University of Alberta

Nanotechnology: The Ethical, Environmental, Economic, Legal and Social Issues (NE^3LS)

by

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Abstract

The overall objective of this thesis is to argue that scientific risk research to support evidence-based regulation of nanotechnology and related research on the environmental, economic, ethical, legal and social issues (NE^3LS) associated with nanoscience and nanotechnology is urgently required to facilitate the responsible research and development, commercialization and public acceptance (or non-acceptance) of nanotechnology in Canada. These issues are contemplated through the lens of environmental stewardship pursuant to the *Canadian Environmental Protection Act*. Given the unique challenges that nanotechnology raises – including the potential for human health and environmental harms – Canadian regulatory agencies, including Environment Canada and Health Canada should consider adopting the International Risk Governance Council's Risk Governance Framework for Nanotechnology.

Acknowledgement

A debt of gratitude is owed to my Supervisor, Mr. Timothy Caulfield and all of my colleagues at the Health Law Institute, whose continual support of my efforts have made this work possible. I would also personally like to thank Terry McIntyre (Environment Canada) and Mark Roseman (Ontario Government) for their insight and generous spirit of collegiality.

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List of Abbreviations

ABA –	American Bar Association
ACST	Advisory Committee on Science and Technology
CEPA	Canadian Environmental Protection Act
CIHR	Canadian Institutes of Health Research
CIPO	Canadian Intellectual Property Office
CWA	Clean Water Act (U.S.)
CWA	Clean Water Act (U.S.)
DEFRA	Department for Environment, Food and Rural Affairs (U.K.)
EPA	Environmental Protection Agency (U.S.)
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act (U.S.)
GE^3LS	Genetics and Genomics: Ethical, Environmental, Economic, Legal and Social Issues
GM	Genetically modified
ICON	International Council on Nanotechnology
IRGC	International Risk Governance Council
ISRP	International Scientific Review Panel
NE^3LS	Nanotechnology: Ethical, Environmental, Economic, Legal and Social Issues
NIOSH	National Institute for Occupational Safety and Health (U.S.)
NRC	National Research Council
OECD	Organization for Economic Cooperation and Development
NINT	National Institute for Nanotechnology (Canada)
NNI	National Nanotechnology Initiative (U.S.)
UNESCO	United Nations Education, Scientific and Cultural Organisation
USPTO	United States Patent and Trademark Office

Chapter 1

Introduction

A. Background

Nanotechnology is expected to have a major impact on societal evolution; indeed it can be argued that this impact is already being felt. The Woodrow Wilson International Center for Scholars has developed an online inventory of products that employ nanoscience or nanotechnology. This inventory lists over 250 products that are currently marketed in the United States, many of which are also marketed in Canada.[1] Products appearing on the inventory include sporting goods, wrinkle and stain resistant fabrics and clothing, wound dressings, sunscreens, cosmetics, computer processors and a variety of surface coatings (including paints and sealants). Lux Research has recently reported that thirty-two billion ($32 billion USD) worth of goods sold in 2005 included some type of nanotechnology; sales are predicted to climb to $2.6 trillion by 2014.[2] This represents an enormous market, and one that is likely to rapidly expand as current research activities translate into further product development and commercialization.

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[1] Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies, Inventory of Nanotechnology Consumer Products, online: Woodrow Wilson International Center for Scholars <http://www.nanotechproject.org/44>. As of August 4, 2006, 276 consumer products were listed in the inventory.

[2] Victor Godinez, "As Nanotech Business Grows, So Does Debate" Dallas Morning News, 18 June 2006, online: DallasNews.com <http://www.dallasnews.com/sharedcontent/dws/bus/stories/061806dnbiznanotech.9b122409.html>.

Within Canada there is a robust, well-funded and active nanoscience community. Initial commercialization activities are already being actively pursued. With this reality, there is a growing recognition that policy development and regulatory activities, including scientific research to support regulation, are lagging significantly behind these activities. The overall objective of this thesis is to argue that scientific risk research to support evidence-based regulation of nanotechnology and related research on the environmental, economic, ethical, legal and social issues (NE^3LS)[3] associated with nanoscience and nanotechnology is urgently required to facilitate the responsible research and development, commercialization and public acceptance (or non-acceptance) of nanotechnology in Canada.[4]

This thesis is divided into four chapters. Chapter 1 provides background information about the relative importance of nanotechnology as a technology enabler and the state of nanoscience and nanotechnology in Canada. Chapter 2 provides an overview of the main NE^3LS issues that have been identified in the literature and suggests that proactive attention to NE^3LS issues is necessary. Most importantly, in the near term scientific research to elucidate the effects of nanomaterials on human health and the environment to inform regulatory decision-making is required. Chapter

[3] For purposes of this paper, NE^3LS research is that research which aims to facilitate the responsible research and development, and use (or non-use) of nanotechnology-enabled products in and by society.

[4] Lorraine Sheremeta & Abdallah S. Daar, "The Case for Publicly Funded Research on the Ethical, Environmental, Economic, Legal and Social Issues Raised by Nanoscience and Nanotechnology (NE^3LS)" (2003) 12:3 Health L. Rev. 74.

3 provides an overview of the main policy challenges raised by nanotechnology. Particular attention is paid to definitional issues and metrology, scientific uncertainty about risks and the pragmatic need for regulatory clarity. Chapter 3 ends with a case-study evaluating the applicability and relevance of the *New Substances Notification Regulations*[5] enacted pursuant to the *Canadian Environmental Protection Act*[6] as applied to C_{60} fullerenes[7] manufactured for research purposes. The case study was chosen for its direct relevance to researchers, research facilities and regulators in Canada. The fourth and final chapter envisions a future for nanotechnology in Canada that is founded on the deliberate application of an innovative risk governance strategy. The main recommendations arising from this work are: (1) that Canada must develop a national strategy for nanotechnology; and (2) that federal regulators, including Environment Canada and Health Canada should adopt the nanotechnology risk governance strategy developed by the International Risk Governance Council (IRGC).

B. Nanoscience and Nanotechnology Defined

Nanoscale science and technology is the dynamic domain of science and technology at the confluence of physics, chemistry, biology, information technology,

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[5] S.O.R./2005-247.

[6] S.C. 1999, c.33 [*CEPA, 1999*].

[7] For purposes of the case-study, the original carbon fullerene, first described by Kroto *et al* in 1985 will be used as the example. See, H.W. Kroto, J.R. Health, S.C. O'Brien *et al* "C_{60}: Buckminsterfullerene" (1985) 318 Nature 162. Fullerenes are geodesic carbon molecules comprised of 60 carbon atoms configured in the shape of a soccer ball. Fullerenes and other geodesic carbon molecules are of ongoing research interest to nanoscientists.

biotechnology and medicine. "Nanoscience" is the study of the base level of organization of matter (organic, inorganic or man-made) that determines its fundamental characteristics and function. It has been described as "the builder's final frontier."[8] For some perspective on dimension, a nanometer, is one-billionth of a metre; a standard sheet of paper is about 100,000 nanometers thick.

At the nanoscale, between approximately 1 - 100 nm, fundamental characteristics of matter that we typically presume immutable (including electrical conductivity, colour, strength, and melting point etc.) can change. By understanding nanoscale phenomena and the characteristics of materials at this scale, it will become increasingly possible to engineer novel materials for use in many applications. Nanotechnology research and development is focused on understanding and creating improved materials, devices, and systems that exploit these novel properties.[9]

The term "nanotechnology" is inherently difficult to define. It represents a series of technologies used independently or in combination to make products,

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[8] National Science and Technology Council Committee on Technology, "Nanotechnology: Shaping the World Atom by Atom", online: World Technology Evaluation Center <http://www.wtec.org/Loyola/nano/IWGN.Public.Brochure/> at 1, citing Richard Smalley.

[9] National Nanotechnology Initiative, "What is nanotechnology?" online: NNI <http://www.nano.gov/html/facts/whatIsNano.html>; See also, US, Nanoscale Science, Engineering, and Technology Subcommittee, *The National Nanotechnology Initiative: Research and Development Leading to a Revolution in Technology and Industry, Supplement to the President's 2006 Budget,* (Arlington, VA: National Nanotechnology Coordination Office, March 2005) online: National Nanotechnology Initiative <http://www.nano.gov/NNI_06Budget.pdf>.

perform tasks and to gain a better understanding of science. Canada's National Research Council describes nanotechnology as:

> [M]anufacturing at the molecular level – building things from molecular or nano-scale components. . . . Nanotechnology proposes the construction of novel nano-scale devices possessing extraordinary properties. Through the development of such instruments and techniques it is becoming possible to study and manipulate individual atoms. This ability is almost in the grasp of humankind.[10]

The Office of the National Science Advisor defines nanotechnology as "the study and manipulation of novel properties arising from matter on the nanoscale."[11]

Through this newfound control over the natural world, nanoscience and the technologies derived from it are expected to have profound societal effects – both positive and negative. For example, it has been predicted that:

> Few industries will escape the influence of nanotechnology. Faster computers, advanced pharmaceuticals, controlled drug delivery, biocompatible materials, nerve and tissue repair, surface coatings, better skin care and protection,

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[10] Online: National Research Council <www.nrc-cnrc.gc.ca/nanotech/about_e.html>.

[11] Canada, Office of the National Science Advisor, *Assessment of Canadian Research Strengths in Nanotechnology*: *Report of the International Scientific Review Panel*,

> catalysts, sensors, telecommunications, magnetic materials and devices – these are just some areas where nanotechnology will have a major impact. Indeed, there is a growing appreciation that it is difficult to find areas of manufacturing and industry where nanoscience and nanotechnology will not have an impact.[12]

The late Nobel Laureate Richard Smalley predicted that:

> [T]he impact of nanotechnology on health, wealth, and the standard of living for people will be at least the equivalent of the combined influences of microelectronics, medical imaging, computer-aided engineering, and man-made polymers in this century.[13]

As in the early days of biotechnology development, there are concerns that undue optimism over the potential benefits of nanotechnology may inspire public mistrust when the promises don't materialize as quickly as hoped and as more becomes known about the associated risks. At present, most Canadians don't know

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November 2005, online: ACST <http://acst-ccst.gc.ca/back/home_e.html> (available by e-mail request to acst-ccst@ic.gc.ca).

[12] UK Advisory Group on Nanotechnology, *New Dimensions for Manufacturing: A UK Strategy for Nanotechnology* (London: Department of Trade and Industry, 2002) at 12. See also Harold Brubaker, " Nanotechnology is Hot, if you're into Mundane Products" *Smalltimes* (9 April 2004), online: Smalltimes <http://www.smalltimes.com/document_display.cfm?document_id=7701>.

[13] Richard E. Smalley, "Prepared Written Statement and Supplemental Material of R.E. Smalley, Rice University, May 12, 1999", online: US Department of Energy <http://www.sc.doe.gov//bes/senate/smalley.pdf>.

what nanotechnology is.[14] Those who do are, for the most part, interested and optimistic about the potential benefits. The overall impact of nanotechnology on society is difficult to gauge in light of unknown and/or unforeseeable risks.

C. Risks and Challenges

There is an emerging body of scientific data that suggests that manufactured nanoparticles may pose significant human health and environmental risks. It is postulated that nanoparticles have different biological effects as compared to larger sized particles of the same material. The small size of nanoparticles renders them inhalable, ingestible and potentially absorbable through the skin. Once internalized, the specific biologic behavior of nanoparticles is not well understood. Biologic fate likely depends on many features including the chemical composition, size, shape, relative surface area, charge etc.[15]

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[14] Edna Einsiedel, "In the Public Eye: The Early Landscape of Nanotechnology Among Canadian and US Publics", in *First Impressions: Understanding Public Views on Emerging Technologies*, Report Prepared for the Canadian Biotechnology Secretariat, September 2005, online: Bioportal <https://bioportal.gc.ca/CMFiles/CBS_Report_FINAL_ENGLISH249SFD-9222005-5696.pdf> at 16.

[15] Vicki L. Colvin, "The Potential Environmental Impact of Engineered Nanomaterials" (2003) 10 Nature Biotechnology 1166; Günter Oberdörster *et al*, "Principles for Characterizing the Potential Human Health Effects from Exposure to Nanomaterials: Elements of a Screening Strategy" (2005) 2:8 Particle and Fibre Toxicology, online: Particle and Fibre Toxicology <http://www.particleandfibretoxicology.com/content/2/1/8>; HM Government, *Characterising the Potential Risks Posed by Engineered Nanoparticles: A First UK Government Research Report* (London: DEFRA, 2005), online: UK Department for Environment, Food and Rural Affairs

Public action groups have been quick to seize on the potential risks of nanomaterials and nanoparticles. In 2003, the ETC Group, a public action group with headquarters in Ottawa, has gone so far as to suggest an immediate "moratorium on the commercial production of new nanomaterials and [to] launch a transparent global process for evaluating the socio-economic, health and environmental implications of the technology".[16] Various public action groups, including Greenpeace, Environmental Defense, the Center for Responsible Nanotechnology, the Foresight Institute, Friends of the Earth and others have waded into the nanotechnology debate.[17] Accordingly, there is a need for government, industry and academia to mobilize rapidly to understand the nature of the risks and to refine regulatory safeguards as appropriate.[18] In an influential article published in 2003, Rice University professor and research scientist, Vicki Colvin, articulated the problem as follows:

<http://www.defra.gov.uk/environment/nanotech/nrcg/pdf/nanoparticles-riskreport.pdf>.

