness. Intergovernmental Organisations also have a responsibility in this context.

Possible cooperative action for the future

52. Governments that have not otherwise done so may wish to consider the relevance of nanotechnology and manufactured nanomaterials for their national situation. This could be done by, for example, integrating nanotechnology considerations into the national profile. Furthermore, the ICCM may wish to consider 1) undertaking intersessional work to explore issues relevant to developing and transition countries on the sound management of nanomaterials and 2) whether the GPA should be amended to address activities related to nanotechnology and manufactured nanomaterials.

53. There is a range of activities underway in academia, NGOs, industry and governments related to the environmental health and safety, and environmentally-beneficial applications of manufactured nanomaterials. Relevant stakeholders should consider making as much of this information as possible publicly available, including through clearinghouses. Progress on this has been made by a number of entities, including the databases of the International Council on Nanotechnology (ICON), the Woodrow Wilson Institute's Project on Emerging Nanotechnologies, the NIOSH Nanoparticle Information Library, and the OECD WPMN's public **Database on Research into the Safety of Manufactured Nanomaterials**. Intergovernmental Organisations and Non Governmental Organisations may be able to make a significant contribution in this regard.

54. Some governments are devoting considerable resources towards research and development focused on new applications based on nanotechnology. Such governments may wish to consider balancing such applications resources with an appropriate level towards research to understand the environmental health and safety implications. Government may be further encouraged to develop comprehensive producer responsibility systems to take into account the specifics of nanotechnology and manufactured nanomaterials.

55. Governments may also wish to consider funding research on nanotechnology applications that may be useful in meeting the actions called for in the Johannesburg Plan of Implementation of the World Summit on Sustainable Development, including such actions in developing countries and countries with economies in transition.

56. The OECD has opened up its two working parties (WPMN and WPN) to active participation by non-member economies and other observers. A number of non-OECD countries have participated to-date, with mutual benefit, including Argentina, Brazil, China, India, Russian Federation, Singapore, and Thailand. Non-OECD countries or other observers with an interest in the issues being explored by the respective working parties may wish to contact the OECD secretariat and participate in those activities. Similarly, countries, NGOs and industry with an interest in participating in ISO TC229 and who are not already doing so may wish to contact their national standards bodies or TC229 itself.

57. Countries, NGOs, industry and IGOs with an interest in the potential environmental benefits of manufactured nanomaterials may wish to consider participating the OECD Conference on the Potential Environmental Benefits of Manufactured Nanomaterials to take place 15-17 July, 2009 at the OECD Conference Center in Paris, France.

58. While the health and environmental safety implications of manufactured nanomaterials continue to be explored, governments and industry should consider taking measures to prevent or minimize

exposure of workers and consumers, and releases to environment, particularly for hazardous manufactured nanomaterials or where there is uncertainty around the environmental and human health impact. Steps to inform downstream users through the whole supply chain via Material Safety Data Sheets (MSDS) or other means should be taken where appropriate.

Other relevant information

International Organizations

- **Organization for Economic Cooperation and Development (OECD) Working Party on Manufactured Nanomaterials (WPMN): www.oecd.org/env/nanosafety**

  - Report of the OECD Workshop on the Safety of Manufactured Nanomaterials: Building Co-operation, Co-ordination and Communication (2006) [ENV/JM/MONO(2006)19]

    Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table:
    1(2006) [ENV/JM/MONO(2006)35];
    2 (2007); [ENV/JM/MONO(2007)16]
    3 (2008) [ENV/JM/MONO(2008)7]; and
    4 (2008) [ENV/JM/MONO(2008)29]

  - Manufactured Nanomaterials: Programme of Work 2006-2008 (2008) [ENV/JM/MONO(2008)2]

  - List of Manufactured Nanomaterials and list of Endpoints for Phase One of the OECD Testing Programme (2008) [ENV/JM/MONO(2008)13/REV]

    Forthcoming publications:

  - Preliminary Analysis of Exposure Measurement and Exposure Mitigation in Occupational Settings: Manufactured Nanomaterials
  - Analysis of Information Gathering Initiatives: Manufactured Nanomaterials
  - Table of Comparison on Information Gathering Schemes: Manufactured Nanomaterials
  - EHS Research Strategies on Manufactured Nanomaterials: Compilation of Outputs
  - Report of the Workshop on Exposure Assessment and Exposure Mitigation
  - Identification and Compilation and Analysis of Guidance Information for Exposure -
  - Measurements and Exposure Mitigation
  - Emission Assessment for Identification of Sources and Release of Airborne -
  - Manufactured Nanomaterials in the Workplace – Compilation of Existing Guidance
  - Comparison of Guidance on Selection of Skin Protective Equipment and Respirators - for Nanotechnology Workplace
  - Sponsorship Programme for Testing Manufactured Nanomaterials: Guidance Manual for Sponsors

- **OECD Working Party on Nanotechnology, http://www.oecd.org/sti/nano**

  - Nanotechnology: an overview based on indicators and statistics (STI Working Paper);
  - The Commercialization of Nanotechnology: Evidence, Impacts and Policy Implications (Monograph); and
  - Review of National STI Policy Approaches to Nanotechnology (Web report).
  - Policy briefs are in preparation on:
  - Public Engagement in Nanotechnology
  - The Commercialization of Nanotechnology.

    Workshop reports:

- Nanotechnology and the Global Challenge of Access to Clean Water: workshop at the Nanotechnology Northern Europe in Copenhagen, Denmark, in September 2008, http://www.nanotech.net;

- Nanotechnology and Public Engagement: a conference and a WPN workshop in Delft, the Netherlands, in October 2008, http://www.oecd.org/sti/nano and http://www.ez.nl/Onderwerpen/Meer_innovatie/Nanotechnologie

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- **Sixth Session of the Intergovernmental Forum on Chemical Safety, Dakar, Senegal, 15 – 19 September 2008 (IFCS Forum VI)**
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- **UNESCO Ethics of Science and Technology Programme,** http://portal.unesco.org/shs/en/ev.php-URL_ID=10581&URL_DO=DO_TOPIC&URL_SECTION=201.html

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- Germany – Federal Environment Agency - Legal appraisal of nanotechnologies, http://www.umweltbundesamt.de/technik-verfahren-sicherheit/nanotechnologie/index.htm

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- United Kingdom – Nanotechnologies at Defra http://www.defra.gov.uk/environment/nanotech/index.htm

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Other participating stakeholders

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