ADDRESSING NANOMATERIALS AS AN ISSUE OF GLOBAL CONCERN

Prepared by
The Center for International Environmental Law (CIEL)

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Executive Summary

Nanotechnology is the manipulation, manufacture and use of the novel physical, chemical and biological properties of substances that exist at the nanoscale: one billionth of a meter or less. The potential overall impact of nanotechnologies on society has been heralded as being on a par with the industrial revolution. Nanoscience and nanotechnologies are revolutionizing our understanding of matter and are likely to have profound implications for all sectors of the economy, including agriculture and food, energy production and efficiency, the automotive industry, cosmetics, medical appliances and drugs, household appliances, computers, and weapons.

No one knows how many products on the market today contain nanoparticles or are manufactured with the help of nanotechnologies. The only inventory available, compiled by the Woodrow Wilson Center for Scholars, identifies over 800 nanotechnology-based consumer products. Many of these are traded internationally.

Nanotechnology is unusual in several respects that simultaneously enhance its potential benefits and risks and complicate consideration of whether and, if so, how to regulate it. Nanotechnology applications use the very different properties that materials have at the nanoscale compared to the same materials made at larger sizes. Nanoscale materials may dissolve differently, have different magnetic properties, react differently to other substances, or reflect light differently than they would in the bulk form.

Nanotechnology promoters stress the potentially beneficial applications that these new technologies may enable, including in developing countries. In contrast, many scientific institutions across the world have underscored the need to assess carefully their possible health and environmental risks. A number of international organizations and civil society groups advocate a careful assessment of the various socio-economic impacts and health and environmental risks that may be associated with nanotechnologies and materials.

A very large knowledge gap exists with regard to basic understanding of the interaction of nanomaterials with environmental and biological systems such as the human body. Estimates suggest that less than three percent of nanotechnology funding is devoted to investigating the health and environmental impacts of nanotechnology and nanomaterials. Nevertheless, the existence of serious adverse effects of some nanomaterials to both human health and the environment, including the potential of some nanomaterials to bioaccumulate and persist in the environment, is clearly established and recognized as such by major scientific institutions in the world. Moreover, as some nanomaterials may have the ability to travel long distances through environmental media such as wind and water, as well as through international trade, there is a distinct possibility that they could contribute to transboundary harm, such that countries may not be able to protect themselves unilaterally from the potential risks.

These factors contribute to the conclusion that nanotechnologies and nanomaterials may present an issue of global concern warranting international action. In view of the specific issues raised by nanotechnologies, an effective framework for undertaking international action will be needed. Such a framework should be global in coverage; precautionary, participatory, and transparent; comprehensive in terms of the scope of risks addressed throughout the life cycle of nanomaterials; and adaptive and flexibly designed so that it can respond to new and unforeseen issues. No such framework now exists.

Several international organizations have begun addressing some of the issues raised by the rapid development of nanotechnologies and the potential environmental health risks of nanomaterials. The Organization for Economic Co-Operation and Development (OECD) has established two working parties: the Working Party on Manufactured Nanomaterials to coordinate research activities among its members; and the Working Party on Nanotechnology to provide advice on a number of policy-related issues. The International Organization for Standardization (ISO) created a technical group (TC 229) to produce standards for classification, terminology and nomenclature, basic metrology, calibration and certification, and environmental issues with respect to nanotechnology. The United Nations Educational, Scientific and Cultural Organization (UNESCO) has worked since 2005 on mapping the wide ethical and political dimensions of nanotechnologies from a global perspective, and on exploring the implications they may have for its members.

Each of these processes can make important contributions to bridging the knowledge gap and mapping the wide scope of issues that need to be addressed. None of these organizations, however, has the combination of capacity, mandate, and universal membership required to adequately and comprehensively address nanotechnology and nanomaterials as an issue of global concern. They thus cannot reasonably be expected to serve as the main forum to address nanotechnologies and nanomaterials as an issue of global concern. Nevertheless, they can play important roles in the context of the needed global framework.

Similarly to those processes, none of the existing multilateral environmental agreements (MEAs) provide the needed global framework for nanotechnologies and nanomaterials. Although none of the chemicals MEAs use particle size to define their scope or obligations, a few could, at least in theory, be used to address some issues linked to the release of nanomaterials into the environment.

The Stockholm Convention on Persistent Organic Pollutants (POPs) could potentially address those nanomaterials that are organic and satisfy the Stockholm criteria of toxicity, persistence, bioaccumulation, and long-range environmental transport. At present, however, the current knowledge gap would likely not support the listing of any existing nanomaterials in the Convention. Moreover, most of the known existing nanomaterials are not organic chemicals.

The Basel Convention on Transboundary Movement of Hazardous Waste could be used to regulate waste containing nanomaterials, provided that they qualify as "hazardous waste" as defined by the Convention. However, given the poor state of current knowledge, it may be difficult or even impossible to define environmentally sound management of some wastes containing nanomaterials. Significant progress will first need to be made to further understand the toxicity of nanomaterials throughout their life cycle, before the provisions of the Basel Convention can be used effectively.

The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (Rotterdam Convention) could be used to provide countries with the right to require their prior informed consent before other countries could export products or articles containing specific hazardous nanomaterials to them. However, the nature of the Rotterdam Convention makes it difficult to list new substances so that they may become subject to its controls; ordinarily, only substances that are already banned or severely restricted in two or more countries may be considered for listing, which means that the Convention takes a somewhat backward-looking, rather than forward-looking, precautionary approach; and new listings are made on a chemical-by-chemical basis, making it difficult for the Convention to address nanomaterials in a comprehensive manner. Moreover, the Rotterdam Convention is not intended to address the regulation of chemicals beyond the tool of prior informed consent in international trade.

The Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (Aarhus Convention) contains important principles about transparency, public participation and access to justice that could guide the creation and operation of a global nanotechnologies framework.

The Strategic Approach to International Chemical Management (SAICM) is a global process that is currently addressing nanotechnology as an emerging issue. As such, it could provide an appropriate forum to begin addressing nanotechnology and nanomaterials as an issue of global concern in a comprehensive manner. It is global and intended to balance relevant North-South concerns; it includes broad participation by governments, international organizations, and civil society; it has an appropriately broad mandate with objectives covering risk reduction, information sharing and governance, all highly relevant in the context of nanotechnologies and nanomaterials as an emerging issue of global concern; and it is based on principles of transparency, public participation and precaution.

List of Acronyms and Abbreviations

BIAC	Business and Industry Advisory Committee to the OECD
BSI	British Standard Association
CEN	European Committee for Standardization
COMEST	World Commission on the Ethics of Scientific Knowledge and Technology
EHS	Environment and Health Safety
EU	European Union
GM	Genetically Modified
GPA	Global Plan of Action
ICCM	International Conference on Chemicals Management
IEC	International Electrotechnical Committee
IFCS	International Forum on Chemical Safety
IO	International Organization
IOMC	Inter-Organization Programme for the Sound Management of Chemicals
ISO	International Organization for Standardization
ITU	International Telecommunication Union
MEA	multilateral environmental agreements
NGO	non-governmental organization
OECD	Organization for Economic Co-Operation and Development
PIC	prior informed consent
POP	persistent organic pollutant
SAICM	Strategic Approach for International Chemicals Management
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risk
TUAC	Trade Union Advisory Committee
UNECE	United Nations Economic Commission for Europe
UNEP	United Nations Environment Programme
UNESCO	United Nations Educational, Scientific and Cultural Organization
USEPA	United States Environmental Protection Agency
WHO	World Health Organization
WPMN	Working Party on Manufactured Nanomaterials
WPN	Working Party on Nanotechnology

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1. Introduction

1. Few technologies have triggered as many comments, hopes, fears and radical statements as nanotechnology. The rapid development of nanotechnology and its growing importance for all aspects of society have been called a "nano-revolution" and heralded as being on a par with the industrial revolution.[1]

2. Nanotechnology promises to be a transformational technology, such as electricity and the steam engine, with profound implications for all sectors of the economy, including agriculture and food, energy production and efficiency, the automotive industry, cosmetics, medical devices and drugs, household appliances, computers, environmental remediation technologies and weapons.[2] Nanotechnology is unusual in several respects that simultaneously enhance its potential benefits and risks and complicate consideration of whether and, if so, how to regulate it. That consideration is further complicated by the potential flow of nanomaterial through international trade channels as both products and wastes, and by the potential long-range transport of some of these materials after their release into the environment.

3. This paper explores questions of how and whether manufactured nanomaterials should be addressed as an issue of global concern. The paper is presented in five Parts:

Part 1 (the present Part) is the Introduction.

Part 2 describes basics of nanotechnology terminology, properties, benefits, and risks.

Part 3 evaluates whether the potential release of nanomaterials into the environment presents an issue of global concern, such that international action is

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[1] For examples, see *The Ethics and Politics of Nanotechnology*, UNESCO, 2006, p.3 ("nano could lead the next industrial revolution"), available at http://unesdoc.unesco.org/images/0014/001459/145951e.pdf

[2] "Some experts consider the emergence of nanotechnology to be an industrial revolution that—much like the invention of electricity—will have an enormous impact on society, the economy and life in general" in *Nanotechnology, small matters, many unknown*, Swiss Re, 2004, p.7 available at http://www.swissre.com/resources/31598080455c7a3fb154bb80a45d76a0-Publ04_Nano_en.pdf

needed, and identifies the essential characteristics of an international approach to this issue of global concern.

Part 4 assesses existing international actions and processes that currently deal with nanomaterials and nanotechnologies.

Part 5 provides an overview of existing multilateral environmental agreements that might be used to address issues raised by nanotechnology and manufactured nanomaterials as an issue of global concern.

4. Numerous other aspects of nanotechnology have been identified and warrant further analysis, but are beyond the scope of this paper. For example, the use of nanotechnology in military applications, human enhancement, or surveillance may raise important questions of ethics, human rights, privacy, equity, and international law.

2. Nanotechnology Basics

2.1. Terminology

5. The use of the term "nanotechnology" commonly refers to the branch of science and engineering devoted to designing, producing and using structures, devices and systems by manipulating atoms and molecules at the nanoscale, i.e., those having one or more dimension on the order of 100 nanometers (100 millionth of a millimeter) or less.[3] The products of these efforts are called "nanomaterials," consisting of nanoparticles and the grouping of these particles into structures that may be larger than nanoscale.

6. Several definitions of "nanotechnology" and "nanotechnology products" have been developed, often for specific purposes. Because nanoscience and nanotechnology have emerged rapidly and recently, the vocabulary used within the contributing disciplines has not always been consistent. Also, there have been, and continue to be, serious challenges what, exactly, should fall within the precise scope of the nanoscale.