[16] ETC Group, *From Genomes to Atoms: The Big Down: Atomtech – Technologies Converging at the Nano-scale* (Winnipeg: ETC Group, January, 2003) online: ETC Group <http://www.etcgroup.org/documents/TheBigDown.pdf> at 25; see also, ETC Group, NanoGeoPolitics: ETC Group Surveys the Political Landscape, July/August 2005, ETC Group Special Report, Communique No. 89, online: ETC Group <http://www.etcgroup.org/documents/Com89SpecialNanoPoliticsJul05ENG.pdf>.

[17] International Risk Governance Council, Survey of Nanotechnology Governance, Volume D: The Role of NGOs, April 2006, online: IRGC: <http://www.irgc.org/irgc/projects/nanotechnology/_b/contentFiles/Survey_on_Nanotechnology_Governance_-_Part_B_The_Role_of_Industry.pdf>.

[18] *Supra*, note 15 (Colvin).

> With the increased presence of nanomaterials in commercial products, a growing public debate is emerging on whether the environmental and social costs of nanotechnology outweigh its many benefits. To date, few studies have investigated the toxicological and environmental effects of direct and indirect exposure to nanomaterials and no clear guidelines exist to quantify these effects.[19]

There is an emerging realization in Canada and elsewhere that research to clarify the human health and environmental effects of nanomaterials is urgently needed support regulation, risk governance and the responsible stewardship of nanotechnology.

D. National Strategic Initiatives & Nanotechnology

Whether exaggerated or not, the potential benefits of nanotechnology are inspiring governments around the world, including Canada's, to invest heavily in nanoscience and nanotechnology research and development.[20] The United States, for example, has unequivocally embraced nanotechnology as a key investment opportunity. The National Nanotechnology Initiative (the "NNI") was established in 2001 with its vision being "a future in which the ability to understand and control

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[19] *Ibid.* at 1166.

[20] Mihail C. Roco, "Broader Societal Issues of Nanotechnology" (2003) 5 J. Nanoparticle Res. 181, online: National Science Foundation <http://www.nsf.gov/crssprgm/nano/reports/BroaderSocIssue.pdf>; The Royal Society and the Royal Academy of Engineering, *Nanoscience and Nanotechnologies: Opportunities and Uncertainties* (London: Royal Society, August 2004), online: The Royal Society <http://www.nanotec.org.uk/finalReport.htm>.

matter on the nanoscale leads to a revolution in technology and industry".[21] To this end, the NNI aims to:

> expedite the discovery, development and deployment of nanotechnology in order to achieve responsible and sustainable economic benefits, to enhance the quality of life, and to promote national security. In the process, the NNI will support the missions of the participating agencies, will ensure continuous leadership by the United States in nanoscale science, engineering and technology, and will contribute to the nation's economic competitiveness.[22]

Since the inception of the NNI, many industrialized and developing countries have similarly adopted strategic initiatives focusing on nanoscience and nanotechnology.[23] As of 2005, over thirty nations, including both developed and developing nations, had implemented or were in the process of implementing nanotechnology strategies.[24] At the time of writing, and despite a recognition of the importance of developing a national strategy for nanotechnology, Canada remains

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[21] *Supra*, note 9 (Supplement to 2006 US Budget) at 5.

[22] *Ibid.*

[23] Mark Roseman, "An Overview of Nanotechnology in Canada, Report 1: Environmental Scan of the Current State of Play" August 2005, a copy of the report can be requested online: Advisory Council on Science and Technology (ACST) <http://acst-ccst.gc.ca/back/home_e.html>.

[24] Mark Roseman, "An Overview of Nanotechnology in Canada, Report 2: A Review and Analysis of Foreign Nanotechnology Strategies" October 2005, a copy of the report can be requested online: Advisory Council on Science and Technology (ACST) <http://acst-ccst.gc.ca/back/home_e.html>. Countries discussed in this report

without one. It remains unclear whether the new Conservative government will move towards developing a national strategy anytime soon.

E. An overview of Canadian competence in nanoscience and nanotechnology

In July 2005, under the previous federal government Canada's National Science Advisor, Dr. Arthur Carty, convened a panel of international experts to assess Canada's relative strengths in nanoscience and nanotechnology. The International Scientific Review Panel (ISRP), chaired by Dr. Carty, was comprised of the following international experts: Mauro Ferrari (Ohio State University), Robert Yang (Applied Science and Technology Research Institute, Hong Kong), Martin Moskovits (University of California, Santa Barbara), David Reihhoudt (University of Twente, the Netherlands), William Pulleyblank (IBM), Fabio Beltram (SNS Physics Laboratory, Pisa, Italy).

In preparation for this review, a team of Canadian experts including Peter Grütter (McGill University), Remi Quirion (CIHR), Nils Peterson (NRC/NINT) and Lori Sheremeta (University of Alberta, Health Law Institute), were asked to prepare papers on Canadian strengths respecting academic research in science and engineering[25], nanomedicine research[26], nanotechnology at the National Research

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include Australia, Germany, Israel, Japan, South Korea, Switzerland, Taiwan and the United States.

[25] Peter Grutter, "A Summary of Nanoscale Academic Research in Science and Engineering" (2005) [unpublished paper, on file with author].

[26] Remi Quirion & Eric Marcotte, "A Summary of Canadian Nanomedicine Research Funding: Strengths and Needs" (2005) [unpublished paper, on file with author].

Council[27] and NE^{3}LS research.[28] These papers, in addition to statistical data compiled by the National Science Advisor's office comprised the background materials for the ISRP's review.

Through the process of that review, there emerged an unequivocal recognition that Canada has a burgeoning talent in the area but, given the climate of international competitiveness, Canada must quickly develop a strategy to compete in those areas in which it has demonstrated strength and expertise.[29] The ISRP recognized that, although Canadian scientists participate broadly in all areas of nanoscience, given the size of the country and the research base, Canada cannot be expected to become *the* leader in each of the key areas in which nanotechnology is anticipated to have an impact. A national nanotechnology strategy would direct Canada's scientific efforts towards those areas in which it currently has a competitive advantage. Though Canada cannot expect to compete with the absolute investment of countries like the United States or Japan, it can seek to invest proportionally and contribute substantially to the development of nanoscience into socially beneficial nanotechnologies. Canada can and should contribute in meaningful ways to the international collaborative efforts that are underway to develop nomenclature and

[27] Nils Petersen, "A Summary of the National Research Council of Canada's Nanotechnology Strengths and Opportunities" (2005) [unpublished paper, on file with author].

[28] Lorraine Sheremeta, "An Overview of NE^{3}LS Research in Canada" (2005) [unpublished paper, on file with the author].

[29] *Supra*, note 11 (International Scientific Review Panel).

measurement standards[30], the characterization of nanomaterials,[31] and the development of well-founded occupational health and safety standards for research scientists and industrial workers who are increasingly exposed to nanoparticulates in the course of their work.[32] In addition, Canada has an important opportunity to adopt and participate in the refinement of a comprehensive risk governance strategy for nanotechnology that has been developed by an interdisciplinary team of experts led by Mike Roco and Ortwin Renn.[33]

Overall, government investment in nanotechnology has risen dramatically since 2000. Figure 1 depicts worldwide government investment in nanotechnology as compared with US government investment in nanotechnology between 1997 and 2003.

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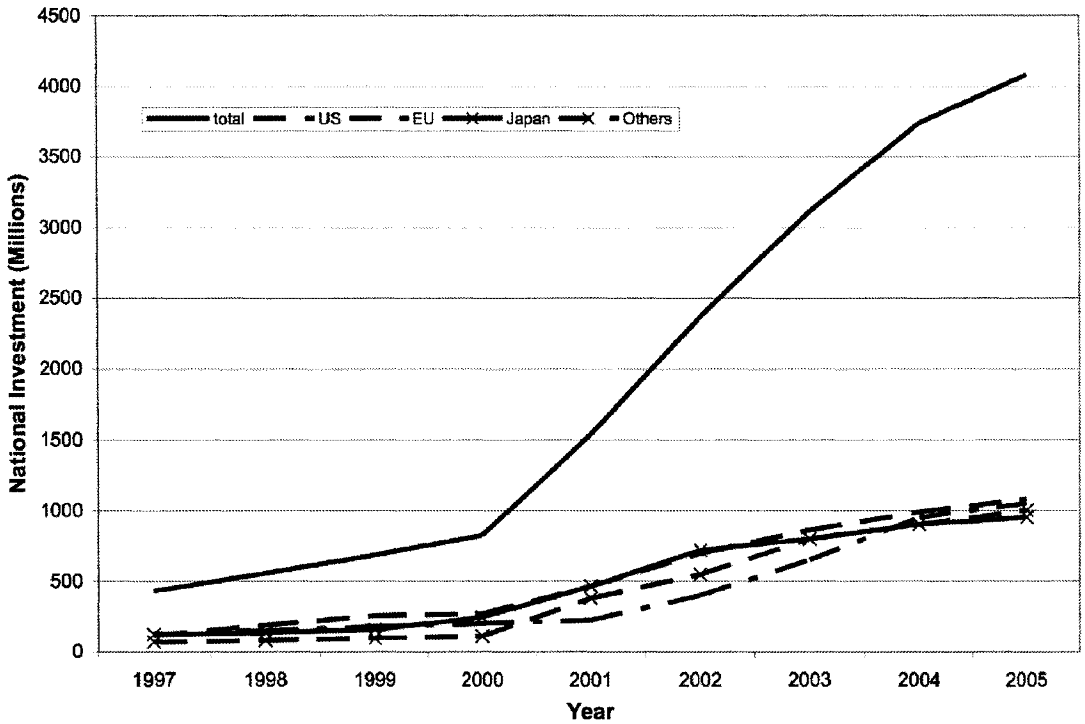
[30] International Standards Organisation (ISO Technical Committee 229), American Society for Testing and Materials (ASTM E56 Committee), Organization for Economic Cooperation and Development (OECD, new working group to be established under the Chemicals Committee), Institute of Electrical and Electronics Engineers (IEEE), International Engineering Consortium (IEC).

[31] International Council on Nanotechnology (ICON), online: ICON <http://icon.rice.edu/>; Organization for Economic Cooperation and Development (OECD), online: OECD <http://www.oecd.org/department/0,2688,en_2649_37015404_1_1_1_1_1,00.html>.

[32] National Institute for Occupational Health and Safety (NIOSH), online: NIOSH <http://www.cdc.gov/niosh/topics/nanotech/>.

[33] International Risk Governance Council (IRGC), online: IRGC <http://www.irgc.org/irgc/projects/nanotechnology/>.

Figure 1-1: National government (and European Union) investments in nanotechnology research and development (1997-2005)[34]



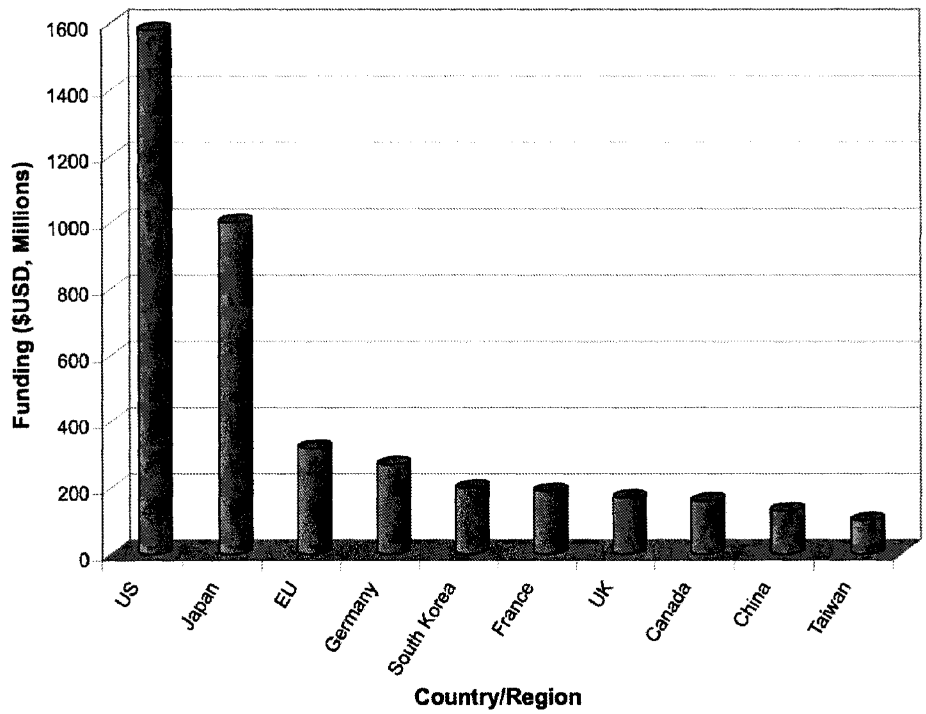
In 2004, Canada's nanotechnology investment was approximately USD $126 million compared to US government investment of approximately $989 million and Japanese government investment of approximately $864 million (see Figure 2).[35] The 2006 budget request for the US NNI was in excess of USD $1 billion and the recently released 2007 budget request for the US NNI is $1.3 billion.[36]

[34] M.C. Roco, "International Perspective on Government Funding in 2005" (2005) 7 Journal of Nanoparticle Research 707 at 709 (data used with permission).

[35] *Supra*, note 24 (Roseman, Report 2) at 4.

[36] *Supra,* note 9 (2006 Budget Supplement); US, Nanoscale Science, Engineering, and Technology Subcommittee, *The National Nanotechnology Initiative: Research and Development Leading to a Revolution in Technology and Industry, Supplement to the President's FY 2007 Budget,* (Arlington, VA: National Nanotechnology

Figure 1-2: Worldwide government nanotechnology funding (2004)[37]



Though Canada's absolute investment is modest when compared to the US and Japan, its investment relative to GDP is substantial and places Canada ahead of the US but behind Japan and Taiwan (see Figure 1-3).

Coordination Office, July 2006) online: National Nanotechnology Initiative <http://www.nano.gov/NNI_07Budget.pdf>.

[37] Office of the National Science Advisor, *Overview of Government Supported Nanotechnology Research Funding in Canada*, September 2005 at 2 (data used with permission).

Figure 1-3: Nanotechnology government funding relative to Gross Domestic Product (2003)[38]

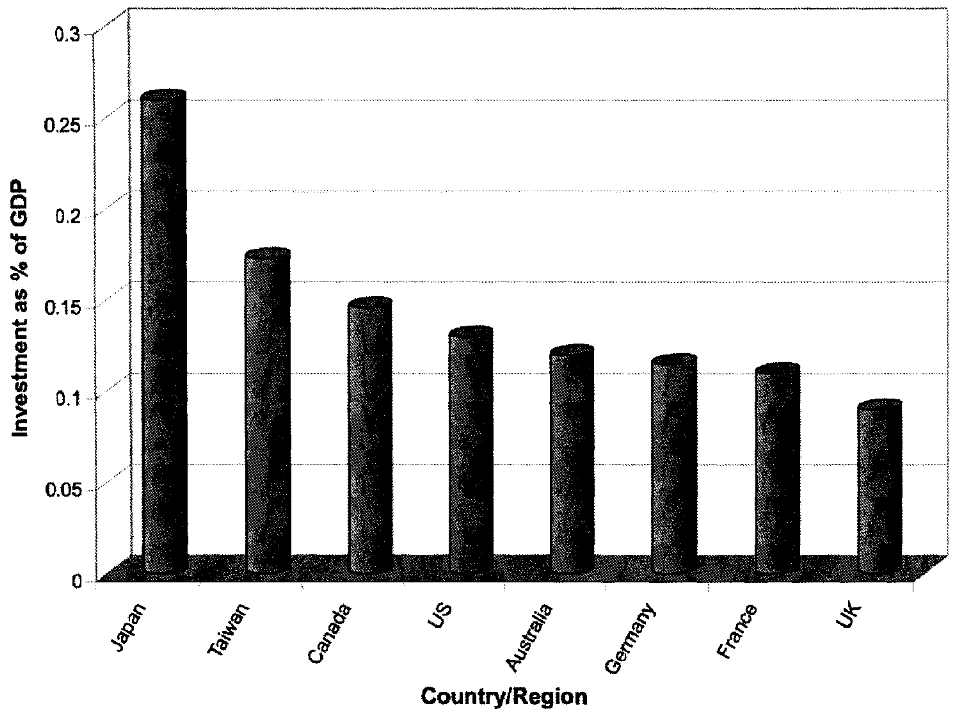
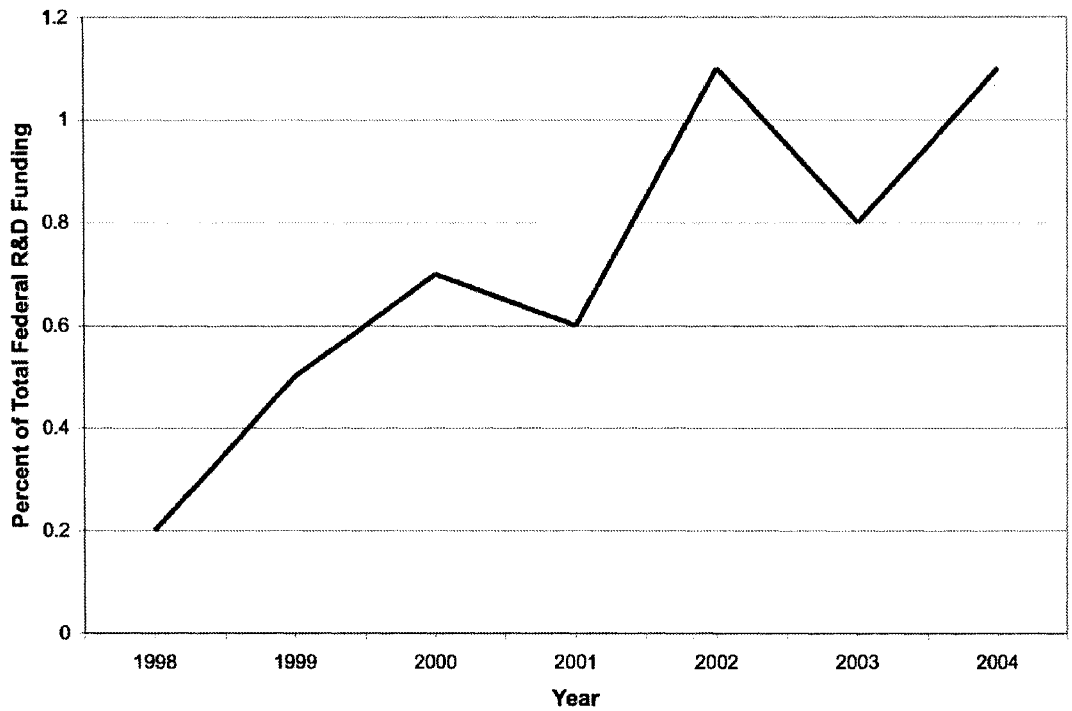


Figure 1-4 depicts Canada's Federal nanotechnology R&D funding as a percentage of total Federal R&D funding between1998 and 2004. Although research funding has been increasing, as of 2004, nanotechnology research funding represented approximately 1% of the Federal Government's total research and development expenditures (Figure 1-4).

[38] *Ibid.* (data used with permission).

Figure 1-4: Federal nanotechnology R&D funding as a percentage of total Federal R&D funding (1998-2004)[39]



In its review, the ISRP noted that a significant component of Canadian investment has been directed towards capital expenditures. Funding to assure continued operations of research programs have not kept pace; this reflects a problem identified in all areas of national research funding (see Figure 1-5). Unless the current shortfall in operational investment is addressed quickly it is envisaged that new state of the art facilities will be under-utilized and talented scientists and research staff may pursue opportunities elsewhere, thereby depriving Canada of a genuine opportunity to succeed in this area.

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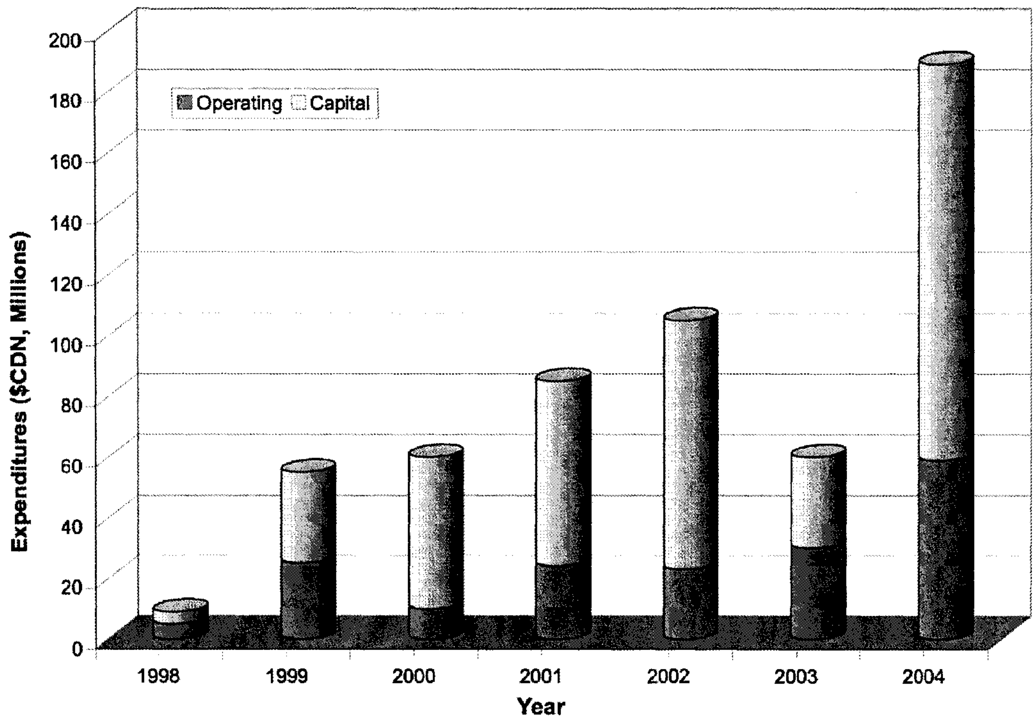
[39] *Ibid.* at 4 (data used with permission).

Figure 1-5: Total government nanotechnology expenditures in Canada (1998-2004)[40]



NE^{3}LS research has, to date, been largely unfunded or funded by government departments and agencies as discrete commissioned works.[41] Virtually all of the federal research funding earmarked for "nanotechnology" has gone towards the

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[40] *Ibid*, at 3 (data used with permission).

[41] See, for example, Lori Sheremeta, "Nanotechnology and the Ethical Conduct of Research Involving Human Subjects" paper commissioned by the Interagency Advisory Panel on Research Ethics, 2004 and subsequently published as: Lorraine Sheremeta, "Nanotechnology and the Ethical Conduct of Research Involving Human Subjects" (2004) 12:3 Health L. Rev. 47, online: Health Law Institute <http://www.law.ualberta.ca/centres/hli/pdfs/hlr/v12_3/12-3-11%20Sheremeta.pdf>; *Supra*, note 28 (Sheremeta); David Castle, "Nanotechnology, Ethics and Governance" paper commissioned by Justice Canada, 2005 [unpublished].

funding of scientific research projects. Despite this, relevant expertise has been amassed in Canada by GE^3LS[42] researchers who have developed both a sense of community and a desire to work as part of science-linked interdisciplinary teams. Canadian GE^3LS researchers have become the defacto leaders of NE^3LS research in Canada.[43] If and when new funding opportunities are made available for NE^3LS research, existing research capacity in the GE^3LS community can be quickly mobilized to address urgent NE^3LS issues. However, without significant funding to build capacity, the GE^3LS community will be unable to provide comprehensive and ongoing coverage of NE^3LS issues.[44]

F. Recommendations of the International Scientific Review Panel

Despite having no formalized national strategy on nanotechnology research and development the ISRP found that Canada had developed relative strengths in a variety of areas including nanomaterials (with a focus on polymer synthesis and characterization), bottom-up synthesis techniques and self-assembly, functional materials and chemical nanostructures, nanophotonics and electronics, and biomedical applications.[45] The International Panel made two general recommendations — firstly that Canada establish 3-4 national nanotechnology

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[42] The acronym GE^3LS is a term coined by Genome Canada that stands for the environmental, economic, ethical, legal and social issues associated with genetics and genomics. The NE^3LS acronym relies on this term that is now well known by most Canadian researchers in the sciences, the social sciences and the humanities.

[43] *Supra*, note 4 (Sheremeta & Daar); *Supra* note 28 (Sheremeta).

[44] *Ibid.* (Sheremeta).

[45] *Supra,* note 11 (International Scientific Review Panel) at 4-6.

research centres with sufficient focus and critical mass to enable an internationally competitive effort in this field. Secondly, it recommended that Canada commit to clearly earmarked funding that integrates and coordinates the efforts of all major granting councils, foundations and research agencies in nanotechnology research.[46]

The ISRP also recommended that "NE^{3}LS research be integrated into nanotechnology research programs where appropriate."[47] In addition, it cautioned against "the creation of a social science research community isolated from nanotechnology research in the natural sciences."[48] The International Panel noted that NE^{3}LS research "will be of increasing importance as nanotechnology progresses and more products based on nanotechnology developments make their way into the marketplace."[49]

The ISRP recommended that Canada should concentrate its efforts in areas where it has unique and complementary strengths. It noted that there are opportunities for Canadian competitiveness in nanotechnology research but there is a need for the creation of "large, well-coordinated and highly talented interdisciplinary research teams in a limited number of areas."[50] It saw a narrowing window of opportunity for Canada to mobilize its efforts to address key gaps in nanotechnology research and

[46] *Ibid.*
[47] *Ibid.*
[48] *Ibid.*
[49] *Ibid.*
[50] *Ibid.*

suggested that there is a discernable shortfall of operating grant support and high-level strategic coordination of research efforts.[51] The Panel opined that Canada's success in the realm of nanotechnology research will require the development of new interdisciplinary research that will focus on research at the intersection of traditional science disciplines and recommended that Canada's strategy should include "clearly earmarked funding and a substantial, high quality interdisciplinary focus if it is to move Canada to the next level of competitiveness."[52] Canada's nanotechnology strategy should include ways of increasing private industry participation in the research and development process, specifically:

> [g]iven the long timelines and technical and marketing uncertainties, the government can and should play a role in helping to manage risk through assessments, collaborative research, testing and demonstration, regulations and standards activities and risk financing and technology transfer strategies.[53]

In addition, the ISRP felt that attempts should be made to introduce nanoscience and nanotechnology into undergraduate curricula so as to ensure early exposure of students to this "fast growing and potentially revolutionary field". In addition,

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[51] *Ibid.*

[52] *Ibid.*

[53] *Ibid.*

attempts should be made early on to engage the public in a "productive discourse" about the potential benefits and risks of nanotechnology.[54]

Canada, though without a national strategy is, and has been, committed to building national capacity in the area of nanotechnology.[55] Towards these efforts, the National Research Council, the province of Alberta and the University of Alberta have created a unique partnership in the National Institute for Nanotechnology (NINT).[56] This unique institute, which formally opened in June 2006, aspires to attract researchers from across Canada and around the world and catapult Canada onto the international nanotechnology stage.[57] Although deemed "the national institute" NINT is one of several NRC institutes with a focus and/or interest in nanotechnology. Other NRC institutes that are relevant to this discussion include, among others, the Steacie Institute for Molecular Sciences (Ottawa), the Institute for

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[54] *Ibid.* at 12.