7. This report uses the various nanotechnology terms in a manner that is consistent with the "Publicly Available Specification on the Vocabulary for Nanoparticles" of the British Standards Institution (BSI 2005) and also used by the Scientific Committee on Emerging and Newly Identified Health Risk (SCENIHR) of the European Commission. These include the following:

Nanoscale: one or more dimensions of the order of 100 nanometer (nm) or less.

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[3] There is a growing debate of whether it is appropriate to define nanoparticles only through their size or to limit the definition to particles under 100 nm. See, for example, *Discussion Paper on Nanotechnology Standardization and Nomenclatures Issues*, Friends of the Earth Australia, August 2008, available at http://www.ecostandard.org/downloads_a/2008-10-06_foea_nanotechnology.pdf). These issues will not be addressed in the present paper.

Nanoscience: the study of phenomena and manipulation of materials at atomic, molecular and macromolecular scales, where properties differ significantly from those at a larger scale.

Nanotechnology: the design, characterization, production and application of structures, devices and systems by controlling shape and size at the nanoscale.

Nanomaterial: material with one or more external dimensions, or an internal structure, which could exhibit novel characteristics compared to the same material without nanoscale features.

Nanoparticle: particle with one or more dimensions at the nanoscale.

Nanostructured: having a structure at the nanoscale.

2.2. Properties, Benefits, Risks

8. Many examples exist in the natural world of structures with one or more dimensions at the nanoscale. Some technologies have, in the past, incidentally involved such nanostructures. Only recently, however, has it been possible to manufacture nanostructures intentionally.

9. Nanotechnology applications frequently give materials very different properties compared to material of the same chemical composition made at larger sizes.[4] These new properties are associated with the very large surface-area-to-volume ratios experienced at these dimensions, and with the quantum effects that are not exhibited by larger-sized particles. Examples include nanomaterials of very thin films used as catalysts and electronics; two-dimensional nanotubes and nanowires for optical and magnetic systems; and nanoparticles used in cosmetics, pharmaceuticals, and coatings.

10. Nanoscale materials may dissolve differently, have different magnetic properties, react differently to chemicals, or reflect light differently than they would in the bulk form. Carbon is a familiar example. The properties of two forms of pure carbon, graphite and diamonds, are well-known. However, when carefully shaped into tiny nanotubes, carbon can become ten times stronger, while remaining ten times lighter, than steel.

11. Nanotechnology applications may have potentially significant, beneficial impacts on society. Nanotechnology has already been embraced by numerous industrial sectors, such as information and communications, but it is also used in sectors such as the food and feed industries, energy technology, and medicines and medical devices, to name a few. Nanomaterials are also promoted as offering new opportunities for the reduction of environmental pollution.

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[4] *Modified Opinion on the Appropriateness of Existing Methodologies to Assess the Potential Risks Associated with Engineered and Adventitious Products of Nanotechnology*, The European Commission, available at http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_003b.pdf. (the 2006 SCENHIR Summary).

12. Nevertheless, "hopes that nanotechnology will be an essential part of solving the globe's energy, food, and water problems should be tempered by recalling a century of revolutionary technologies that failed to live up to their early promises such as nuclear energy, supersonic airplanes or gene therapy."[5] As the United Nations Environment Programme (UNEP) *Global Environmental Outlook 2007* (the *2007 GEO Year Book*) notes, the potential new opportunities of nanotechnologies for the reduction of environmental pollution and impacts need to be carefully assessed:

> Public and private organizations have been quick to recognize the apparent benefits of nanotechnology, but there is a corresponding need to assess the full costs of this emerging field, including the life cycle costs of products. For example, many nanostructured materials save energy while being used but their manufacture may be very energy intensive. Cost-benefits analysis must take into account the true environmental impacts of these materials – and the fate and transport of nanoparticles released in the environment must be more fully investigated. [6]

13. Furthermore, the emergence of these new nanomaterials has raised concerns about their potential health and environmental impacts. In 2006, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENHIR), an independent scientific committee advising the European Commission, published a revised opinion noting that "these newly identified processes and their products may expose humans, and the environment in general, to new health risks, possibly involving quite different mechanisms of interference with the physiology of human and environmental species."[7]

14. Based on this 2006 revised opinion, the Directorate General for Health and Consumer Protection of the European Commission stated:

> The new materials may also represent new health risks. Humans have developed mechanisms of protection against various environmental agents of different sizes. However, until recently, they had never been exposed to synthetic nanomaterials and their specific characteristics. Therefore the normal human defense mechanisms associated with, for example, immune and inflammatory systems may well not be able to respond adequately to these nanoparticles. In addition, nanoparticles may also disperse and persist in the environment, and therefore have an impact on the environment.[8]

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[5] See, Gary.E. Marchant and Douglas J. Sylvester, "*Transnational Models for the Regulation of Nanotechnology*," Journal of Law, Medicine and Ethics, Winter 2006, p.1, available at http://cns.asu.edu/cns-library/documents/Marchant_Independent.pdf.
[6] *Global Environmental Outlook*, United Nations Environment Programme, 2007, p.66, available at http://www.unep.org/geo/yearbook/yb2007/PDF/GYB2007_English_Full.pdf.
[7] Supra, note 4, at 8. Available at http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_003b.pdf.
[8] See the European Commission Summary presentation of the 2006 SCENIHR report, question 1, "*what is nanotechnology*," level 2, available at http://ec.europa.eu/health/opinions2/en/nanotechnologies/l-2/1-introduction.htm.

3. Do Nanotechnologies and Materials Comprise an Issue of Global Concern such that International Action Is Warranted?

15. Faced with the dramatic societal changes that nanotechnologies may bring, and responding to concerns expressed by both civil society and the scientific community, a number of countries have begun to review the capacity of their national regulatory systems to adapt to the new nano-paradigm and to address some of the specific issues raised by the rapid development of nanotechnologies.[9] Nevertheless, as David Rejeski, Director of the Woodrow Wilson Center for Scholars Project on Emerging Nanotechnologies, notes, "most countries are taking a wait-and-see approach, assuming that existing regulations will deal with nanotechnology, even if new materials emerge with radically different properties."[10,11]

16. Moreover, recent history demonstrates that the nature of many chemicals, including international trade in such substances, requires them to be managed at the international level throughout their life cycles, notwithstanding the regulatory activities that individual States may undertake. For example, the fact that Persistent Organic Pollutants (POPs) are toxic, last a long time in the environment, bioaccumulate, biomagnify, and can travel long distances through wind and water, convinced States that the environmental health risks of POPs could be addressed effectively only through a global, legally binding approach.[12] Similarly, the 2002 Global Mercury Assessment, published by UNEP and the Inter-Organization Programme for the Sound Management of Chemicals (IOMC), concluded that mercury is an issue of global concern due to its significant negative effects on human health and the environment, its ability to bioaccumulate in ecosystems, its persistence in the environment once anthropogenically introduced, and its long-range atmospheric transport,[13] even though a large number of countries had been regulating many mercury uses and sources for years.[14] Trade in dangerous substances has also been recognized as an issue of global concern, warranting

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[9] See, for example, *Regulatory Aspect of Nanomaterials*, Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, COM(2008) 366 final, 17 June 2008, available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0366:FIN:EN:PDF.

[10] *Comment on a Framework Convention for Nanotechnology*, Environmental Law Reporter, vol. 38, No. 8, p. 10519.

[11] *Novel Material in the Environment: The Case of Nanotechnology*, UK Royal Commission on Environmental Pollution, November 2008, at para. 4.14 and 4.16, available at http://www.rcep.org.uk/novel%20materials/Novel%20Materials%20report.pdf.

[12] "The governing council . . . [c]oncludes that international action, including a global legally binding instrument, is required to reduce the risks to human health and the environment arising from the release of the twelve specified persistent organic pollutants." UNEP Governing Council Decision 19/13 C of 7 February 2007.

[13] See *Global Mercury Assessment*, UNEP Chemicals, 2002, p. 228 and following. Available at http://www.chem.unep.ch/MERCURY/Report/Final%20report/final-assessment-report-25nov02.pdf.

[14] See, for example, Directive 2007/51/EC of the European Parliament and of the Council of 25 September 2007 amending Council Directive 76/769/EEC relating to restrictions on the marketing of certain measuring devices containing mercury, available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:257:0013:0015:EN:PDF; Global Mercury Assessment, s*upra* note 13, section 9.2.3 for a general overview.

the negotiation and adoption of international instruments such as the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (the Basel Convention).[15]

17. These examples demonstrate that international frameworks may be necessary when countries, acting alone, cannot address the challenges posed by the production, use, transport, trade, or disposal of certain substances and technologies. While responsible action by individual countries is essential, the environmental, health and other societal challenges potentially posed by nanotechnologies may be simply too broad to be addressed solely through national initiatives, and may require an international regulatory framework to support collective action.

18. The balance of this Part identifies criteria that could characterize an issue of global concern, evaluates whether nanotechnologies and nanomaterials fulfill these criteria, and identifies some of the characteristics that international actions with respect to nanotechnology and nanomaterials should have.

3.1. Identifying criteria that may characterize an issue of global concern

19. The rapid development of nanotechnologies and commercialization of nanomaterials should be examined first in light of customary principles of international environmental law, as they are now enshrined in the 1992 Rio Declaration on Environment and Development (the Rio Declaration) and other international instruments. For example, the principle of addressing transboundary damages of industrial processes by means of international law is reinforced by Rio Principle 19, which called for information exchange "at an early stage and in good faith" on activities that "may have a significant adverse transboundary environmental effect."[16] UNEP recognized the relevance of this principle in the context of the rapid development of nanotechnologies in its *2007 GEO Year Book*, which states that "[i]ncreased international cooperation is also needed to address transboundary issues involving the development and use of nanomaterials and products."[17]

20. The rise of nanotechnologies as an object of enhanced international cooperation, and the potential need for an international regulatory framework for nanotechnologies, should also be evaluated in light of other parts of the Rio Declaration, namely: Principle 6, relating to the special attention and needs of developing countries; Principle 13, on the further development of international law regarding liability and compensation for adverse effects of environmental damages; and Principle 14, relating to the relocation and transfer

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[15] See Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, Preamble ("Mindful that growing threat to human health and the environment posed by the increased generation and complexity, and transboundary movements of hazardous wastes and other wastes…") available at http://www.basel.int/text/con-e-rev.pdf.
[16] Rio Declaration on Environment and Development, adopted on 13 June 1992, available at http://www.unep.org/Documents.Multilingual/Default.asp?DocumentID=78&ArticleID=1163.
[17] S*upra* note 6, p. 2.

to other States of any activities that cause severe environmental degradation, or are found to be harmful to human health.[18]

21. As discussed in the International Forum on Chemical Safety (IFCS) thought starter, *International Transport of Lead and Cadmium via Trade: An International Concern?*, three common considerations underlie the development of most multilateral chemicals and environmental agreements:

(i) The international community perceives that certain substances or activities present an unacceptable risk to human health or the environment.