[55] *See, for example, Speech From the Throne to Open the Third Session of the Thirty-Seventh Parliament of Canada*, February 2, 2004. It is expressly stated that: "We want a Canada that is a world leader in developing and applying the path-breaking technologies of the 21st Century – biotechnology, environmental technology, information and communications technologies, health technologies, and *nanotechnology*." [Emphasis added].

[56] *See generally,* "NRC Nanotechnology Institute to be Among the World's Most Advanced", online: National Institute for Nanotechnology <http://nint-innt.nrc-cnrc.gc.ca/newsroom/article4_e.html> (13 March 2003). The 15,000 m^2 quiet facility will cost $40M to build. A further $80M will be spent on equipment, staff and operations. These costs are to be shared by the NRC ($60M), the Alberta Government and the University of Alberta ($60M). The Federal government has committed an additional $12M per year for operating costs commencing in year six. The NRC is committed to providing $24M per year in infrastructure support.

National Measurement Standards (Ottawa), the Biotechnology Research Institute (Montreal), the Plant Biotechnology Institute (Saskatoon), the Industrials Materials Institute (Boucherville & Saguenay), the Institute for Research in Construction (Ottawa), and the Institute for Aerospace Research (Ottawa & Montreal).

It is important that Canada protect the nanotechnology investments that it has made to date. Failure to be strategic at this point in time will put past investments and future economic potential in jeopardy. In the calculus deciding whether or not to develop a national strategy, this potential loss must be considered.

G. The Mobilization of Public Action Groups Against Nanotechnology

Recent events suggest that society appears poised to engage a deeply polarized debate over the benefits and risks of nanotechnology. Many non-governmental organizations (NGOs) are directing their attention, to some degree or another, towards nanotechnology. In 2003, Canada's own ETC Group fuelled controversy when it recommended a moratorium on commercial production of new nanomaterials and the creation of a global process to evaluate the economic, health and environmental implications of nanotechnology. [58] The ETC Group is joined by

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[57] "Flagship Nanotechnology Institute's New Home Features Canada's Quietest Space" (22 June 2006) online: National Research Council <http://www.nrc-cnrc.gc.ca/newsroom/news/2006/nint06-nr_e.html>.

[58] See *e.g.*, *Supra*, note 16 (*The Big Down)*. The stated goal of this report is to "translate the complex scientific information and to catalyze widespread public debate" (at 6). In conclusion it is the position of the ETC that "[g]iven the concerns raised over nanoparticle contamination in living organisms, governments should declare an immediate moratorium on commercial production of new nanomaterials

other public action groups that have expressed interest, if not deep concerns, about nanotechnology; they include, among others, Greenpeace, the Friends of the Earth, the Center for Responsible Nanotechnology, the Foresight Nanotech Institute, Demos and the Natural Resources Defense Council.[59]

The caution urged by public action groups and shared by many in industry is salient in light of an increasing number of reports in the academic literature and in the popular press that nanoparticles may pose health risks to animals and humans.[60] It has been predicted that failure by governments and industry to acknowledge the concerns raised by the critics of nanotechnology may lead to a backlash, similar to that experienced in the context of agricultural biotechnology.[61] Early recognition of the

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and launch a transparent global process for evaluating the socio economic, health and environmental applications of the technology"(at 25); See also, ETC Group, "No Small Matter II: The Case for a Global Moratorium" (2003) 7:1 ETC Group Occasional Paper Series, online: ETC Group <http://www.etcgroup.org/documents/Occ.Paper_Nanosafety.pdf>.

[59] IRGC, *White Paper on Nanotechnology Risk Governance*, White Paper No. 2 (Geneva: IRGC, 2006) [unpublished paper, on file with the author]; see also, IRGC, *White Paper on Risk Governance: Towards an Integrative Approach* (Geneva: Swiss Reinsurance Company, 2006) online: IRGC <http://http://www.irgc.org/irgc/projects/risk_characterisation/_b/contentFiles/IRGC_WP_No_1_Risk_Governance_(reprinted_version).pdf>.

[60] See, for example, Thomas C. Long, Navid Saleh, Robert D. Tilton, Gergory V. Lowry & Bellina Veronesi, "Titanium Dioxide (P25) Produces Reactive Oxygen Species in Immortalized Bran Microglia (BV2): Implications for Nanoparticle Neurotoxicity" (2006) Envir. Sci & Technol. (7 June 2006) DOI: 10.1021/es060589n; Ben Wootliff, "Nanoparticles Might Move from Mom to Fetus" *Smalltimes* (14 January 2004) online: Smalltimes <http://www.smalltimes.com/document_display.cfm?document_id=7223>; Rick Weiss, "Nanotech Product Recalled in Germany," *Washington Post* (5 April 2006).

[61] A. Mnyusiwalla, A.S. Daar & P.A. Singer, "'Mind the Gap': Science and Ethics in Nanotechnology" (2003) 14 Nanotechnology R9; see also G. Pascal Zachary, "Ethics

political and economic realities, societal concerns and underlying environmental and human safety issues is essential as Canada moves towards responsible stewardship of nanotechnology.[62]

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for a Very Small World" (2003) 137 Foreign Policy 108; *Supra*, note 16 (Nano Geo Politics).

[62] M.C. Roco, "The Emergence and Policy Implications of Converging New Technologies Integrated from the Nanoscale" (2005) 7 Journal of Nanoparticle Research 129.

Chapter 2

An Overview of Key NE^{3}LS Issues

A. Introduction

The purpose of this chapter is to provide an overview of the main ethical, environmental, economic, legal and social issues (NE^{3}LS issues) that have been raised in nanotechnology discourse.[1] Though some have argued that the ethical, environmental, economic, legal and social issues arising in the context of nanotechnology are not necessarily new, the UK Royal Society aptly noted that "effort will need to be spent ... irrespective of whether [the issues] are genuinely new ... or not."[2] Given the current level of government investment, the potential of nanotechnology to impact all economic sectors and to transform the way in which we live, a careful and proactive consideration of NE^{3}LS issues is prudent.

Each of the following NE^{3}LS issues will be discussed in turn, as discrete sections of this chapter, the purpose being to identify the issue and highlight its

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[1] This chapter is a substantially reworked version of a paper prepared for Health Canada. See, Lorraine Sheremeta, "Nanotechnology: The NE^{3}LS Issues", Synthesis paper prepared for Health Canada, July 2005 [unpublished, paper on file with author]; See also, Royal Society and the Royal Academy of Engineering, *Nanoscience and Nanotechnologies: Opportunities and Uncertainties* (London: Royal Society, August 2004) at 51, online: Royal Society and Royal Academy of Engineering <http://www.nanotec.org.uk/finalReport.htm>; Lorraine Sheremeta & Abdallah S. Daar, "The Case for Publicly Funded Research on the Ethical, Environmental, Economic, Legal and Social Issues Raised by Nanoscience and Nanotechnology (NE^{3}LS)" (2003) 12:3 Health L. Rev. 74; Armin Grunwald, Nanotechnology: A New Field of Ethical Inquiry? (2005) 11 Science & Engineering Ethics 187.

[2] *Ibid.* (Royal Society).

relevance to the Canadian setting; policy recommendations will be presented as appropriate:

- Risks to human health and the environment
- Regulatory issues
- Economic impacts of nanotechnology
- Privacy and civil liberties
- Convergence and human enhancement
- Military uses of nanotechnology
- Public consultation and education

B. Risks to Human Health and The Environment

Though knowledge about of the impact of manufactured nanoparticles[3] and nanomaterials[4] is incomplete, several preliminary reports raise important questions about potential effects on human health and the environment.[5] Scientific uncertainty

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[3] The term "manufactured nanoparticles" refers to nanoscale particles that are purposefully made as opposed to those which are naturally occurring or are the incidental products of combustion.

[4] Nanomaterials are materials with a base structure in the range of 1-100 nm. A nanocomposite is a material made by combining nanomaterials with other materials, the goal being to create composites with desired characteristics (e.g. increased strength).

[5] See, R. Dagani, Nanomaterials: Safe or Unsafe?" Chem. & Eng. News, 28 April 2003; Vicki L. Colvin, "The Potential Environmental Impact of Engineered Nanomaterials" (2003) 10 Nature Biotechnology 1166; Kevin L. Dreher, "Health and Environmental Impact of Nanotechnology: Toxicological Assessment of Manufactured Nanoparticles" (2004) 77 Toxicological Sciences 3; Chiu-Wing Lam *et al*, "Pulmonary Toxicity of Single-Wall Carbon Nanotubes in Mice 7 and 90 Days After Intra-Tracheal Instillation" (2004) 77 Toxicological Sciences 126; D.B. Warheit *et al*, "Comparative Pulmonary Toxicity Assessment of Single-Wall Carbon Nanotubes in Rats" (2004) 77 Toxicological Sciences 117.

in this area is problematic and is creating unease for regulators, industry participants and the relevant publics.[6] In Canada and elsewhere, concerns have been raised that nanotechnology products have been launched on the market following a relatively short research and development phase. In addition, occupational and public exposure to nanoparticles is expected to increase dramatically as more products, including medicinal products and foods incorporating nanoparticles, reach the market.[7] Recent media reports of a nanotechnology consumer product recall in Germany[8] and of potential risks associated with titanium dioxide nanoparticles in sunscreen[9], although highly contested, are spawning much debate in the popular press. In the wake of these and other similar reports, a remarkable consensus has emerged amongst both

[6] Swiss Re, *Nanotechnology – Small Matter, Many Unknowns* (Rüschlikon: Swiss Reinsurance Company, 2004) online: Swiss Re <http://www.swissre.com/INTERNET/pwswpspr.nsf/fmBookMarkFrameSet?ReadForm&BM=../vwAllbyIDKeyLu/ULUR-5YAFFS?OpenDocument> at 3.

[7] *Ibid.* at 6. *Supra*, note 5 (Dreher) at 3-4. See also, OECD International Futures Programme & Allianz, *Small Sizes that Matter: Opportunities and Risks of Nanotechnologies* (June 2005) online: OECD <http://www.allianz.com/Az_Cnt/az/_any/cma/contents/796000/saObj_796424_allianz_study_Nanotechnology_engl.pdf>.

[8] Rick Weiss, "Nanotech Product Recalled in Germany," *Washington Post* (5 April 2006); ETC Group, Press Release, "Nanotech Product Recall Underscores Need for Nanotech Moratorium: Is the Magic Gone?" (7 April 2006) online: ETC Group <http://www.etcgroup.org/article.asp?newsid=559>; "Has All the Magic Gone?" *The Economist* (12 April 2006).

[9] Liz Thrall, "Study Links $Ti0_2$ Nanoparticles With Potential for Brain Cell Damage" (7 June 2006) online: Environmental Science and Technology <http://pubs.acs.org/subscribe/journals/esthag-w/2006/jun/tech/lt_nanoparticles.html>, citing Thomas C. Long, Navid Saleh, Robert D. Tilton *et al*, "Titanium Dioxide (P25) Produces Reactive Oxygen Species in Immortanized Brain Microglia (BV2): Implications for Nanoparticle Neurotoxicity" (2006) 40:14 Envir. Sci. Technol. 4346.

proponents and detractors of nanotechnology that attention to human health and environmental risks is urgently required.[10]

The diminutive size of nanoparticles alters biological activity in ways that are not yet fully understood.[11] More data regarding the mechanisms of inducing toxicity, dose metrics, exposure pathways and environmental fate are needed to inform regulatory and policy approaches to nanotechnology.[12] Although numerous concerns have been raised, there exists no conclusive data to suggest that the problems raised by nanoparticles and nanomaterials will be major or insurmountable.[13]

In the short term, it is anticipated that the greatest potential for exposure to manufactured nanoparticles will be in the workplace – mainly in university and

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[10] Andrew Nel, Tian Xia, Lutz Mädler *et al*, "Toxic Potential of Materials at the Nanolevel" (2006) 311 Science 622.

[11] ILSI Research Foundation/Risk Science Institute Nanomaterial Toxicity Screening Working Group, "Principles for Characterizing the Potential Human Health Effects from Exposure to Nanomaterials: Elements of a Screening Strategy" (2005) 2(8) Particle and Fibre Toxicology, online: Pub Med Central <www.pubmedcentral.nih.gov/picrender.fcgi?artid=1260029&blobtype=pdf>.

[12] United States Environmental Protection Agency, Nanotechnology Workgroup, *Nanotechnology White Paper (External Review Draft)* (2 December 2005) online: EPA <http://www.epa.gov/osa/pdfs/EPA_nanotechnology_white_paper_external_review_draft_12-02-2005.pdf> at 24. A final version of this paper is expected to be published in 2006.

[13] *Supra,* note 10 (Nel *et al*) at 627; Christine Ogilvie Robichaud, Dicksen Tanzil, Ulrich Weilenmann *et al*, "Relative Risk Analysis of Several Manufactured Nanomaterials: An Insurance Industry Context" (2005) 39 Envir. Sci. Technol. 8985.

industrial laboratories and manufacturing facilities.[14] At least one trade union has been quick to pick up on this fact.[15] In the US, the National Institute for Occupational Safety and Health (NIOSH) has expressly recognized that there is a need to understand the impact of nanoparticle exposure on human health and to develop appropriate exposure monitoring and control strategies to protect workers.[16] Participants at a recent workshop hosted by the RAND Corporation on nanotechnology and occupational health and safety identified four main problem areas that demand attention; they are: first, the potential that knowledge gaps will hinder the development and introduction of new nanomaterials into the marketplace; second, that a lack of scientific understanding of broad classes of nanomaterials is precluding the development of effective worker protections; third, that the allocation of funds, from both public and private sources to address occupational health and safety concerns related to nanomaterials is not commensurate with the push to develop them; and last, that cooperation between federal government agencies and

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[14] *Supra*, note 1 (Royal Society) at 70; C.L. Tran, K. Donaldson, V. Stones et al, *A Scoping Study to Identify Hazard Needs for Addressing the Risks Presented by Nanoparticles and Nanotubes* (December 2005), online: DEFRA <http://www.defra.gov.uk/environment/nanotech/nrcg/pdf/hazarddata-scoping.pdf >; R.J. Aitken, K.S. Creely, C.L. Tran, Nanoparticles: An Occupational Hygiene Review, Research Paper 274, 2004, online: Health & Safety Executive <http://www.hse.gov.uk/research/rrpdf/rr274.pdf>.

[15] Deborah Smith, "Particles Could Pose Health Risk" *Sydney Morning Herald* (26 September 2005).

[16] NIOSH, "Position Statement on Nanotechnology: Advancing Research on Occupational Health Implications and Applications" online: NIOSH <http://www.cdc.gov/niosh/topics/nanotech/position.html>. NIOSH actively promotes strategic mulitidisciplinary research that "builds on the Institute's experience in defining the characteristics, properties, and effects of ultrafine particles such as welding fume and diesel particulate which have some features in common with engineered nanomaterials."

between the public and private sectors is needed to facilitate rapid developments in this pressing area.[17] These same issues have also been highlighted in numerous other reports and academic publications.[18]

Knowledge about the impact of manufactured nanoparticles on the environment is similarly incomplete. It is hoped and anticipated that nanotechnology will spur the development of many new environmentally friendly processes and products.[19] This is of great importance as the world's population, economic growth and the consumption of energy and material resources continues to explode.[20] Nanotechnology enabled sensors that can already be used for real-time detection of biological and chemical contaminants and exposure assessment for use in environmental applications.[21] Green manufacturing processes will inevitably lead to

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[17] James T. Bartis & Eric Landree, *Nanomaterials in the Workplace: Policy and Planning Workshop on Occupational Safety and Health.* Proceedings of a Conference Held October 17, 2005, online: Rand Corporation <http://www.rand.org/pubs/conf_proceedings/CF227/>, summary at ix.

[18] *Supra*, note 12 (EPA); *Supra*, note 1 (Royal Society); *Supra*, note 6 (Swiss Re); *Supra*, note 11 (ILSI); Andrew D. Maynard & Eileen D. Kuempel, "Airborne Nanostructured Particles and Occupational Health" (2005) 7 J. Nanoparticle Research 587; International Risk Governance Council, Survey of Nanotechnology Governance, Volume D: The Role of NGOs, April 2006, online: IRGC: <http://www.irgc.org/irgc/projects/nanotechnology/_b/contentFiles/Survey_on_Nanotechnology_Governance_-_Part_B_The_Role_of_Industry.pdf>.

[19] Ernie Hood, "Looking as we Leap" (2004) 112 Environmental Health Perspectives A740.

[20] World Resources Institute, *The Weight of Nations: Material Outflows from Industrial Economies* (Washington DC: World Resources Institute) 2000. This report predicts that in the next 50 years the world's population will grow by 50%, economic activity will grow by 500% and global energy and materials use will triple.

[21] *Supra*, note 12 (EPA) at 18.

the production of more and better materials for a variety of uses with less consumption of energy, reduced solvent use and fewer waste products. Nanotechnology is expected to spur improvements in water treatment, energy production and efficiency, materials science, land use and development and air quality.[22]

Nanoparticles and nanomaterials are increasingly manufactured for use in a wide variety of consumer products. Carbon nanotubes, for example, are incorporated into a variety of consumer products to enhance strength. At the end of their useful lives, products containing nanoparticles and nanomaterials will need to be recycled or discarded as refuse. Accordingly, there is an increased likelihood that, in future, nanoparticles will be released (intentionally or unintentionally) into the air, water, soil and groundwater. The environmental impact of such releases is unknown.

In 2004, the US Environmental Protection Agency's Science Policy Council struck an intra-agency Nanotechnology Workgroup tasked with preparation of a White Paper on nanotechnology. In December the draft Nanotechnology White Paper was publicly released for comment. The paper describes "the issues that EPA must address to ensure that society benefits from advances in environmental protection that nanotechnology may offer, and to understand any potential risks from environmental exposure to nanomaterials."[23] The proposed recommendations in the draft White

[22] *Ibid.*

[23] *Ibid.*

Paper fall in to six main themes: (1) pollution prevention and stewardship; (2) research; (3) risk assessment; (4) collaboration and leadership; (5) cross-agency workgroup; and (6) training. EPA's recommendations are reproduced below.

- *Pollution Prevention, Stewardship and Sustainability* - EPA should engage resources and expertise to encourage, support, and develop approaches that promote pollution prevention, sustainable resource use, and good product stewardship in the production and use of nanomaterials. Additionally, the Agency should draw on new, "next generation" nanotechnologies to identify ways to support environmentally beneficial approaches such as green energy and green manufacturing.

- *Research* - EPA should undertake, collaborate on, and catalyze research on the various types of nanomaterials to better understand and apply information regarding their: chemical identification and characterization; environmental fate; environmental detection and analysis; potential releases and human exposures; human health effects assessment; ecological effects assessment; and environmental technology applications.

  Risk Assessment -EPA should conduct case studies on several engineered or manufactured nanomaterials. Such case studies would be useful in identifying unique considerations for conducting risk assessments on nanomaterials. The case studies would also aid in identifying information gaps, which would help map areas of research to inform the risk assessment process.

Collaboration and Leadership - EPA should continue and expand its collaborations regarding nanomaterial applications and potential human health and environmental implications.

Cross-Agency Workgroup - EPA should convene a standing cross-Agency group to foster information sharing on nanotechnology science and policy issues.

Training - EPA should continue and expand its nanotechnology training activities for scientists and managers.[24]

At present, Canada's efforts relating to human health and the environmental impact of nanomaterials are difficult to gauge. The US appears to be leading these efforts. As we move forward, Canada must strategically and transparently dedicate resources to answering the questions posed by EPA and others. In the meantime, the Canadian government must clearly enunciate its regulatory position on nanotechnology. Communication tools and strategies are needed to ensure that people who want and need reliable information about nanotechnology governance can access it quickly and easily. At present, this is not the case.

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[24] *Ibid.* at 2.

C. Regulatory Issues

As previously noted, nanotechnology is expected to broadly impact every segment of the Canadian economy (See, Table 2-2, page 50). Because of the diversity of materials and of the products implicated, the regulation of nanotechnology, including the regulation of nanoparticles, nanomaterials and products incorporating them will be a challenge for regulators.

Relevant laws, regulations, rules and standards relevant to nanotechnology may be promulgated by international and/or national organizations and/or by federal or provincial governments. Nanoparticles, as raw materials, are chemical substances and are regulated under a variety of statutes falling under the purview of Environment Canada and Health Canada. Products that incorporate nanoparticles or nanomaterials may fall under various regulatory regimes depending on the final products that incorporate them. For example, laws governing foods, drugs, cosmetics, medical devices, natural health products, feeds, pesticides, chemical substances (new or existing), hazardous materials, and the environment may apply. In addition, laws governing waterways, fisheries, oceans, air quality and transportation may be implicated in the governance of nanotechnology.

Figure 2-1 provides a detailed overview of the possible routes of exposure to nanoparticles and nanomaterials based on current and anticipated future applications. It serves to highlight the complex interaction of chemical substances in the environment and the ways in which materials are dispersed through the ecosystem.

Figure 2-1: Possible exposure routes for nanoparticles based on current and potential future applications.[25]

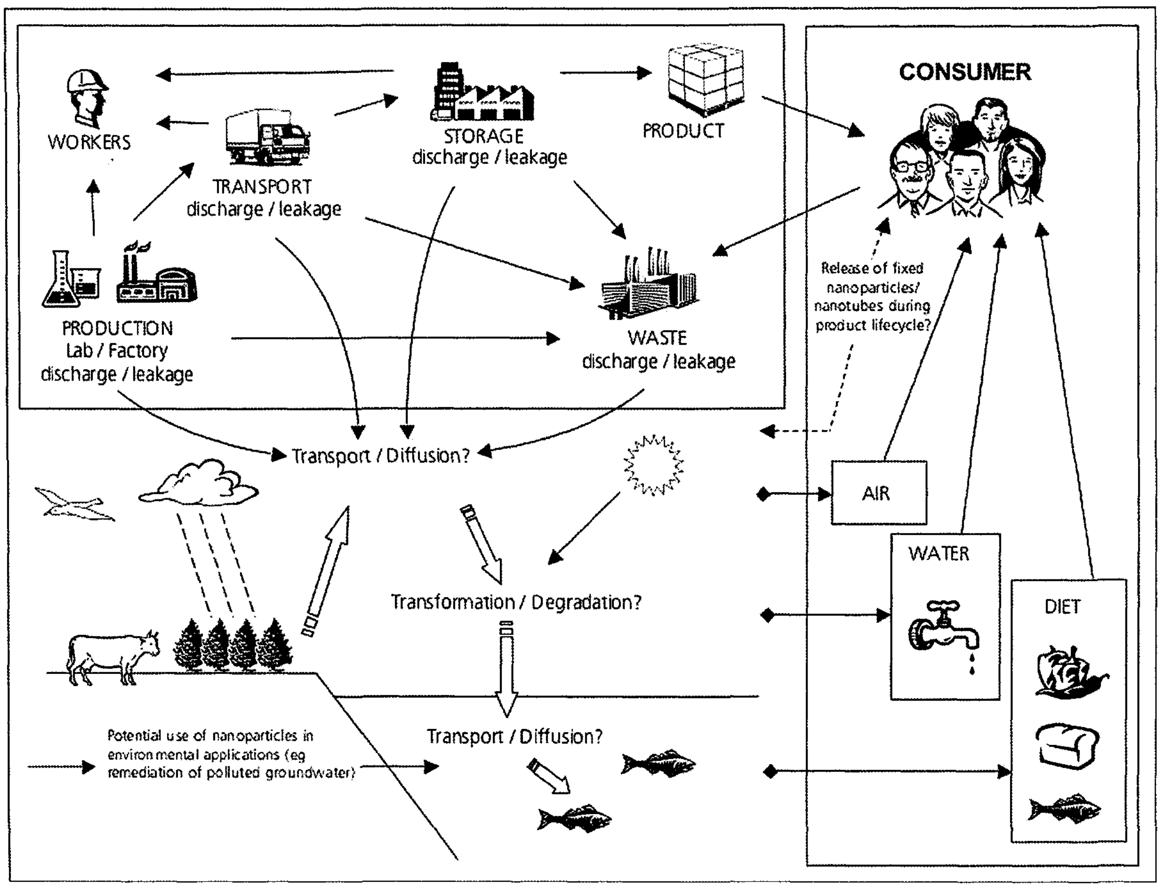

Table 2-1 provides an overview of the main federal statutes that are envisioned to be relevant in the consideration of nanotechnology.[26] The link between

[25] *Supra*, note 1 (Royal Society) at 37 (used with permission).

[26] Lorraine Sheremeta, "Nanotechnology: Legal and Regulatory Challenges" (Presentation delivered at the Federal Workshop on the Health and Environmental Implications of Nanoproducts" Ottawa, Ontario, March 29, 2006) [unpublished, on file with author].

the list of statutes and regulations and the governance of nanotechnology become readily apparent when the list is considered in light of Figure 2-1.

Table 2-1: Some of the Main Canadian Federal Departments, Statutes and Regulations Relevant to Nanotechnology

Environment Canada
Canadian Environmental Protection Act, R.S.C. 1999, c. 33 • *New Substances Notification Regulations (Chemicals and Polymers)*, S.O.R./2005-247 • *Persistence and Bioaccumulation Regulations*, S.O.R./2000-107
Canadian Environmental Assessment Act, R.S.C. 1992, c.37
Fisheries Act, R.S.C. 1985, c. F-14.
Agricultural Products Act, R.S.C. 1985, c. 20.
Feeds Act, R.S. 1985, c. F-9
Fertilizers Act, R.S. 1985, c. F-10
Pest Control Products Act, R.S.C. 1985, c. P-9
Oceans Act, S.C. 1996, c. 31
Arctic Waters Pollution Prevention Act, R.S.C. 1985, c. A-12
Health Canada
Food and Drugs Act, Chapter R.S., c. F-27, s. 1 • *Food & Drugs Regulations*, C.R.C. c. 870 • *Medical Devices Regulations*, S.O.R./98-282 • *Cosmetics Regulations*, C.R.C., c.869 • *Natural Health Products Regulations*, S.O.R./2003-196
Hazardous Products Act, R.S.C. 1985, c. H-3 • *Controlled Products Regulations*, S.O.R./88-66 • *Ingredient Disclosure List*, S.O.R./88-64
Workplace and Public Safety Programme • Work Hazardous Materials Information System (WHMIS)
Employment & Immigration
Canada Labour Code, R.S.C. 1985, c. L-2. • *Canada Occupational Health and Safety Regulations*, S.O.R./86-304 • *Provincial Labour Codes & Occupational Health and Safety Codes* • Work Hazardous Materials Information System (WHMIS)

Given the scientific uncertainty about the human and environmental hazards associated with nanomaterials, the relevant regulatory authorities face a daunting task of determining whether interim precautions or voluntary measures should be implemented while scientific data is amassed that will facilitate the development of durable, evidence-based responses (regulatory or otherwise) to quantifiable risks.[27]

In 2003 the UK Royal Society and Royal Academy of Engineering concluded that the existing regulatory frameworks in the UK are sufficiently broad to encompass nanotechnologies and that a new regulatory framework is not needed.[28] In the United States, a recent report by J. Clarence (Terry) Davies of the Woodrow Wilson International Center for Scholars in the United States, supports the view that a new nanotechnology law is needed in that country.[29] The United States EPA argues that in the United States, federal authority to regulate nanomaterials pursuant to the *Toxic Substances Control Act* and other relevant statutes is sufficient to regulate

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[27] Robert F. Service, "EPA Ponders Voluntary Nanotechnology Regulations" (2005) 309 Science 36.