(ii) An action (or failure to act) by one or more countries may increase the risk of harm to other countries from the substances or activities.

(iii) These potentially affected countries find it difficult or impossible to protect themselves unilaterally from the increased risk.[19]

22. The following sub-sections of this part will evaluate the applicability of each of these criteria to nanomaterials to assess the potential for nanotechnologies and nanomaterials to be considered an issue of global concern.

3.2. Potentially unacceptable risks of nanomaterials to human health and the environment: Toxicity, persistence and bioaccumulation

3.2.1. Toxicity of nanomaterials

23. The unique physicochemical properties of nanomaterials may be associated with a similarly unique toxicity profile. In effect, "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."[20]

24. "Toxicity and fate of nanoparticles is [sic] 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."[21] There are, to date, no known screening processes that would help identify the specific properties or characteristics that

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[18] See *supra* note 16.

[19] Erika Rosenthal & Glenn Wiser, *International Transport of Lead and Cadmium via Trade: an International Concern?* Intergovernmental Forum on Chemical Safety Thought Starter, U.N. Doc. IFCS/FORUM-VI/03.TS (2008), available at http://www.who.int/entity/ifcs/documents/forums/forum6/f6_03ts.en.doc.

[20] Background information in relation to the emerging policy issues of nanotechnology and manufactured nanomaterials, SAICM/ICCM.2/INF/34, §8, available at http://www.saicm.org/documents/iccm/ICCM2/meeting%20documents/ICCM2%20INF34%20nano%20background%20E.pdf.

[21] A. Nel, T. Xia, N. Li, *Toxic potential of materials at the nanolevel*, Science, Vol. 311:622-627, 2006 abstract available at http://www.ncbi.nlm.nih.gov/pubmed/16456071; Oberdörster G, et. al., *Principles for characterizing the potential human health effects from exposure to nanomaterials: elements of a screening strategy*, Particle and Fibre Toxicology 2:8, 2005 available at http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1260029.

would be of particular concern in terms of health or environmental toxicity. Thus, it is not feasible to produce a general toxicity profile for nanomaterials under the present state of knowledge.

25. Due to the large variety of nanoparticles and nanomaterials and the fast-evolving discoveries in this sector, the knowledge gap for producing such a profile is tremendous. Furthermore, despite that knowledge gap, the funding dedicated to investigate the potential health and environmental impacts of nanotechnologies remains very limited, with only an estimated three to five percent of nanotechnology research funding being spent on investigating the potential health and environmental impacts of nanomaterials.[22]

26. Nevertheless, there is already compelling evidence of the environmental or human toxicity of certain nanomaterials, including the potential for certain types of carbon nanotubes to mimic the effect of asbestos, causing severe pathologies such as granulanomas and mesothelioma.[23] Other preliminary studies have demonstrated that high oral doses of nanoparticle zinc powder can cause severe damage to organs or changes in physiological function.[24] Adverse environmental impacts of some nanomaterials have also been established. For example, nanoparticle titanium dioxide (TiO_2) can cause mortality or behavioral or physiological changes in species such as water fleas, fish or algae that are used as environmental indicator species, especially when exposed to UV light.[25] Also, high levels of nanoscale aluminum stunt root growth in five major commercial crops species.[26]

27. In its most recent scientific opinion, the SCENHIR wrote that despite considerable and 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,

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[22] For US and EU figures, see *supra* note 6, at 62.

[23] "It was demonstrated that similar inflammatory reactions can be induced by these specific nanotubes as induced by asbestos." See *Opinion on the Most Recent Developments in the Risk Assessment of Nanomaterials*, SCENIHR, 19 January 2009, at 9, available at http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_023.pdf.

[24] Bing Wang, et al., *Acute Toxicity of Nano-and Micro-scale Zinc Powder in Healthy Adult Mice*, abstract and article outline available at http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6TCR-4H3JJCB-2&_user=10&_rdoc=1&_fmt=&_orig=search&_sort=d&view=c&_acct=C000050221&_version=1&_urlVersion=0&_userid=10&md5=f033c5a3e5ab94ebec8e3e5448d25287.

[25] See, for example, K. Hund-Rinke & M. Simon, *Ecotoxic Effect of Photocatalytic Active Nanoparticles (TiO2) on Algae and Daphnids*" 2006, Environ Sci Poll Res 13(4):225-232, abstract available at http://www.informaworld.com/smpp/content~content=a909166265~db=all or B. Lovern & R. Klaper *Daphnia Magna Mortality When Exposed to Titanium Dioxide and Fullerene (c60) Nanoparticles*, Environ Toxicol Chem 25(4):1132-1137, 2006, abstract available at http://www.setacjournals.org/perlserv/?request=get-abstract&doi=10.1897%2F05-278R.1&ct=1.

[26] "*Particle surface characteristics may play an important role in phytotoxicity of alumina nanoparticles*," Yang L, Watts DJ (2005), Toxicol Lett. Volume 158(2):122-32, available at http://nanotoxcore.mit.edu/tox%20core/nano%20toxicity%20papers/Yang,%20Watts,%202005.pdf.

indicating a potential for bioaccumulation in species at the end of that part of the food chain.[27]

28. In consequence, although there is no general toxicity profile for nanomaterials yet, the existing evidence of toxicity for certain types of nanomaterials, including those with some of the largest production output (namely carbon nanotubes), and the established potential for acute and long-term toxicity of other existing nanomaterials, points toward the existence of potential unacceptable risks to human health and the environment.

3.2.2. Bioaccumulation of nanomaterials

29. The factors that make it presently impossible to develop a general toxicity profile of nanomaterials similarly make it difficult fully to evaluate their uptake into, and distribution within, the human body. As a result, information currently available on the potential for bioaccumulation of nanomaterials is limited.

30. Nevertheless, based on existing environmental studies, the United States Environmental Protection Agency (USEPA) and other environmental regulatory agencies have acknowledged that "[b]acteria and living cells can take up nanosized particles, providing the basis for potential bioaccumulation in the food chain."[28]

31. In its 2006 revised opinion, the SCENHIR reported that "[m]aterials with very low solubility or degradability could accumulate within biological systems and persist there for long durations."[29] Indeed, available information on nanomaterials points toward the potential for bioaccumulation of some nanoparticles (e.g., quantum dots).[30] Studies published in 2007 show that the presence of some nanoparticles enhances the bioaccumulation of other toxic substances in aquatic organisms.[31] Moreover, recent studies show that, not only do nanoparticles bioaccumulate in individual organisms, but they can also be transferred to the offspring of exposed organisms, thereby risking an intergenerational toxic legacy from nanomaterials.[32]

32. The potential for nanomaterials to bioaccumulate in living organisms and to enhance the bioaccumulation of other toxic substances may pose severe risks to human health and, by extension, possibly to other animals.

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[27] *Supra* note 23 at, p.55.
[28] *Nanotechnology White Paper*, USEPA, at p. 50, February 2007 available at http://www.epa.gov/OSA/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf (citing Biswass and Wu, 2005)
[29] *Supra* note 7, at p. 21.
[30] See *supra* note 23, at p.10
[31] Zhang et. al., *Enhanced Bioaccumulation of Cadmium in Carp in the Presence of Titanium Dioxide Nanoparticles*, Chemosphere, vol. 67, no1, pp. 160-166, 2007, abstract available at http://www.ncbi.nlm.nih.gov/pubmed/17166554?ordinalpos=9&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DefaultReportPanel.Pubmed_RVDocSum.
[32] Takeda *et al.*, *Nanoparticles Transferred from Pregnant Mice to Their Offspring Can Damage the Genital and Cranial Nerve Systems*, Journal of Health Science, Volume 55, number 1, February 2009

3.2.3. Persistence of nanomaterials in the environment

33. Available data on the potential persistence of nanoparticles in the environment remain scarce. However, as is the case for bioaccumulation, some nanoparticles are likely to behave in the same way as their bulk precursors. If nanomaterial is engineered from a bulk material that is not biodegradable, then the potential for the nanomaterial to persist in the environment is quite strong. According to the USEPA *Nanotechnology White Paper*, "[m]any of the nanomaterials in current use are composed of inherently nonbiodegradable inorganic chemicals, such as ceramics, metals and metal oxides, and are not expected to biodegrade."[33] Furthermore, the specific characteristics of some nanomaterials, such as their capacity to form aggregates or have very low solubility or degradability, indicate that they may have a strong potential for persistence in the environment.[34]

34. Significant investigative research is urgent and necessary to better assess the potential for environmental persistence of manufactured nanomaterials. When considered in light of the potential of some nanomaterials to cause adverse health effects and to bioaccumulate, the very likely persistence in the environment of at least some nanomaterials points to their high potential to present an unacceptable risk to human health, thus giving rise to an issue of global concern warranting international action.

3.3. An act or omission by one or more countries may increase the risk of harm to others

35. According to Principle 2 of the Rio Declaration, "States have, in accordance with the Charter of the United Nations and the principles of international law . . . the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national control."[35] Under Principle 14, "States should effectively cooperate to discourage or prevent the relocation and transfer to other States of any activities and substances that cause severe environmental degradation or are found to be harmful to human health."

36. The rapid and as-yet poorly regulated development of nanotechnology and nanomaterials risks violating both of these principles. Because the potential damages caused by nanomaterials, if realized, are likely to carry cross-border consequences, a State's failure adequately to regulate the production, use, or disposal of nanomaterials could cause transboundary damages to another State. As with any other type of emerging technology, especially in times of economic crisis, some States might be tempted to enter a "race-to-the-bottom," in terms of labor and environmental standards, in order to attract investment and outpace their rivals in the short term development of new applications. The prevention of these possibilities is likely to require the adoption of global minimum environmental and labor standards for nanotechnologies, which will only be feasible through coordinated international action.

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[33] *Supra* note 28, at p. 50.
[34] *Supra* note 23.
[35] *Supra* note 16.