[28] *Supra*, note 1 (Royal Society) at 85-88. DEFRA has since funded a regulatory gap analysis of the main environmental statutes applicable to nanotechnology. See, Qasim Chaudhry, James Blackburn, Peter Floyd *et al*, *A Regulatory Gaps Study for the Products and Applications of Nanotechnology: Final Report* (March 2006) online: DEFRA <http://www2.defra.gov.uk/research/project_data/More.asp?I=CB01075&M=KWS&V=Nanotech&SUBMIT1=Search&SCOPE=0>. Though gaps in nanotechnology governance have been identified, the general view is that a new law or a new legal framework is not needed.

[29] J. Clarence Davies "Managing the Effects of Nanotechnology" January 2006, online: Project on Emerging Technologies <www.nanotechproject.org/index.php?id=39> at 18-21. *But see*, *supra*, note 12 (EPA); *See also*, *supra*, note 27 (Service).

nanotechnology.[30] The American Bar Association Section of Environment, Energy and Resources (SEER) recently published a comprehensive series of papers which, when taken together, comprise a regulatory gap analysis of core U.S. federal environmental statutes vis a vis nanotechnology. In general, the papers concur with EPA's position and conclude that the agency possesses sufficient legal authority under the statutes to address the challenges it is likely to encounter as it assesses the risks and benefits associated with nanotechnology.[31]

In Canada, a preliminary assessment of Ministerial Authority conferred by *CEPA, 1999* suggests that Canada's existing legal framework is sufficient to meet the major challenges raised by nanotechnology. Importantly, although the Ministerial authority and the overall '*framework*' may sufficiently broad, statutory and/or regulatory amendments may be needed once a better understanding of the effects of nanoparticles is attained. Effective regulation of nanotechnology demands a framework that is readily adaptable and responsive to new information about hazards and risks. Sufficiency of Canada's legal framework to regulate nanotechnology has yet to be assessed in a comprehensive fashion.

In light of the existing scientific uncertainty, Canada must compel its relevant government departments to evaluate existing statutes and regulations to determine

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[30] Jim Willis, "EPA and Nanotechnology" (Presentation delivered at the Canadian Embassy Science Diplomats Luncheon, Washington, D.C., 27 March 2006) [unpublished].

[31] Online: American Bar Association <http://www.abanet.org/environ/nanotech/>.

whether there are gaps or whether they are sufficiently robust to protect human health and the environment from hazards, if any, that are unique to nanotechnology. Given that new scientific data is emerging and new applications of nanotechnology may impact other areas of regulation in ways that are currently unforeseen, such evaluations must be iterative in nature. The international community should work together to ensure the rapid transfer of relevant information and data about developments in the area. International standard setting should be a priority.[32] In this regard, various organizations, including the Organization for Economic Cooperation and Development (OECD)[33], the United Nations Educational, Scientific and Cultural Organisation (UNESCO)[34] and the International Standards Organization (ISO)[35] have

[32] ETC Group, *From Genomes to Atoms: The Big Down: Atomtech – Technologies Converging on the Nano-scale* (Winnipeg: ETC Group, January 2003) online: ETC Group <www.etcgroup.org/documents/TheBigDown.pdf> [hereinafter "The Big Down"].

[33] OECD, *Report of the OECD Workshop on the Safety of Manufactured Nanomaterials: Building Cooperation, Coordination and Communication*, ENV/JM/MONO(2006)19 online: <http://appli1.oecd.org/olis/2006doc.nsf/43bb6130e5e86e5fc12569fa005d004c/b69b32217944d8a1c125715e0038d403/$FILE/JT03208175.PDF> (28 April 2006). This report documents a joint Special Session of the OECD Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology on the potential implications of manufactured nanomaterials for human health and environmental safety held on 9 December 2005 in Washington, D.C.. In response, the OECD Chemicals Committee created a Working Party on the Health and Environmental Safety Implications of Manufactured Nanomaterials the objective being to help share the burden to harmonize approaches to reduce the burden on industry and to facilitate global markets.

[34] UNESCO, "Nanotechnology & Ethics Expert Group: Report of the First Meeting" (Paris, 5-6 July 2005) online: UNESCO <http://portal.unesco.org/shs/en/file_download.php/616570f1b2c4e9ff2d19874f0112c637NanotechReport1.pdf>.

[35] International Standards Organization, TC229 Chairman's Speech at Tokyo banquet, June 2006, online: ISO

convened committees that are involved in the move towards international harmonization.

Absent specific evidence to warrant statutory or regulatory reform, Canadian regulators should follow closely the scientific developments and policy debates arising in other jurisdictions. Specific reviews and reforms undertaken by government departments in other jurisdictions or recommendations made by international organizations, including the OECD and others, should be monitored and considered by Canadian regulators. The UK Royal Society and the Royal Academy of Engineering recommended that, until more is known, the release of manufactured nanoparticles into the environment should be avoided, that nanoparticles be treated as hazardous materials, and that the use of free manufactured nanoparticles in environmental applications be prohibited until it can be demonstrated that the benefits outweigh the risks.[36] Canadian regulators may legitimately agree or disagree with these (and other) recommendations that have been made or that will be made in the future. However, failure to transparently defend action or inaction in light of recommendations made by influential organizations is irresponsible.

As in other jurisdictions, policy decisions made by Canadian policy-makers relating to nanotechnology will inevitably be subject to political pressure and to

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<http://isotc.iso.org/livelink/livelink/fetch/2000/2122/4191900/4192161/4191901/TC_229_Chairman_s_speech_at_Tokyo_banquet__June_2006.pdf?nodeid=5459232&vernum=0>.

[36] *Ibid.* at 85.

criticism. Failure, on the part of policy-makers, to present reasoned justifications for their decisions has the potential to undermine an already tenuous public confidence in Canadian regulatory authorities. At present, there has been little, if anything, communicated to Canadians by federal government departments about nanotechnology or the respective positions of government departments about regulatory requirements specifically relevant to nanomaterials and products containing them. In the United States, federal websites including the Environmental Protection Agency and the Food and Drug Administration have posted information relevant to manufacturers and the general public.[37]

(i) *Application of the Precautionary Principle*

One area of particular interest for legal scholars is the proposed application of the precautionary principle to nanotechnology. Of the many formulations of the precautionary principle that have been published, the common denominator appears to be the "prevention of possible harms in the face of uncertainty".[38] The simplest interpretation of the precautionary principle is that "it is better to be safe than sorry."[39] As one example, the 1998 Wingspread Declaration proposes that: "when an

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[37] See, for example, US Food and Drug Administration, "FDA Regulation of Nanotechology Products", online: FDA <http://www.fda.gov/nanotechnology/regulation.html>. In this short online document, the US FDA explains its position on nanotechnology and notes that "there are several issues under discussion in various forums related to the FDA's regulation of nanotechnology products."

[38] Joshua MacLeod, "Unifying the Precautionary Principle" (2004) 34 Environmental Law Reporter News and Analysis 10891 at 10891.

[39] Robert W. Hahn & Cass R. Sunstein, "The Precautionary Principle as a Basis for Decision Making" (2005) 2:2 The Economist's Voice at 1; Paul C. Lin-Easton, "It's

activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically."[40] Carolyn Raffensperger, executive director of the Science and Environmental Health Network is quoted as stating that "the precautionary principle requires a different kind of science ... the precautionary principle invites us to put the ethics back into science."[41] Canadian law professor, Jamie Benidickson describes the precautionary principle as a "cluster of basic principles" including:

> the proposition that early preventive action is appropriate even in the absence of scientifically documented need when delay would impose increase costs and greater risks of environmental harm. Precaution also entails recognition of the importance of leaving wide margins of tolerance or room for maneuver to

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Time for Environmentalists to Think Small – Real Small: A Call for the Involvement of Environmental Lawyers in Developing Precautionary Policies for Molecular Nanotechnologies" (2001) 14 Georgetown International Environmental Law Review 107; Jason Wejnert, "Regulatory Mechanisms for Molecular Nanotechnology" (2004) 44 Jurimetrics 323; Harlan Reynolds "Nanotechnology and Regulatory Policy: Three Futures" (2003) 17 Harvard Journal of Law and Technology 179; Foresight Institute, "Foresight Guidelines on Molecular Nanotechnology" (Version 4), 2004, online: Foresight Institute <http://www.foresight.org/guidelines/current.html>.

[40] Wingspread Statement on the Precautionary Principle, online: Global Development Research Center <http://www.gdrc.org/u-gov/precaution-3.html>. See also, John D. Graham, "The Perils of the Precautionary Principle: Lessons from the American and European Experience" presentation at the Regulatory Forum, The Heritage Foundation, Washington D.C., 20 October 2003 [unpublished]. In this presentation, Graham notes that the Swedish philosopher Per Sandin "has documented 19 versions of the precautionary principle in various treaties, laws and academic writings." See, Per Sandin, "Dimensions of the Precautionary Principle" (1999) 5 Human & Ecological Risk Assessment 923.

[41] *Supra*, note 38 (MacLeod) at 10892, citing David Appell, "The New Precautionary Principle" Scientific American, January 2001 at 18.

permit natural adaptation to human interference. Pushing the envelope is not a good idea. In addition, the precautionary principle implies a shift in the onus of proof to those who propose initiatives, innovations and activities whose environmental impact is not fully understood."[42]

The precautionary principle has been the subject of harsh criticism. For example, commentators Robert Hahn and Cass Sunstein argue that:

> [the] tradeoff between wealth and health makes the precautionary principle hard to implement not merely where regulation removes benefits, or introduces or increases other risks, but in any case in which the regulation costs a significant amount.
>
> For this reason, the precautionary principle raises doubts about many expensive regulations. The most general point is that, the precautionary principle is frequently paralyzing: It can stand as an obstacle to regulation and nonregulation, and to everything in between. [43]

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[42] Jamie Benidickson, *Environmental Law*, 2nd Edition (Toronto: Irwin Law, 2002) at 21-22.

[43] *Supra*, note 39 (Hahn and Sunstein) at 3. See also, Indur M. Goklany, "From Precautionary Principle to Risk-Risk Analysis" (2002) 20 Nat. Biotech. 1075; Henry I. Miller & Gregory Conko, " Precaution Without Principle" (2001) 19 Nat. Biotech. 303; Carolyn Raffensperger & Katherine Barrett, "In Defense of the Precautionary Principle" (2001) 19 Nat. Biotech. 811. Bernhard Jank & Johannes Ruth, "The Precautionary Principle" (2000) 18 Nat. Biotech. 697; Anne Geddes Shalit, "The Precautionary Principle" (2000) 18 Nat. Biotech. 697.

They, and others, argue that the precautionary principle is unhelpful and may in fact be harmful on the basis that it stands to deprive society of significant benefits.[44]

The ETC Group, Greenpeace and Swiss Re have each recommend adherence to some form of the precautionary principle. In its strict interpretation, the precautionary principle demands that proactive protective measures be taken in the face of *possible* risk. The ETC Group, though advocating the "precautionary approach", acknowledges that "the precautionary principle has gained considerable acceptance, especially in Europe, [though] it is not universally defined or embraced."[45] In their report, Swiss Re opts for a reasoned precautionary approach that is described as follows:

> In view of the dangers to society that could arise out of the establishment of nanotechnology, and given the uncertainty currently prevailing in scientific circles, the precautionary principle should be applied whatever the difficulties. The handling of nanotechnologically manufactured substances should be carefully assessed and accompanied by appropriate protective measures. This is particularly important for individuals whose jobs expose them to

[44] *Ibid.*

[45] *Supra*, note 32 (The Big Down) at 72. See also, Mags D. Adams, "The Precautionary Principle and the Rhetoric Behind It" (2002) 5:5 J. of Risk Res. 301; Jonathan B. Wiener & Michael D. Rogers, "Comparing Precaution in the United States and Europe" (2002) 5:4 J. of Risk Res. 317; R.E. Lofstedt & D. Vogel, "The Changing Character of Regulation: A Comparison of Europe and the United States" (2001) 21:3 Risk Analysis 399.

nanoparticles on a regular basis. At the same time, no reasonable expense should be spared in clarifying the current uncertainties associated with nanotechnological risks.[46]

The *Canadian Environmental Protection Act*, 1999 incorporates the precautionary principle in its preamble wherein it provides that "the Government of Canada is committed to implementing the precautionary principle that, 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".[47] Other Canadian statutes, including the *Canadian Environmental Assessment Act*[48], and the *Oceans Act*[49], refer specifically to the precautionary principle or "approach". The Supreme Court of Canada in its 2001 decision *114957 Canada Ltée (Spraytech Société d'arrosage) v. Hudson (Town)* suggests that the

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46 *Supra,* note 6 (Swiss Re) at 47.

47 S.C. 1999, c. 33 (preamble). In addition, section 6(1.1) obliges the CEPA National Advisory Committee to apply the principle in "providing advice and recommendations to the Ministers on regulations proposed under Subsection 93(1); on a cooperative, coordinated intergovernmental approach for the management of toxic substances; and on other environmental matters that are of mutual interest to the government of Canada and other governments to which this Act relates." Section 76.1 requires the ministers to apply the principle (and a "weight of evidence" approach) when "conducting an interpreting the results" of "a screening assessment under Section 74, a review of a decision of another jurisdiction under Subsection 75(3), or a priority substance list assessment of whether a substance is "toxic or capable of becoming toxic". For elucidation of Environment Canada and Health Canada's approach to the precautionary principle, see, Environment Canada & Health Canada, "Internal Guidance Document on The Canadian Environmental Protection Act, 1999 and the Precautionary Principle: Improved Decision Making under Uncertainty" September 2005 [unpublished].

48 S.C. 1992, c. 37, s. 4(2).

precautionary principle has, in fact, crystallized into a norm of customary international law.[50] The substance of the principle remains unclear.

In a 2003 report entitled "A Federal Framework for the Application of Precaution in Science-Based Decision Making About Risk",[51] the Government of Canada elucidated 10 key principles -- five "general principles of application" and "five principles for precautionary measures" which can be summarized as follows:

Five General Principles of Application

1. The application of precaution is a legitimate and distinctive decision-making approach within risk management.
2. It is legitimate for decisions to be guided by society's chosen level of protection against risk.
3. Sound scientific information and its evaluation must be the basis for applying precaution; the scientific information base and responsibility for producing it may shift as knowledge evolves.

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49 S.C. 1996, c. 31, Preamble (¶ 6).

50 [2001] 2 S.C.R. 241; 1002 S.C.C. 40 at ¶ 31-2 citing David Freestone and Ellen Hey, eds., *The Precautionary Principle and International Law* (Boston: Kluwer Law International, 1996) at 41; J. Cameron and J. Abouchar, "The Status of the Precautionary Principle in International Law" in . Freestone and E. Hey, eds., *The Precautionary Principle and International Law* (Boston: Kluwer Law International, 1996) at 52; O. McIntyre and T. Mosedale, "The Precautionary Principle as a Norm of Customary International Law" (1997) 9 J. Env. L. 221 at 241.

51 Government of Canada, *Federal Framework for the Application of Precaution in Science-Based Decision Making About Risk* (Ottawa: Privy Council Office, 2003) online: Privy Council Office <http://www.pco-bcp.gc.ca/default.asp?Language=E&Page=Publications&doc=precaution/precaution_e.htm>.

4. Mechanisms should exist for re-evaluation the basis for the decisions and for providing a transparent process for further consideration.
5. A high degree of transparency, clear accountability and meaningful public involvement are appropriate.

Five Principles for Precautionary Measures

6. Precautionary measures should be subject to reconsideration on the basis of the evolution of science, technology and society's chosen level of protection.
7. Precautionary measures should be proportional to the potential severity of the risk being addressed and to society's chosen level of protection.
8. Precautionary measures should be non-discriminatory and consistent with measures taken in similar circumstances.
9. Precautionary measures should be cost effective, with the goal of generating (i) an overall net benefit for society at least cost, and (ii) efficiency in the choice of measures.
10. Where more than one option reasonably meets the above characteristics, the least trade-restrictive measure should be applied.[52]

In a 2005 internal guidance document, Environment Canada and Health Canada describe the application of the precautionary principle as follows:

> The precautionary principle functions along a continuum that accounts, on a case-by-case basis, for: the degree and type of suspected damage, accounting

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[52] *Ibid.*

for the potential for seriousness or irreversibility and the potential nature and distribution of the harm – the "threat"; and, the level of uncertainty related to the potential for damage. Provided there is a basis to establish a scientific suspicion of serious or irreversible damage, the precise level of scientific uncertainty required to justify action under CEPA 1999 therefore varies depending on the circumstances. In general, the more serious or potentially irreversible the threat, the less should be the reliance on full scientific certainty before preventive action can be justified.

Where the threat is serious or irreversible, a preponderance or balance of evidence may be sufficient to justify some form of preventive action. It may be appropriate to act based only on a prima facie indication of potential for harm. In some cases, the availability or feasibility of cost-effective alternatives to the substance, product or activity suspected of posing a risk also may be relevant both to a decision to take precautionary action and to the type of precautionary action selected.[53]

After giving consideration to calls for a moratorium on the development and release of new nanomaterials, the Royal Society and the Royal Academy of Engineering "do not think that there is either the body of scientific evidence to warrant this intervention or a consensus that this is necessary on a precautionary basis." Rather, they recommend taking steps to minimize exposure to nanoparticles

[53] *Supra*, note 47 (Environment Canada & Health Canada).

while the uncertainties about the hazards are studied.[54] In its response to the Royal Society Report, the UK Government formally agreed with this recommendation.[55]

Policy-makers in Canada must determine how the precautionary principle should be applied in the context of nanotechnology. It is this author's position that strict application of the precautionary principle would be out of step with the position articulated by Environment Canada and Health Canada. Rather, a meted approach – as described above – that emphasizes "transparency, effective communication of risks and public involvement in risk assessment and risk management processes"[56] is appropriate. Rapid reduction of these stated principles to defensible practice is urgently needed.

D. Economic Impacts of Nanotechnology & Commercialization Challenges

There is plenty of evidence to suggest that nanotechnology will have an enormous impact on national economies as well as on the global economy. It is expected that all economic sectors will be impacted. Current trends in nanotechnology development suggest that this will be the case (see Table 2-2).

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[54] *Supra,* note 1 (Royal Society, at 83).

[55] HM Government, *Response to the Royal Society and Royal Academy of Engineering Report 'Nanoscience and Nanotechnology: Opportunities and Uncertainties'* (London: Department of Trade and Industry, 2005) at ¶ 41-43, online: Office of Science and Technology <http://www.ost.gov.uk/policy/issues/nanotech_final.pdf>.

[56] *Supra*, note 51 (Environment Canada and Health Canada).

Table 2-2: Examples of Nanotechnology Products Developed Across Economic Sectors[57]

Auto Industry •Lightweight constructions •Paint & exterior coatings •Catalysts •Tires •Sensors	**Chemical Industry** •Paint fillers •Composite materials •Adhesives •Magnetic fluids •Water purification & remediation	**Engineering** •Protective coatings for tools and machines •Lubricant free bearings •Machine ceramics
Electronics •Displays •Sources of lasers & lighting •Data memory •Filters •Conductive, anti-static coatings	**Construction** •Materials •Insulation •Flame retardants •Surface coatings for wood, floors, stone, tiles, roofs etc	**Medicine** •Drug delivery systems •Rapid testing systems •In-vivo diagnostics/sensors •Prostheses and implants •Antimicrobial agents
Textiles •Surface coatings •Smart textiles •Military battle suits	**Energy** •Fuel cells & solar cells •Batteries •Capacitors •Fuel additives	**Cosmetics** •Sunscreens •Lipsticks •Skin creams •Toothpaste
Food & Agriculture •Packaging products •Food additives •Nutrient delivery systems •Pesticides •Tools for soil remediation	**Household** •Ceramic coatings for irons •Odor removers •Cleaning products •Disinfectants •Abrasives	**Recreation** •Ski wax •Tennis rackets/balls •Golf clubs •Anti-mildew coatings for boats •Anti-fog coatings

Though is virtually impossible to reliably predict global market figures, the National Science Foundation is widely cited for the proposition that the global nanotechnology market, including ICT, will top $1 Trillion by 2011-2015.[58] Between 1997 and 2004, government investment in nanotechnology increased more than six-

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[57] Adapted from, Environmental Law Institute, *Securing the Promise of Nanotechnology: Is US Environmental Law Up to the Challenge* (Washington, DC: Environmental Law Institute, October 2005) at C2.

[58] *Supra*, note 1 (Royal Society) at 1, citing Roco & Bainbridge, 2001.

fold from approximately $430 Million to over $3.5 Billion.[59] By these estimates, Mihail Roco, chair of the United States National Science and Technology Council's subcommittee on Nanoscale Science, Engineering and Technology, and Senior Advisor on Nanotechnology to the National Science Foundation, suggests that nanotechnology has the potential to create seven million jobs overall in the global market.[60] The late Nobel laureate, Richard Smalley, predicted that "the impact of NT on health, wealth, and the standard of living for people will be at least the equivalent of the combined influences of microelectronics, medical imaging, computer-aided engineering, and man-made polymers in this century." Governments around the world recognize the potential of nanotechnology and are investing heavily in nanotechnology research and development. If accurate, these predictions suggest that nanotechnology will have far-reaching implications for people throughout the world.

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[59] M.C. Roco, "International perspective on Government Nanotechnology Funding in 2005" (2005) 7 J. Nanoparticle Res. 707 at 709.

[60] Mihail C. Roco, "Broader Societal Issues of Nanotechnology" (2003) 5 J. Nanoparticle Res. 181 at 182, online: National Science Foundation <http://www.nsf.gov/crssprgm/nano/reports/BroaderSocIssue.pdf>.

i) Commercialization Challenges

A major objective of nanoscience and nanotechnology is the development of new and useful products that will make our lives better. Inevitably, private industry will play a major role in the translation of nanoscience and nanotechnologies to society. As in other areas of technological innovation, intellectual property rights will be used to facilitate this process. Although nanotechnology remains in its infancy, charges against the accrual and exploitation of intellectual property, especially patents, have already been raised.

Intellectual property is the defacto currency of technology innovators. Detractors, including the ETC Group, argue that it is the means by which "corporate concentration" is effected.[61] Concerns about intellectual property and new technologies are not new. The patenting of life forms and the rush to patent uncharacterized human gene sequences stirred a protracted debate over gene patenting.[62] Gene patents continue to be criticized by some as doing more harm than good. Some argue that they discourage research and innovation and place unfair

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[61] *Supra*, note 32 (Big Down); ETC Group, Nanotech's "Second Nature" Patents: Implications for the Global South, Communiques No. 87 & 88, 2005, online: ETC Group <http://www.etcgroup.org/documents/Com8788SpecialPNanoMar-Jun05ENG.pdf>.

[62] National Research Council, *Intellectual Property Rights and Research Tools in Molecular Biology* (Washington DC: National Academies Press, 1997), online: NAP <http://books.nap.edu/html/property/>; Organisation for Economic Cooperation and Development, *Genetic Inventions, Intellectual Property Rights & Licensing Practices*, 2002, online: OECD <www.oecd.org/dataoecd/42/21/2491084.pdf>; Lori Pressman, Richard Burgess, Robert M. Cook-Deegan *et al*, "The Licensing of DNA Patents by US Academic Institutions: An Empirical Survey" (2006) 24 Nat. Biotech. 31.

monopoly power in the hands of industry at the expense of society. At present, there is a lack of empirical data to support these concerns and, in fact, data to suggest that working solutions are commonly reached between patent holders and users.[63] The theoretical problem of the "anticommons", as described by Michael Heller and Rebecca Eisenberg, in their 1998 Science Magazine article on gene patenting, has been co-opted by new opponents of nanotechnology patenting.[64] Peer-reviewed academic literature on nanotechnology patenting is beginning to emerge.[65] Though nanotechnology has already created certain institutional challenges for patent offices around the world, including the United States Patent and Trademark Office

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[63] See, Joseph Strauss, "Genetic Inventions and Patents – A German Empirical Study" (Presentation delivered at the BMBF and OECD Workshop on Genetic Inventions, Intellectual Property Rights and Licensing Practices, Berlin, January 24-25, 2002) [unpublished]; Dianne Nicol and Jane Nielsen, "Patents and Biotechnology: An Empirical Analysis of Issues Facing Australian Industry" Centre for Law & Genetics Occasional paper No. 6, online: Centre for Law & Genetics <http://www.law.unimelb.edu.au/ipria/publications/pubfliers/BiotechReportFinal.pdf >; OECD, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (Berlin: OECD, 2002), online: OECD <http://www.oecd.org/dataoecd/42/21/2491084.pdf>.

[64] Michael A. Heller and Rebecca S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Innovation" (1998) 280 Science 698. *But see*, F. Scott Kieff, "Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science - A Response to Rai & Eisenberg" (2001) 95 NW. U. L. Rev. 691; F. Scott Kieff, "Perusing Property Rights in DNA," in F. Scott Kieff, ed., *Perspectives on Property of the Human Genome Project* (Elsevier, 2003).

[65] Mark Lemley, "Patenting Nanotechnology" (2005) 58 Stanford L. Rev. 601; Bhaven N. Sampat, "Examining Patent Examination: An Analysis of Examiner and Applicant Prior Art" (NBER Summer Institute Working Paper, 2004); Zan Huang *et al* "Longitudinal Patent Analysis for Nanoscale Science and Engineering: Country, Institute and Technology Field" (2003) 5 Journal of Nanoparticle Research 333; Raj Bawa, S.R. Bawa, Stephen B. Maebius, Ted Flynn, Chiming Wei, "Protecting New Ideas and Inventions in Nanomedicine with Patents" (2005) 1 Nanomedicine: Nanotechnology, Biology & Medicine 150; L. Mazzola, "Commercializing Nanotechnology" (2003) 21 Nat. Biotech. 1137.