37. Furthermore, when assessing whether an international coordinated approach in this regard is required, one should consider the possibility that, in the absence of such an approach, international trade law could have a "chilling effect" on the ability or willingness of individual States to take unilateral measures to address an environmental or health risk that can be traced to international trade. Nevertheless, World Trade Organization (WTO) rulings suggest that trade-related environmental and health measures taken by States pursuant to multilateral efforts should not run afoul of WTO rules.[36] Legal scholars have commented:

> [T]he potential for conflicts between international trade law and unilateral efforts by States to protect themselves from environmental health risks that may result from international trade may be a factor in determining whether unilateral action or an international, coordinated approach would be most effective in avoiding, reducing or mitigating health and environmental harms caused by the international trade of these metals throughout their lifecycles.[37]

3.4. Countries find it difficult or impossible to protect themselves unilaterally from increased risks

38. When States perceive that it is difficult or impossible to protect themselves unilaterally from a transboundary risk to human health or the environment, they historically have made use of international agreements to address the problem. Examples include treaties regarding international watercourses, hazardous wastes, ozone depleting substances, biological diversity, endangered species, greenhouse gases, and persistent organic pollutants (POPs). The existence of a similar situation in nanotechnology and nanomaterials, particularly if there is widespread recognition of international vulnerability to the risk of harm, is therefore a key factor in evaluating whether the risks constitute a global concern warranting an international, coordinated approach.[38]

3.4.1. Long-range transport of nanomaterials

39. The capacity of nanomaterials to be transported over long distances by wind, water, and wildlife is highly dependent on an array of factors, including the size of the particles, their individual bioaccumulation and persistence properties as discussed above, as well as the chemical properties of the medium considered (e.g., water pH).

40. Although there is still a very large knowledge gap in these areas that makes the long-range environmental transport capacities difficult to assess, according to studies cited by the USEPA *Nanotechnology White Paper*, "[s]ea surface microlayers. . . may have the potential to sorb nanoparticles and transport them in aquatic environments over

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[36] *Report of the Appellate Body, United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/RW, adopted on 21 Nov. 2001, paras. 111-34; N. Bernasconi-Osterwalder, et al, *Environment and Trade: A Guide to WTO Jurisprudence*, 128-35 (Earthscan: London, 2006).
[37] *Supra* note 20, at § 56.
[38] See *id.* at § 53.

long distances."[39] Furthermore, according to the UNEP *2007 GEO Year Book*, "engineered nanoparticles can remain airborne over a long period because of their small size and light weight. This may increase the likelihood that they will travel long distances, cross borders and interact with gases and other airborne particles."[40] In addition to the proven bioaccumulative and persistent qualities of some nanomaterials, we should anticipate that long-range environmental transport of some nanomaterials is likely and should therefore be considered.

41. Another aspect should also be taken into account when investigating the capacity of nanomaterials to be transported long distances. Nanotechnologies have moved from being an object of research in 2000, to an ensemble of technologies worth $18.2 billion in 2008, and are projected to be worth several trillion US dollars by the middle of the next decade.[41] Meanwhile, the available inventory, compiled by The Project on Emerging Nanotechnologies, identifies more than 800 nanotechnology-based consumer products in the market today.[42] Most of these products are available via the Internet and may be transported across the planet through trade. A large portion of those consumer products are electronic devices. For example, mobile phones and computers, which are known to be the object of major secondary trade, mostly end up in developing countries in the Global South, either as second-hand appliances or waste. This aspect of long-range transport through international trade should not be overlooked when assessing the capacity of nanomaterials to travel long distances from where they are produced throughout their life cycles.

42. Long-range transport of nanomaterials, whether through trade or environmental transport, severely impairs the ability of States to protect themselves unilaterally from associated risks. An international, coordinated approach is the only effective way to address these risks.

3.4.2. Avoiding a North-South nano divide

43. In the modern era of international environmental law, States have acknowledged the interdependence of development and environmental issues. Principle 5 of the Rio Declaration summarizes this interdependence: "All States and all people shall cooperate in the essential task of eradicating poverty as an indispensable requirement for sustainable development, in order to decrease the disparities in standards of living and better meet the needs of the majority of the people of the world."[43] In accordance with Principle 5, bridging the existing North-South development divide and preventing its expansion should be considered when addressing the development of nanotechnologies.

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[39] *Supra* note 28, at p. 49 (citing Moore, 2006; Schwarzenbach et al., 1993); and *supra* note 33.
[40] *Supra* note 6 at 67 (citing Biswas and Wu, 2005).
[41] See, for example, *Societal Implications of Nanoscience and Nanotechnology*, M.C. Roco, & W. Bainbridge, eds., 2001 (mentioning the figure of US $1 trillion by 2015 or Lux research mentioning the 2008 figure and forecasting $3.1 trillion in revenue across the value chain by 2015).
[42] Woodrow Wilson Center for Scholars Project on Emerging Nanotechnologies, http://www.nanotechproject.org/inventories/consumer/.
[43] *Supra* note 16.

44. Some scholars have argued that the introduction of many previous technologies, for example, during the industrial revolution, has benefited the rich, while further marginalizing the poor.[44] UNESCO specifically noted the possibility of this divide further widening as a result of nanotechnology in its report, *The Ethics and Politics of Nanotechnologies*: "As with previous advances in science and technology, developing nations risk being distanced by a 'knowledge divide' if they cannot find ways to participate on equal footing with other countries."[45] This report, among other evidence, shows the potential for nanotechnology to widen existing divides by creating a specific North-South "nano divide."

45. As noted by a report from the Meridian Institute regarding the opportunities and risks of nanotechnologies for the poor, adequately managing the potential health and environmental risks of nanomaterials requires advanced infrastructures, know-how and an efficient and enforceable regulatory framework that may not be available to a number of developing countries.[46] Thus, trade patterns of nanotechnology goods and wastes could expose developing countries to negative health impacts from products containing nanomaterials, which could, in turn, have detrimental effects on their sustainable development, regardless whether such countries develop nanotechnologies on their own.

46. In addition, "[t]here 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)."[47]

47. Considering the globalization of the economy and existing trade patterns, it will be impossible for States to unilaterally limit the potentially devastating effects of an increased North-South nano divide. Managing the various concerns created by a potential North-South nano divide through a coordinated international approach could therefore be a very effective tool. This approach could allow developing countries to adequately manage the potential health and environmental risks of this new technology, and could offer a path that increases the possibility that nanotechnologies contribute to achieving the 2015 United Nations Millennium Goals and the SAICM 2020 goal.

3.4.3. Limiting trade disruption

48. Based on the experience of the past decade in the development of biotechnology and its trade-related consequences, there is a clear risk that nanotechnology could lead to

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[44] For an example of the societal impacts of technology introductions, see R.W. Fogel, *The Escape From Hunger and Premature Death, 1700-2100: Europe, America and the Third World*, 2004.
[45] *Supra* note 1.
[46] See *Nanotechnology and the Poor, Opportunities and Risks*, January 2005, at 10, available at http://www.meridian-nano.org/gdnp/NanoandPoor.pdf.
[47] *Supra* note 20, at 7.

serious international trade disruptions.[48] This may be exacerbated by the fact that political and regulatory attitudes towards new technologies, and the risks they may present, vary greatly among the various regions of the planet. For example, the precautionary approach practiced in Europe can have very different results than the business and market-friendly approach prevalent in the United States.[49]

49. These contrasting approaches can result in regulatory systems in which the lack of data on the safety of a substance or product can lead to restricted market access (the "no data-no market" rule), or systems in which the burden of the proof of safety of a substance or product is placed on the regulator, rather than the producer. Given the general lack of data in the field of nanomaterials safety, and the fast development of the nanotechnology market, this difference in approach could result in significant market disruptions. These market disruptions, if not dealt with in an adequate time and manner, could prove highly detrimental to the development of the technology and potentially beneficial applications, especially for developing States, as has been the case for trade in genetically modified plants and organisms.

50. Harmonization of the trade-related aspects of nanotechnologies is difficult or impossible through uncoordinated or unilateral actions. Avoiding nanotechnology market disruptions through international regulatory convergence can only be achieved by a coordinated international approach that enhances opportunities for responsible development of nanotechnologies and makes social acceptance of nanomaterials more likely.

3.5. Adequately addressing nanotechnology and nanomaterials as an issue of global concern

51. The preceding analysis suggests that at least some nanotechnology products are likely to represent an unacceptable risk to human health and the environment; that the failure to address that risk by one or more countries could increase the risks of harm to other countries and to world stability (*e.g.*, by widening the North-South divide and disrupting trade); and that it could be impossible for a country to protect itself unilaterally from the increased risk. Despite the very early stage of development of nanotechnologies and the nano-market, and the very large knowledge gap on the intrinsic properties of nanomaterials, nanotechnologies and manufactured nanomaterials may present an issue of global concern.

52. Nanotechnologies and nanomaterials raise a large number of closely interconnected issues that may be effectively addressed only through an international cooperative framework. As discussed below, that framework should be: (1) global,

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[48] Marcus Schaper,. *Nanotechnology and the Lessons (Not) Learnt from the Transatlantic Biotechnology Dispute*, 2006 (Europe and the United States appear to be headed on a collision course with regard to nanotech that promises to run almost perfectly parallel to the ongoing dispute about the adequate regulation of biotech in foods) abstract available at http://www.allacademic.com/meta/p_mla_apa_research_citation/0/9/8/9/3/p98930_index.html.

[49] See *supra* note 1, at 16.

participatory, and transparent; (2) comprehensive in terms of risks, life cycle and issues addressed; (3) adaptable and flexible; (4) precautionary; and (5) effective.

53. Global, participatory and transparent: As an issue of global concern, manufactured nanomaterials and nanotechnologies represent a challenge for the entire international community and therefore warrant a global framework of cooperation. The need for a global framework is particularly apparent after considering the cross-boundary harmful impacts of nanomaterials on human health and the environment, as well as the broader development issues such as preventing the widening of the North-South nano divide, preventing international trade disruptions, and preventing a race to the bottom in the regulation of nanotechnologies and materials. In particular, if the issue of the North-South nano divide is to be adequately addressed, all members of the international community will need to help balance the interests and concerns of developing countries against the market interests of those countries leading the development of nano-sciences and applications. The inclusion of all stakeholders is vital to adequately address trade disruption, social acceptance, and all other concerns, while also providing transparency in all aspects of a negotiated framework. Experience "has established that active participation from a broad and diverse range of NGOs enhances the quality of decision-making and increases the legitimacy of decisions made."[50]

54. Comprehensive. "A multi-pronged approach is likely to be the most effective way to address environmental, health, and safety concerns, given the complexity and likely pervasiveness of the technology, the uncertainty regarding the potential hazards, and the multimedia nature of the environmental problems that could arise."[51] The framework should thus have a sufficiently broad mandate to address nanotechnology and nanomaterials in a comprehensive way. This mandate should allow the process to address, in a comprehensive manner, the wide set of issues raised by the rapid development of nanotechnologies and dispersion of manufactured nanomaterials. The mandate might include: managing the wide scope of potential harmful effects of nanomaterials to environment and human health, including transboundary effects; considering nanomaterials through their whole life cycle, from research and development to disposal; addressing issues of transboundary harm; addressing the risks of a widening of the existing North-South divide; making sure that nanotechnologies are "socially directed towards solving the problems that are the most urgent for the largest number of people";[52] and limiting trade disruption, while addressing the social acceptability of nanomaterials.

55. Adaptable and flexible. "A generic issue facing any future regulation of nanotechnology will be how to keep the regulatory structure current and properly aligned

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[50] Glenn M. Wiser, *Transparency in 21st Century Fisheries Management: Options for Public Participation to Enhance Conservation and Management of International Fish Stocks*, 2000, at p.33, abstract available at http://www.informaworld.com/smpp/content~content=a906025821~db=all.

[51] L.K. Breggin & L.Carothers, *Governing Uncertainty: The Nanotechnology Environmental, Health, and Safety Challenge*, 2006, available at http://www.eli.org/pdf/research/nanotech/nanocolumbiaarticel%20final.pdf.

[52] See *supra* note 1, at 19.

with this rapidly evolving technology."[53] Due to the knowledge gap that is slowly being bridged, and the extent of discoveries still to be made in nanoscience and nanotechnology, this framework should be flexible and capable of adapting to the evolution of scientific knowledge, as well as to the fast evolving market situation of nanomaterials. In the meantime, according to the UK Royal Commission on Environmental Pollution, bridging the knowledge gap in this context might take "several decades"[54]; "as a consequence, and however good the research effort, significant uncertainties and area of ignorance will remain."[55]

56. Precautionary. Acknowledging the existing serious concerns regarding the health and environmental impacts of nanomaterials despite the early stage of development of nanoscience, UNEP recommended that the precautionary principle should be used in "[e]valuating the potential environmental impacts of engineered nanomaterials prior to their mass production…"[56] In accordance with Principle 15 of the Rio Declaration,[57] an adequate comprehensive international framework should therefore include a precautionary approach. This approach is also supported by Swiss Re, one of the world leaders in reinsurance,[58] as well as by UK's Royal Society, the world oldest scientific institution.[59] This need for a precautionary approach was also supported by the Forum VI of the Intergovernmental Forum on Chemical Safety (IFCS), in Dakar, Senegal, which recommended that "[g]overnments and industry apply the precautionary principle as one of the general principles of risk management throughout the life cycle of manufactured nanomaterials."[60]

57. Effective. It is essential that any new international cooperative framework must be effective. For example, such a framework should include all relevant States, and should have appropriate institutional and financial support. A related question—whether to address nanotechnologies and nanomaterials under either a voluntary or a legally binding framework—may be affected by many considerations. As detailed in UNEP's *Study on Options for Global Control of Mercury*,

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[53] See *supra* note 5, at 8.
[54] *Summary of the publication 'Novel material in the environment: The Case of Nanotechnology'* UK Royal Commission on Environmental Pollution, November 2008 p.13, available at http://www.rcep.org.uk/novel%20materials/Novel%20materials%20summary.pdf.
[55] See *supra* note 54.
[56] See *infra* note 6 at 73 ("Evaluating the potential environmental impacts of engineered nanomaterials prior to their mass production is essential to address the environmental and health concerns and to develop sustainable nanotechnologies.").
[57] Principle 15 of the Rio Declaration states: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."
[58] "The precautionary principle should be applied whatever the difficulties", See *supra* note 2, p. 47.
[59] *Nanoscience and nanotechnologies*, The Royal Society and The Royal Academy of Engineering, 2004, at Recommendation R4 p.85, available at http://www.nanotec.org.uk/report/chapter10.pdf.
[60] *Final report from the VIth session of the Intergovernmental Forum on Chemical Safety, Dakar, Senegal,* 15-19 September 2008. IFCS/FORUM-VI/07w, available at http://www.saicm.org/documents/iccm/ICCM2/meeting%20documents/ICCM2%20INF5%20IFCS%20Forum%20VI.doc.

> Voluntary political commitments may allow for greater experimentation, adaptation and flexibility, because they are easier to change than legally binding commitments, which typically require a formal amendment process. That said, a variety of approaches have been used in binding international environmental agreements to provide flexibility in light of changing scientific knowledge or other factors. . . . When negotiating a policy instrument, they may be strategic in balancing the ambitiousness of a commitment against its enforceability.[61]

The question of whether nanotechnologies and nanomaterials should be dealt with through a voluntary or binding instrument warrants a separate study and will therefore not be addressed here.

4. Existing International Processes Addressing Nanotechnology or Nanomaterials

58. Various issues linked to the rapid development of nanotechnologies and widespread release of nanomaterials are already being addressed by a number of international processes. This Part will briefly describe the most prominent of these processes, and then assess their potential role in addressing nanomaterials as an issue of global concern.

4.1. Organization for Economic Co-Operation and Development (OECD)

4.1.1. OECD Working Party on Nanotechnology and Working Party on Manufactured Nanomaterials

59. International cooperative activities on nanotechnology are quite recent. Long before becoming the object of potential international cooperation, nanomaterials and nanotechnologies were considered a new field of human knowledge[62] with large potential as a driver of innovation and economic development.[63] In this context, the OECD, whose main objectives include supporting economic growth and contributing to growth in world trade,[64] was the first international organization to address the subject of nanotechnology.

[61] Study on Options for Global Control of Mercury, UNEP(DTIE)/Hg/OEWG.1/2, available at http://www.chem.unep.ch/mercury/OEWG/documents/c3)/English/K0762755%20OEWG-1-2.pdf.

[62] On 29 December 1959, Physicist Richard Feynman presented his now famous talk, *There's plenty of room at the bottom*, available at http://www.its.caltech.edu/~feynman/plenty.html. It first mentioned the possibility of direct manipulation of individual atoms as a more powerful form of synthetic chemistry than those used at the time. The talk explored applying such ideas to denser computer circuitry and nano-medicine bots. In 1986, K. Eric Drexler further explored the Feynman's idea and explored new ones such as self-replication, now considered the next frontier of nanotechnologies in his book, *Engines of Creation: The Coming Era of Nanotechnology*, available at http://e-drexler.com/p/06/00/EOC_Cover.html

[63] See, for example, *Shaping the World Atom by Atom*, the National Science and Technology Council Committee on Technology and The Interagency Working Group on Nanoscience, Engineering and Technology, 1999, available at http://www.wtec.org/loyola/nano/IWGN.Public.Brochure/IWGN.Nanotechnology.Brochure.pdf.

[64] See OECD website, "About OECD," at http://www.oecd.org/pages/0,3417,en_36734052_36734103_1_1_1_1_1,00.html.

60. The OECD first acknowledged the opportunities and challenges posed by nanotechnologies in 2005 during a special session on the potential implications of manufactured nanomaterials for human health and environmental safety. This special session was held during the 38th Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology.

61. In September 2006, the OECD formed the Working Party on Manufactured Nanomaterials (WPMN) as a subsidiary body of its Chemicals Committee. The declared aim of this Working Party is to "promote international co-operation in human health and environment safety related aspects of manufactured nanomaterials in order to assist their safe development."[65]

62. The OECD WPMN consists of the 30 OECD members,[66] the European Union, and a number of observers. Observers include: the ISO Technical Committee 229,[67] the World Health Organisation (WHO), the United Nations Environmental Program (UNEP), the Business and Industry Advisory Committee to the OECD (BIAC), the Trade Union Advisory Committee to the OECD (TUAC), environmental NGO representatives, and representatives from a number of non-OECD countries.[68]

63. The OECD WPMN currently has eight different projects:[69]

- **Development of an OECD Database on Human Health and Environmental Safety (EHS) Research**, chaired by Australia. The main objective of this project is developing a global resource that identifies research projects addressing EHS issues associated with manufactured nanomaterials.
- **EHS Research Strategies on Manufactured Nanomaterials (including Occupational Health and Safety),** chaired by Germany. This project aims to improve information exchange and identify common research needs to help address EHS issues associated with manufactured nanomaterials and then undertaking to meet those research needs.
- **Safety Testing of a Representative Set of Manufactured Nanomaterials**, co-chaired by the United States and European Union. The aim of this project

[65] OECD Environment, Health and Safety News, 21 November 2007, http://www.oecd.org/dataoecd/2/57/39618090.pdf.
[66] Australia, Austria, Belgium, Canada, Czech republic, Denmark, European Commission, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Korea, Luxemburg, Mexico, Netherlands, New Zealand, Norway, Poland, Portugal, Slovak Republic, Spain, Sweden, Switzerland, Turkey, United Kingdom, and the United States.
[67] See *infra* Section 4.2.
[68] China, Thailand, Brazil, Russia and Singapore.
[69] See *Current development / activities on the safety of manufactured nanomaterials / nanotechnologies*, OECD, ENV/JM/MONO(2008)29, 2008, available at http://www.olis.oecd.org/olis/2008doc.nsf/LinkTo/NT0000799E/$FILE/JT03257288.PDF.

is to agree on a representative set of manufactured nanomaterials to be tested for their safety, using appropriate test methods.[70]

- **Manufactured Nanomaterials and Test Guidelines**, co-chaired by the United States and European Union. The objectives of this project are: 1) to review existing OECD test guidelines for adequacy in addressing manufactured nanomaterials, and 2) to identify the needs in the development of new or revised existing test guidelines.
- **Co-operation on Voluntary Schemes and Regulatory Programs**, chaired by Canada. The goals of this project are: 1) to identify common elements of the various national information gathering initiatives, in place or planned; 2) to identify applicable current and proposed regulatory regimes, examining how they address information requirements, hazard identification, risk assessment, exposure mitigation, and risk management of manufactured nanomaterials; and 3) to share information on existing or proposed guidance documents on practices to reduce occupational or environmental exposure to, or releases of manufactured nanomaterials.
- **Co-operation on Risk Assessment**, chaired by the United Kingdom. The aim of this project is to evaluate risk assessment approaches for manufactured nanomaterials through information exchange and identify opportunities to strengthen and enhance risk assessment capacity.
- **The Role of Alternative Methods in Nano Toxicology**, chaired by the United Kingdom. This project aims at evaluating and, where applicable, validating *in vitro* and other methodologies.
- **Exposure Measurement and Exposure Mitigation** chaired by the United States. The objective of this project is to develop guidelines on exposure measurement and exposure mitigation, with an initial focus on occupational settings.

64. In addition to the WPMN, the OECD directorate for science, technology and industry created the Working Party on Nanotechnology (WPN) in March 2007 to "advise on emerging policy-relevant issues in science, technology and innovation, related to the responsible development and use of nanotechnology."[71] The WPN has six focus areas:

- The **Indicators and Statistics Program**, led by Canada. This group focuses on collecting and reviewing data on, *inter alia*, worldwide research and development activities, applications, and definitions. The group aims to provide reliable, comparable and validated indicators and statistics for nanotechnology.

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[70] See the list of 14 selected representative nanomaterials and endpoints for testing at http://www.olis.oecd.org/olis/2008doc.nsf/LinkTo/NT000034C6/$FILE/JT03248749.PDF.
[71] *OECD Working Party on Nanotechnologies (WPN): Vision statement*, available at http://www.oecd.org/document/35/0,3343,en_21571361_41212117_42378531_1_1_1_1,00.html.

- The **Companies and Business Environments Program**, led jointly by Canada and Switzerland, surveys the commercialization of nanotechnology and analyzes its impact on business activity.
- The **International Research Collaboration Program**, led by the Netherlands, aims to facilitate international research collaboration by identifying relevant websites.
- The **Outreach and Public Engagement Program**, led by the United Kingdom, seeks to identify and promote good communication and public engagement activities.
- The **Policy Dialogue Program**, led jointly by France and Ireland, surveys science and technology policies relating to nanotechnology in OECD countries.
- The **Global Challenges: Water Program**, led by the OECD, examines the opportunities for nanotechnology in addressing the global challenge of providing accessible and affordable drinking water to all.[72]

4.1.2. The role of OECD activities in addressing nanotechnologies and nanomaterials as issues of global concern

65. The OECD's activities regarding nanotechnology and manufactured nanomaterials are beneficial for the better understanding of the issues raised by the rapid development of nanotechnologies and trade in nanotechnological products. They may not, however, substitute for a comprehensive and global cooperation framework warranted to address nanotechnologies and manufactured nanomaterials as an issue of global concern.[73]

66. The OECD's objectives include, among other things, boosting employment, supporting sustainable economic growth, contributing to growth in world trade, and maintaining financial stability.[74] However, addressing issues such as limiting transboundary effects from toxic chemicals or avoiding the North-South nano divide, which are considered issues of global concern and critical to nanotechnologies and nanomaterials, do not belong to OECD's objectives. Therefore, nanotechnological issues may not be adequately and comprehensively addressed by the OECD.

67. Furthermore, the OECD's membership consists of only a limited number of countries and is dominated by the wealthiest nations of Europe, North America and Asia.[75] Its outreach is therefore limited to its membership and, to a lesser extent, the observers. The OECD may not provide an adequate forum for addressing the various

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[72] *OECD presentation on the Working Party on Nanotechnologies (WPN)*, 2008, available at http://www.oecd.org/dataoecd/55/8/40994143.pdf.
[73] See *supra* sub-section 3.5 of this study
[74] See OECD website, 'About OECD', at http://www.oecd.org/pages/0,3417,en_36734052_36734103_1_1_1_1_1,00.html.
[75] See *supra* note 66.

issues that make nanotechnologies and manufactured nanomaterials an issue of global concern (*e.g.*, as an unacceptable risk to human health and the environment, where the action or inaction by one country creates risks, which will prove difficult if not impossible to for other countries to protect themselves unilaterally). As an issue of global concern, manufactured nanomaterials and nanotechnologies represent a challenge for the entire international community and therefore warrant a global framework of cooperation.

68. Although the OECD seems to welcome the participation of non-member countries,[76] participation to the WPMN and WPN is governed by the rules set out in the outreach strategy of the chemical committee of OECD,[77] which provides for the consideration of a number of elements when establishing contact with non-members, including:

- Whether and in what ways association of non-members with its work would be of benefit to the OECD;
- Whether economic growth and/or the welfare of members are influenced to a significant degree by the policy orientations of non-members;
- Whether non-member participation will facilitate the achievement of the mandate and the program of work of the Chemicals Committee or one or more of its subsidiary bodies;
- The consequences that non-members' participation might have on the working methods, program of work and Secretariat resources allocated to the work under the Chemicals Committee;
- Whether, in the case of full participants, the non-member has been found to be willing and able to commit to the relevant OECD Acquis, as appropriate; and
- The full range of vehicles to engage non-members in the work of the Chemicals Committee.[78]

69. These conditions limit the capacity of the WPN and WPMN to address issues presented by the rapid development of nanotechnologies and rapid growth in the trade of nanomaterials. Although the OECD's inability to address these issues adequately may have ramifications for non-member countries, addressing this limitation may not be a priority of member countries, the main promoters of nanotechnologies and nanomaterials.

70. Both the WPN and WPMN have great promise as tools to bridge the existing knowledge gap in the field of nanotechnology and manufactured nanomaterials. They can, therefore, contribute significantly to development and implementation of a

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[76] See *supra* note 20 at § 56.
[77] Available at http://www.oecd.org/document/48/0,3343,en_2649_34365_35077680_1_1_1_1,00.html.
[78] *Outreach Strategy for the Chemical Committee: Elements to be Considered in Relation to Participation of Non-Members*, OECD, available at http://www.oecd.org/document/48/0,3343,en_2649_34365_35077680_1_1_1_1,00.html.

comprehensive global cooperation framework, but they may not be the best forum to develop the architecture of such a framework.

4.2. Standardization Bodies

71. Three bodies are responsible for the planning, development and adoption of international standards. The International Organization for Standardization (ISO) is responsible for all sectors except for: electrotechnical, which is the responsibility of the International Electrotechnical Committee (IEC), and most telecommunications technologies, which are largely the responsibility of the International Telecommunication Union (ITU). These standardization bodies are described briefly below, and then assessed for their ability to address nanotechnology and nanomaterials as an issue of global concern.

4.2.1. International Organization for Standardization (ISO)

72. ISO is a legal association, the members of which are the national standardization bodies of some 158 countries, supported by a Central Secretariat based in Geneva, Switzerland.[79]

73. The primary objectives of the ISO are to facilitate the international coordination and unification of industrial standards.[80] In 2005, ISO established Technical Committee 229 (TC 229) to produce standards for classification, terminology and nomenclature, basic metrology, calibration and certification, and environmental issues with respect to nanotechnology. TC 229 also aims at developing standardized test methods that will focus on physical, chemical, structural, and biological properties of nanomaterials.[81] The British Standards Institution (BSI) chairs TC 229,[82] which currently consists of 28 Participating Countries[83] and eight Observer Countries.[84,85]

74. According to the ISO, "[m]any of the standards developed by TC 229 will be anticipatory since most nanotechnological development, and the resulting business, lies in the future. The implementation of anticipatory standards for nanotechnology will accelerate the adoption of nanotechnology-based products, particularly by identifying

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[79] See ISO/TC 229 Business Plan, at p.2, available at http://isotc.iso.org/livelink/livelink?func=doc.Fetch&nodeid=6507632
[80] http://www.iso.org/iso/about/the_iso_story/iso_story_founding.htm.
[81] *Nanotechnology Standards for Health, Safety, and Environmental Factors*, Nanotechnology Law Report, 2008, available at http://publicaa.ansi.org/sites/apdl/Documents/News%20and%20Publications/Other%20Documents/Series%20on%20Nanotechnology%20Standardization/Nano-Law-Report-WG3-07-08.pdf
[82] http://www.iso.org/iso/iso_technical_committee?commid=381983.
[83] "A member body of ISO is the national body "most representative of standardization in its country." Member bodies are entitled to participate and exercise full voting rights on any technical committee and policy committee of ISO. See http://www.iso.org/iso/about/iso_members/member_bodies.htm.
[84] "Correspondent members do not take an active part in the technical and policy development work, but are entitled to be kept fully informed about the work of interest to them." See http://www.iso.org/iso/about/iso_members/correspondent_members.htm.
[85] *Supra* note 79 at 6.

standard measurement and characterization methodologies for nanomaterials and nanodevices."[86]

75. TC 229 has four working groups:

- Working group 1 on **Terminology and Nomenclature** is convened by Canada. The objectives of this group are to define and develop unambiguous and uniform terminology and nomenclature in the fields of nanotechnology to facilitate communication and to promote common understanding.

- Working group 2 on **Measurement and Characterization** is convened by Japan and aims at developing standards for measurement, characterization, and test methods for nanotechnologies, taking into consideration needs for metrology and reference materials.

- Working group 3 on **Health, Safety and the Environment** is convened by the United States, and aims at developing "science-based standards in the area of health, safety and environmental aspects of nanotechnologies."[87]

- Working group 4 on **Material Specifications** is convened by China. At the time of publication the exact scope of this working group was still being drafted. However, working group 4 is currently developing three work items to examine raw materials with respect to their purpose in a variety of uses. The first two work items specify the characteristics and measurement methods for engineered nanoscale titanium dioxide (nano TiO_2) and calcium carbonate (nano $CaCO_3$). BSI directs the third work item, a guide to specifying nanomaterials.[88]

76. Although most of the 28 standards currently under development under TC 229 are in the proposal or preparatory stages,[89] two have already been published: ISO/TS 27687:2008, on terminology and definition for nano objects, i.e. nanoparticle, nanofibre and nanoplate; and ISO/TR 12885:2008, on health and safety practices in occupational settings relevant to nanotechnology.

77. According to the OECD and ISO, the WPN, WPMN and TC 229 routinely coordinate through their secretariats and national representatives.

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[86] *Id.* at 5.
[87] *Id.* at 13.
[88] For more information on the TC 229 working group, see *id.* at *11*; see also Dr. Peter Hatto, *ISO presentation of TC 229*, /FORUM-VI/6 INF, available at http://www.who.int/ifcs/documents/forums/forum6/f6_06inf.en.doc.
[89] See http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_tc_browse.htm?commid=381983&published=on&development=on.

4.2.2. Other standardization bodies

78. Although the ISO is the major international standardization organization, other global or regional bodies undertake activities that are relevant to nanotechnology and nanomaterial standardization.

79. The International Electrotechnical Committee (IEC) has created a technical group modeled after the ISO TC 229: the IEC Technical Committee 113 (TC 113). The purpose of this technical committee, which consists of 15 participating members and 11 observer members and is chaired by the German National Committee, is to deal with relevant nanotechnological considerations when developing generic standards for electrical and electronic products and systems. These typically concern optics, magnetics and electromagnetics, electroacoustics, multimedia, telecommunication, and energy production. The TC 113 seeks to develop standards in these areas on terminology and symbols, measurement and performance, reliability, design and development, and electromagnetic compatibility.[90]

80. The European Committee for Standardization (CEN) defines itself as a business facilitator in Europe that tries to remove trade barriers for European industry and consumers. It defines its mission as fostering the European economy as a part of global trade, the welfare of European citizens, and the environment.[91] Through its services, it provides a platform for the development of European Standards and other technical specifications. CEN created a technical group (TC 352) at the end of 2005, dedicated to developing standards addressing various aspects of nanotechnology and nanomaterials.[92]

81. For topics of mutual interest to ISO TC 229 and CEN, it is expected that work should be carried out under the Vienna Agreement (a cooperation agreement between ISO and CEN), which grants a leading role to ISO.[93]

4.2.3. The role of standardization bodies in addressing nanotechnologies as an issue of global concern

82. Nanomaterials and nanotechnologies generally fulfill all criteria accepted by the international community in defining an issue of global concern.[94] In this regard, they raise a number of issues, including issues specific to the area of chemicals management, such as toxicity, bioaccumulation and long-range transport. They also raise broader development issues such as the widening of the North-South divide or the risk of disruption of international trade. Each of these issues warrants a comprehensive global cooperation framework on nanotechnology and nanomaterials, with a mandate to deal with such broad issues.

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[90] See http://www.iec.ch/support/tcnews/2006/tcn_1106/tcn_news2.htm.
[91] See http://www.cen.eu/cenorm/aboutus/index.asp.
[92] See http://www.cen.eu/CENORM/sectors/sectors/nanotechnologies/index.asp.
[93] See CEN TC 352 business plan executive summary, available at http://www.cen.eu/nr/cen/doc/ExecutivePDF/508478.pdf.
[94] See Section 3 of this study.

83. The objective of ISO and other standardization bodies is generally limited to facilitating trade through the harmonization of standards. Thus, standardization bodies cannot be considered adequate fora for the comprehensive consideration of nanomaterials and nanotechnologies as an issue of global concern. They may, however, have an important role to play in creating a common language and a common frame of reference for the development of a reliable nanotechnology market through the standardization of vocabulary, scientific definitions, and tools for risk assessment.

4.3. UNESCO

4.3.1. UNESCO's activities relating to nanotechnology

84. Since the 1970s, the science and technology activities of the United Nation Educational, Scientific and Cultural Organization (UNESCO) have mostly dealt with ethical questions,[95] the objective being to promote principles and ethical norms to guide scientific and technological development and social transformation. "The increasing awareness of ethical problems in relation to science and technology was manifested in the establishment by the member states of UNESCO, in 1998, of the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST)."[96]

85. Nanotechnology was considered in two COMEST meetings held in Rio de Janeiro in December 2003 and Bangkok in March 2005. Following these meetings, the division of Ethics and Technology of UNESCO decided to establish an expert group on nanotechnology.[97]

86. A primary report drafted by this expert group in 2005 called for 1) awareness raising and debates on nanotechnologie, 2) ethics education, and 3) research and development policies. This report recommended the drafting of voluntary guidelines on scientific ethics and nanotechnology as a way to inspire the development of national regulations, as well as the creation of National Commissions or Committees to deal with emerging technologies.[98]

87. Based on this report, the UNESCO Expert Group on Nanotechnology published a study in 2006 entitled "Ethics and Politics of Nanotechnology."[99] This publication first acknowledges the fact that "nanotechnology might pose new forms of hazard or exposure to risks, and therefore new questions about how to deal with them."[100] The study then mentions the actions that corporations and researchers take to address the risks and the benefits of nanotechnology, and those that they fail to take in addressing ethical and political issues. In this context, risk management procedures are cited as accurately

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[95] See *supra* note 1.
[96] *Id.* at 4.
[97] Outline of a Policy Advice on Nanotechnologies and Ethics, April 2006, available at: http://portal.unesco.org/shs/fr/files/9702/11502051321NanoPolAdvice_Outline_Apr06.pdf/NanoPolAdvice_Outline_Apr06.pdf.
[98] *Supra* note 97.
[99] See *supra* note 1.
[100] *Supra* note 1 at 14.

stating the risks (and occasionally the benefits) of newly created substances, materials and devices, but as not addressing any of the wider issues about the ethical or political meaning of this risk. Issues such as who will bear the risk, how the risk will be distributed internationally, and who will be given the power to make decisions based on these analyses, are not addressed by these risk management procedures.[101]

88. The report also points to several other ethical and political concerns related to the development of nanotechnology including consumer awareness, labeling and the promotion of standards and regulations on nanoparticles, intellectual property, and the degree of confidence in scientific evidence held by experts and the public at large.[102]

89. By drawing parallels with the introduction of genetically modified (GM) food, and lessons from other past environmental and food crises, UNESCO advocates that international organizations serve as effective mediators or facilitators in the dialogue between the public and scientists. "If nanotechnology research is to be socially directed towards solving the problems that are the most urgent for the largest number of people, then there is a need for people and institutions who can connect scientists, funders and entrepreneurs in search of problems with local experts and experts in areas other than nanotechnology." [103]

4.3.2. UNESCO's potential role in a global cooperation framework for nanotechnologies and nanomaterials

90. The mandate of UNESCO is to "contribute to peace and security by promoting collaboration among the nations through education, science and culture. . . ."[104] UNESCO's mandate does not encompass addressing issues such as management of dangerous chemicals or their transboundary effects. Thus, although UNESCO is a global inter-governmental organization whose membership consists of 193 member States and six associate members,[105] it cannot serve as the main forum for comprehensively addressing all aspects of nanotechnologies and manufactured nanomaterials as an issue of global concern.

91. However, as mentioned in UNESCO's *Outline of a Policy Advice on Nanotechnology and Ethics*, "UNESCO can take initiatives to map the ethical dimensions of nanotechnologies from a global perspective, and to explore implications for its Members States and possible actions for the Organization."[106] UNESCO should therefore actively participate in the global cooperation framework regarding nanotechnology and manufactured nanomaterials.

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[101] *Id.*
[102] *Id.* at17.
[103] *Id.* at 19.
[104] Article 1 of the Constitution of the United Nations Educational, Scientific and Cultural Organization, adopted in London on 16 November 1945, available at http://www.un-documents.net/unesco-c.htm.
[105] See UNESCO's web site at http://portal.unesco.org/en/ev.php-URL_ID=11170&URL_DO=DO_TOPIC&URL_SECTION=201.html.
[106] *Supra* note 97 p.1.

4.4. The Strategic Approach to International Chemical Management

92. The Strategic Approach to International Chemicals Management (SAICM) is a policy framework adopted by the International Conference on Chemicals Management, on 6 February 2006 in Dubai, to foster the sound management of chemicals. SAICM was developed to support the achievement of the goal that, by the year 2020, chemicals are produced and used in ways that minimize adverse impacts on the environment and human health, as agreed at the 2002 World Summit on Sustainable Development in Johannesburg.[107]

93. Following a call to participant stakeholders to nominate what they considered to be emerging issues for consideration by the second International Conference on Chemical Management (ICCM-2), on 10-15 May 2009, in Geneva, Switzerland, several participants suggested that ICCM-2 should discuss the issue of nanotechnologies and manufactured nanomaterials. Pursuant to the input from Japan,[108] the Inter-Organization Program for the Sound Management of Chemicals (IOMC),[109] and the International Forum on Chemical Safety (IFCS),[110] nanotechnology and manufactured nanomaterials were nominated as an emerging issue to be considered by ICCM-2. In this context, Switzerland and the United States prepared two papers to stimulate discussion on the issue.[111]

5. The Potential of Multilateral Environmental Agreements

94. In *The Ethics and Politics of Nanotechnology*, UNESCO concluded that "the most pressing issue may not be determining the exact toxicity of nanoparticles, but creating new and enforcing old regulations on industries who create and process these new materials" [112] to address both eco-toxicological aspects of nanomaterials and broader social and ethical impacts. A number of existing multilateral environmental agreements (MEAs) dealing with international chemicals management, such as the Stockholm Convention on Persistent Organic Pollutants (POPs) or the Basel Convention, could prove relevant in addressing some of the issues raised by nanotechnology and

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[107] See SAICM homepage at http://www.saicm.org/index.php?ql=h&content=home.
[108] See *Compilation of submissions received from stakeholders to the questionnaire on emerging policy issues*, SAICM/InfDisc/INF/1, at p.12, 13 available at http://www.saicm.org/documents/OELTWG/Informal%20discussions/ID%20INF1%20issues%20compilation.pdf.
[109] See *supra* note 108, at 64-70.
[110] *Id.* at 41-45.
[111] *Background information in relation to the emerging policy issues of nanotechnology and manufactured nanomaterials*, SAICM/ICCM.2/INF/34, available at http://www.saicm.org/documents/iccm/ICCM2/meeting%20documents/ICCM2%20INF33%20emerging%20issues%20list.pdf; *Proposed Element of Cooperative Work on Nanotechnology* incorporated into document SAICM/ICCM.2/10/Add.1. available at http://www.saicm.org/documents/iccm/ICCM2/emerging%20issues/Nano/Proposed%20cooperative%20actions%20on%20nano.doc.
[112] See *supra* note 1, at 15.

manufactured nanomaterials as an issue of global concern. This Part will provide an overview of existing MEAs that might be used to address such issues.

5.1. The Stockholm Convention

95. POPs are toxic chemicals that can remain intact in the environment for long periods, travel long distances throughout the environment, and accumulate in the fatty tissue of humans and wildlife.[113] The Stockholm Convention is a global treaty to protect human health and the environment from POPs. It was adopted 22 May 2001 and entered into force on 17 May 2004.[114]

96. Because the Stockholm Convention does not distinguish pollutants on the basis of particle size, it could be used to regulate nanomaterials that exhibit the characteristics of POPs. Some nanomaterials have been shown to exhibit the POPs criteria of toxicity, persistence, bioaccumulation and long distance environmental transport. However, most existing manufactured nanomaterials would arguably not fall within the scope of the Stockholm Convention because they are not organic (inorganic) compounds.[115] For example, because zinc powder is an inorganic compound, it may not fall within the scope of the Stockholm Convention. Similarly, although carbon allotropes, such as carbon nanotubes, have been shown to mimic the effects of asbestos,[116] they are not considered organic; therefore, they also may not fall within the scope of the Convention.

97. In the case of bioaccumulation, the presence of certain nanomaterials may enhance the bioaccumulation of other toxic substances in aquatic organisms,[117] even though the nanomaterials themselves are not bioaccumulative. This type of effect may not be covered by the Stockholm Convention; thus, such nanomaterials may not be subject to the Convention.

98. In summary, the Stockholm Convention is designed to address chemicals that possess the specific characteristics of POPs. Although some nanomaterials may belong in this category, and could therefore be dealt with under the Stockholm Convention, the Convention may cover only a fraction of existing nanomaterials that raise issues of global concern. Moreover, the Convention would likely not be capable of addressing the broader societal issues raised by the manufacture and release of nanomaterials.

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[113] See Stockholm Convention on Persistent Organic Pollutants (POPs), annex D, art. 1 (b), (c), (d), and (e), U.N. Doc. UNEP/POPS/CONF/4 available at http://chm.pops.int/Portals/0/Repository/convention_text/UNEP-POPS-COP-CONVTEXT-FULL.English.PDF.

[114] See http://chm.pops.int/Convention/tabid/54/language/en-US/Default.aspx#convtext.

[115] Organic compounds are defined as any member of a large class of chemical compounds whose molecules contain carbon. For historical reasons, a few types of compounds such as carbonates, simple oxides of carbons and cyanides as well as the allotropes of carbon are considered inorganic. See http://en.wikipedia.org/wiki/Organic_compound.

[116] See section 3.2.1.

[117] See *supra* note 31.

5.2. The Basel Convention

99. The Basel Convention aims to protect human health and the environment against the adverse effects resulting from the generation, management, transboundary movement and disposal of hazardous and other wastes. It came into force in 1992 and now has 172 Parties.[118]

100. Transboundary movements of waste containing nanomaterials that fit the Basel Convention's definition of hazardous wastes should fall within the scope of the Convention. Under the Convention, such wastes include, for example, "chemical substances arising from research and development. . . which are not identified and/or are new and whose effects on man and/or the environment are not known."[119] The question of whether waste containing nanomaterials could or should be considered hazardous waste requires more in-depth study, taking into account on-going debates surrounding the definition of hazardous wastes under the Basel Convention.

101. The concept of environmentally sound management of wastes[120] is used throughout the Basel Convention to define the obligations of the Parties in relation to transboundary movements of hazardous and other wastes, as, for example, in Article 4, §§ 2(e),[121] 2(g),[122] or 8.[123] However, the United Kingdom Royal Commission on Environmental Pollution notes that with regard to nanomaterials, "there is a consensus that mechanisms of toxicity are poorly understood"[124] and specifies "our inquiries suggested that very little thought has been given to their environmental impact as they become detached from products in use or at the point of final disposal."[125] Given this poor state of current knowledge, it may be difficult or even impossible to define environmentally sound management of some wastes containing nanomaterials.

102. While the Basel Convention can potentially be used to address transboundary movement of waste containing nanomaterials, significant progress will first need to be made to further understand the toxicity of nanomaterials throughout their life cycle, before the provisions of the Basel Convention can be used effectively.

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[118] http://www.basel.int/ratif/convention.htm accessed on 25 April 2009.

[119] See Basel Convention, Annex 1, section Y14. "Waste chemical substances arising from research and development or teaching activities which are not identified and/or are new and whose effects on man and/or the environment are not known."

[120] Article 2.8 defines environmentally sound management of hazardous wastes as "taking all practicable steps to ensure that hazardous wastes or other wastes are managed in a manner which will protect human health and the environment against the adverse effects which may result from such wastes."

[121] Each Party shall take the appropriate measures to: "Not allow the export of hazardous wastes or other wastes to a State or group of States (…) if it has reason to believe that the wastes in question will not be managed in an environmentally sound manner (…)."

[122] "Each Party shall take the appropriate measures to Prevent the import of hazardous wastes and other wastes if it has reason to believe that the wastes in question will not be managed in an environmentally sound manner."

[123] "Each Party shall require that hazardous wastes or other wastes, to be exported, are managed in an environmentally sound manner in the State of import or elsewhere."

[124] See *supra* note 11, at 30.

[125] *Id.* at 6.

5.3. The Rotterdam Convention on Prior Informed Consent

103. The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (the Rotterdam Convention) was signed in Rotterdam, The Netherlands, on 10 September 2004 and entered into force on 24 February 2004.[126] This Convention creates legally binding obligations for the implementation of the Prior Informed Consent (PIC) procedure. It applies to banned[127] or severely restricted[128] chemicals and severely hazardous pesticide formulations that are listed in Annex III, the "PIC list." Parties may export listed substances to other Parties only if the prospective importing Party first provides its informed consent. A number of types of chemicals are not included in within the Convention's scope, including "pharmaceuticals, [both] human and veterinary drugs,"[129] and "[c]hemicals used as food additives."[130]

104. To date, no State has adopted a specific regulation with regard to nanomaterials, and no nanomaterial has been banned, restricted or labeled as hazardous in any State Party to the Convention. The Rotterdam Convention does not, therefore, apply to any nanomaterial so far. In the event that a Party to the Rotterdam Convention wishes to nominate a nanomaterial to be listed on Annex III, it would have to comply with the procedures laid out in Articles 5 and 7.

105. The Rotterdam Convention could be used to provide countries with the right to require their prior informed consent before other countries could export products or articles containing specific hazardous nanomaterials to them. However, the nature of the Convention makes it difficult to list new substances so that they may become subject to its controls; ordinarily, only substances that are already banned or severely restricted in two or more countries may be considered for listing, which means that the Convention takes a somewhat backward-looking, rather than forward-looking, precautionary approach. New listings are made on a chemical-by-chemical basis, making it difficult for the Convention to address nanomaterials in a comprehensive manner. Moreover, the

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[126] See http://www.pic.int/home.php?type=t&id=5&sid=16.
[127] Article 2(b) of The Convention for the Application of Prior Informed Consent Procedure for Certain hazardous Chemicals and Pesticides in International Trade (Rotterdam Convention) defines a banned chemical as a "chemical all uses of which within one or more categories have been prohibited by final regulatory action, in order to protect human health or the environment. It includes a chemical that has been refused approval for first-time use or has been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process and where there is clear evidence that such action has been taken in order to protect human health or the environment." Available at http://www.pic.int/en/ConventionText/ONU-GB.pdf.
[128] Article 2(c) of the Rotterdam Convention defines a severely restricted chemical as a "chemical virtually all use of which within one or more categories has been prohibited by final regulatory action in order to protect human health or the environment, but for which certain specific uses remain allowed. It includes a chemical that has, for virtually all use, been refused for approval or been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process, and where there is clear evidence that such action has been taken in order to protect human health or the environment."
[129] Article 3(e).
[130] Article 3(f).

Rotterdam Convention is not intended to address the regulation of chemicals beyond the tool of prior informed consent in international trade.

5.4. The Aarhus Convention

106. The United Nations Economic Commission for Europe (UNECE) Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (the Aarhus Convention) was adopted on 25 June 1998 in the Danish city of Aarhus. It entered into force on 30 October 2001.[131] The objective of the Aarhus Convention is to "guarantee the rights of access to information, public participation in decision-making, and access to justice in environmental matters."[132] The Aarhus Convention is open to non-UNECE States, but none have become parties so far.

107. As its formal title suggests, the Aarhus Convention contains three broad themes or "pillars": access to information; public participation; and access to justice. It also contains a number of general features, such as the definition of "public authorities."[133] The Aarhus Convention aims to establish common, general standards to strengthen the effectiveness and legitimacy of environmental policies.[134] The Convention also contains a more general requirement on Parties to promote the application of its principles within the framework of international bodies in matters relating to the environment.[135]

108. Rather than providing a framework to address nanotechnology and nanomaterials as an issue of global concern, the provisions of the Aarhus Convention lay down principles that could guide the operations of a future global cooperation framework on nanotechnology and nanomaterials, warranted by the recognition of these topics as an issue of global concern.

5.5. SAICM

109. SAICM is a global process including delegations from over 160 States[136] and twelve inter-governmental organizations, including the OECD, WHO and ILO.[137] NGOs

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[131] See http://www.unece.org/env/pp/.
[132] UNECE Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (Aarhus Convention), 25 June 1998, art. 1, available at http://www.unece.org/env/pp/documents/cep43e.pdf.
[133] http://www.unece.org/env/pp/contentofaarhus.htm.
[134] "Vision and Mission" of the Aarhus Convention Strategic Plan, adopted by the Meeting of the Parties to the Aarhus Convention, in Riga, Latvia, 13 June 2008, available at http://www.unece.org/env/pp/LTSP/LTSP_draft_for_public_comment_v_2007_03_06.doc.
[135] Aarhus Convention art. 3.7.
[136] See the list of SAICM national focal points, available at http://www.saicm.org/documents/List%20of%20SAICM%20National%20Focal%20Points%20web.doc.
[137] See the list of SAICM focal points in Intergovernmental Organizations available at http://www.saicm.org/documents/List%20of%20SAICM%20IGO%20Focal%20Points%20web.doc.

have the status of full participants[138] in the SAICM process, which now includes 60 NGO focal points.[139]

110. SAICM's broad mandate includes "[e]nvironmental, economic, social, health and labour aspects of chemical safety," as well as "[a]gricultural and industrial chemicals, with a view to promoting sustainable development and covering chemicals at all stages of their life-cycle, including in products."[140] The SAICM Overarching Policy Strategy states that the SAICM's objectives include "ensuring that existing, new, and emerging issues of global concern are sufficiently addressed by means of appropriate mechanisms."[141] The objectives also cover risk reduction, information sharing, and governance, which are all highly relevant to addressing nanotechnologies and nanomaterials as an emerging issue of global concern. The SAICM process puts a strong emphasis on balancing North-South concerns.[142] It includes specific approaches and provisions which are particularly relevant to addressing nanomaterials as an issue of global concern, particularly those relating to transparency, public participation, and precaution.[143]

5.6. Conclusion

111. As an issue of global concern, nanotechnologies and nanomaterials warrant a global cooperative framework that allows them to be addressed in a comprehensive manner. Such a framework should be global, participatory, and transparent; comprehensive in terms of risks, life cycle and issues addressed; adaptable and flexible to take into account new experience and scientific knowledge; precautionary; and effective. While existing international instruments and processes can be used to help bridge the knowledge gap, they are insufficient to address all of the issues raised by nanotechnologies and nanomaterials in a comprehensive manner.

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[138] See "*Implementing the Strategic Approach to International Chemical Management*", presentation prepared by the SAICM secretariat, September 2006, Slide 11, available at http://www.unep.org/civil_society/GCSF8/pdfs/SAICMSep06.ppt.
[139] See the list of SAICM NGO focal points at http://www.saicm.org/documents/List%20of%20SAICM%20NGO%20Focal%20Points%20web.doc.
[140] SAICM Overarching Policy Strategy Articles 3(a) and (b), available at http://www.saicm.org/documents/saicm%20texts/SAICM_publication_ENG.pdf.
[141] *Id.* para. 14(g).
[142] *Id.* paras. 8(a), 10(a), 10(b), 15(a), and 17(b).
[143] See, for example, *id.* para. 16(b) in relation to cross sectoral governance, para. 16(k) with regard to promoting mutual supportiveness between trade and environmental policies, para. 15(c) to adequately address confidential and commercial information, and para. 14(e) on applying the precautionary principle.