(USPTO)[66] and the Canadian Intellectual Property Office (CIPO) there are no unique ethical issues associated with the granting nanotechnology patents. Having said this, insofar as nanotechnology and biotechnology converge in the rapidly developing field of synthetic biology, the debate over nanotechnology patenting may converge with the gene patenting debate.[67] In addition, nanotechnology innovations that relate to genetic technologies may serve to heighten the debate that has arisen in that field.

Several issues have been identified in the legal literature, that relate to nanotechnology patent accrual and exploitation.[68] First, it has been argued that nanotechnology is unique in that it traverses various industrial fields and economic sectors (see, Table 4) and that this characteristic may prove challenging for persons seeking to identify relevant prior art for patent prosecution and for those seeking to find relevant licensable technologies for use. In an attempt to overcome this problem, the USPTO has created a new patent class for nanotechnology patents.[69] Second, it has been reported that in the nanotechnology arena there is unparalleled patenting of

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[66] Blaise Mouttet, "Nanotechnology and the U.S. Patent and Trademark Office: The Birth of a New Patent Class" (2005) 2 Nanotechnology Law and Business 260.

[67] See, for example, Steven A. Benner, "Redesigning Genetics" (2004) 306 Science 625; Lei Wang, "Expanding the Genetic Code" (2003) 302 Science 584; Minna Allarakhia and Anthony Wensley, "Innovation and Intellectual Property Rights in Systems Biology" (2005) 23 Nat. Biotech. 1485; Robert F. Service, "Biology Offers Nanotechs a Helping Hand" (2002) 298 Science 2322.

[68] Lorraine Sheremeta, "Nanotechnology and the Extension of the Gene Patent Debate" (Presentation delivered at the Health Law Institute, Biotechnology Patents and Policy Workshop, Banff, Alberta, May 27, 2006) [unpublished].

[69] *Supra*, note 66 (Mouttet).

foundational nanotechnology discoveries as well as significant university patenting.[70] Third, nanotechnology patents are expected to be problematic for patent offices for two reasons: (1) the sheer number of patents filed will overburden the existing examination capacity; and (2) the technical complexity of nanotechnology patents will challenge the technological expertise of the examiners.[71] Fourth, as in other technological fields (genetics in particular), uncertainty surrounding the existence of a definable research exemption in Canada may adversely impact research in the area.[72] Last, if unchecked, the accrual of patents by universities and private sector firms in the developed world will further concentrate economic power in the developed world (see Table 2-3) and will adversely impact the ability of the developing world to benefit from socially beneficial technologies. [73]

With respect to the last point, the ETC Group is concerned about the number of nanotechnology patents that are being granted (see Figure 1) and about who is obtaining patent rights (see Table 2-3). They report that academia, industry and the US military are among those most aggressively seeking patent protection.

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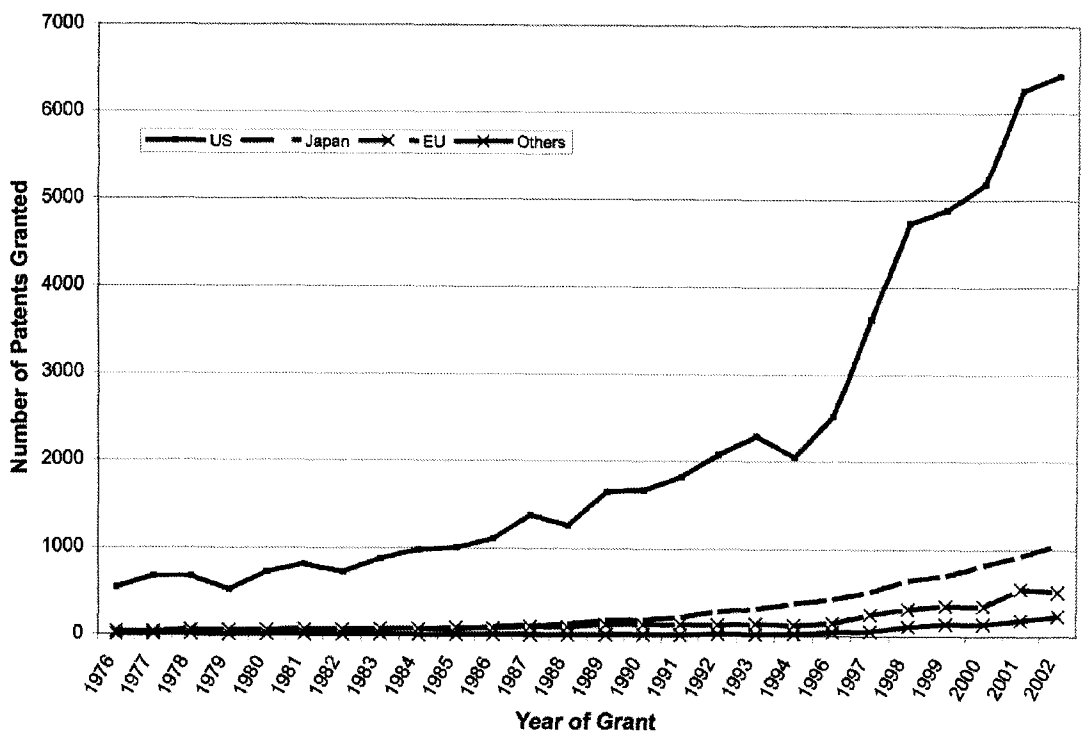
[70] *Supra*, note 65 (Lemley).

[71] *Supra*, note 65 (Sampat).

[72] For the U.S. perspective, see, generally, Stephen B. Maebius & Harold C. Wegner, "Merck v. Integra: The Impact of a Broader "Safe Harbor" Exemption on Nanobiotechnology" (2005) 2 Nanotechnology Law and Business 254.

[73] *Supra*, note 61. (Second Nature). This report concludes that the rhetoric on the potential benefits of nanotechnology for the developing world have "ignored the realities of technology transfer and intellectual property" and that to the extent that multinational corporations and university start-ups have secured foundational patents over nanotechnological developments could mean that researchers in the developing world are shut out (at 18-19).

Figure 2-2: Number of nanotechnology patents granted in the United States, Japan, European Union and Others.[74]



[74] *Supra*, note 65 (Huang *et al*) at 336. This graph was created using the data published in Table 3 of the this paper. The European Union is represented in this analysis by the UK, France, Italy, Switzerland and the Netherlands. China and Taiwan, Korea and Australia fall under the category of "others". The algorithm used to search nanotechnology patents by Huang *et al* includes the following keywords: Self-assembly, atomic force microscope, scanning tunneling microscop, atomistic simulation, biomotor, molecular device, molecular electronics, molecular modeling, molecular motor, molecular sensor, molecular simulation, quantum computing, quantum dot, quantum effect and nano (and variations of these terms).

Table 2-3: Top-ranked patent assignees in USPTO Class 977 Nanotechnology Patents (as at May 25, 2005)[75]

Company/Institution	Headquarters	Patents Issued
Canon Kabushiki Kaisha	Japan	49
IBM	United States	47
Silverbrook Research	Australia	28
United States of America	United States	16
Hitachi, Ltd.	Japan	16
Seagate Technology	United States	16
Micron Technology, Inc.	United States	14
Eastman Kodak Company	United States	13
Olympus Optical Co., Ltd.	Japan	10
University of California	United States	9
Rohm & Haas Company	Germany	9
Polaroid Corporation	United States	9
Sony Corporation	Japan	8
Molecular Imaging Corporation	United States	8

A frequently cited concern is that if nanotechnology succeeds in achieving the goals that have been set, those who are most likely to benefit are those "8.6% of the 2025 population who live in Western industrial democracies."[76] Some feel that the gap between the rich and poor will become even more dramatic than it is today. This possibility is raised in a number of the documents reviewed. The ETC Group is of the opinion that "by 2015, the controllers of Atomtech will be the ruling force in the world economy."[77] There is, therefore an obligation to proactively consider the

[75] *Supra*, note 61 (Second Nature) at 9 (used with permission).

[76] Alexander Huw Arnall, *Future Technologies, Today's Choices* (London: Greenpeace Environmental Trust, 2003), online: Greenpeace.org <http://www.greenpeace.org.uk/MultimediaFiles/Live/FullReport/5886.pdf> [hereinafter "Greenpeace"] at s. 2.5.3.2.

[77] *Supra*, note 32 (The Big Down) at 43.

potential impact of nanotechnology on the people of the world at to attempt to ensure that it benefits the maximum number for the greatest good.[78]

In the context of nanotechnology patenting, the challenge is to effectively reconcile the needs of industry with the needs of researchers and of the broader society and to maintain public trust in research and commercialization. Though the public appears to be generally supportive of nanotechnology research, the over-emphasis on the commercial aspect as opposed to societal good may inspire a backlash against nanotechnology and the products it inspires.[79] If this happens it will mirror the experiences associated with the introduction of genetically modified organisms.

E. Privacy & Civil Liberties

Surveillance, sensing and imaging technologies are giving us an increasing ability to collect, store and process vast amounts of highly personal and sensitive

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[78] A. Mnyusiwalla, A.S. Daar & P.A. Singer, "'Mind the Gap': Science and Ethics in Nanotechnology" (2003) 14 Nanotechnology R9; Fabio Salamanca-Buentello, Deepa L. Persad, Erin B. Court *et al*, "Nanotechnology and the Developing World" (2005) 2:4 PloS Medicine e97, online: Joint Centre for Bioethics <http://www.utoronto.ca/jcb/home/documents/PLoS_nanotech.pdf>. See also, Meridian Institute, Report of the International Dialogue on Responsible Research and Development of Nanotechnology (2004) online: Meridian Institute: <http://www.nanoandthepoor.org/Attachment_F_Responses_and_Background_Info_040812.pdf; UN Millennium Project Task Force on Science, Technology and Innovation, "Innovation: Applying Knowledge in Development" (2005) online: UNMP <http://unmp.forumone.com/eng_task_force/ScienceEbook.pdf>.

[79] George Gaskell et al, "In the Public Eye: Representations of Biotechnology in Europe" in G. Gaskell and M. Bauer, eds., *Biotechnology 1996-2000: The Years of Controversy* (London: Science Museum, 2001).

data. Some argue that these technologies can make us more secure. Others fear that they will be used strip away personal privacy and to undermine personal security. In the healthcare context the ability to collect, store and analyze large amounts of data gives scientists the ability to mine human genetic data to find those genetic differences that are relevant for health and disease and for the development of safe and effective tailored drug therapies.[80] These same abilities, however, have the potential to be used contrary to the rights of the person to whom the data refer. Employability and insurability could potentially be affected. Advances in sensor and chip technologies could be used to monitor every aspect of the economy and society. Conversely, biosensors and chips could be used to monitor contaminants in the environment, the workplace, the food chain, and in drinking water. The debate over the FDA's recent approval of the Verichip, an implantable RFID microchip for health record storage, infant protection, wander protection and asset tracking brings these complex privacy and security issues to the fore.[81]

The privacy issues raised by these technological developments are not different in kind than those raised by past developments in the area of information technology. They may differ in magnitude. It is important that, as new technologies

[80] Francis Collins, "A Vision for the Future of Genomics Research: A Blueprint for the Genomic Era" (2003) 422 Nature 1.

[81] Anna Bahney, "High Tech, Under the Skin" The New York Times (2 February 2006), G1; Janice Hopkins Tanne, "FDA Approves Implantable Chip to Access Medical Records" (2004) 329 BMJ 1064; Kim Zetter, "To Tag or Not to Tag" (9 August 2005) online: Wired News <http://www.wired.com/news/politics/privacy/1,68271-0.html>.

emerge, existing legal frameworks need to be monitored. Additional safeguards may be necessary in some instances.[82]

Canadian policy-makers are encouraged to actively consider the issue of personal privacy and security in a variety of contexts and from a variety of perspectives. It seems that, for now, nanotechnology doesn't warrant extraordinary measures. Nanotechnology should be incorporated into current privacy discussions (particularly in the areas of health, security and commerce). It should also be incorporated into and into horizon scanning programs to ensure that future threats to privacy and security can be foreseen.

F. Nanotechnology & Convergence

Nanotechnology will facilitate the further convergence of technologies, including biotechnology, information technology and cognitive science.[83] Each of these technologies, on its own, holds vast potential for economic growth, job creation

[82] A.M. Anderson & V. Labay, "Ethical Considerations and Proposed Guidelines for the Use of Radio Frequency Identifiers: Especially Concerning Public Safety and National Security" (2006) 12:2 Science & Engineering Ethics 265.

[83] M.C. Roco & W.S. Bainbridge, *Converging Technologies for Improving Human Performance: Nanotechnology, Biotechnology, Information Technology and Cognitive Science* (Washington D.C.: National Science Foundation, 2003). M.C. Roco & W.S. Bainbridge, "Converging Technologies for Improving Human Performance: Integrating from the Nanoscale" (2002) 4:4 J. Nanoparticle Res. 281; M.C. Roco, "Nanotechnology: Convergence with Modern Biology" (2003) 14 Current Opinion in Biotechnology 337; See also, A. Nordmann, *Converging Technologies – Shaping the Future of European Societies*, (Brussels: European Commission, 2004); D. Castle, R. Loeppky and M. Saner, *Convergence in Biotechnology Innovation: Case Studies and Implications for Regulation*, (Guelph:

and national security and has been pursued vigorously by governments around the world. It is anticipated that enormous potential exists at the interfaces of these four primary technologies (e.g. nano-bio-info-cogno ("NBIC"); nano-bio; nano-bio-IT). When these technologies are strategically combined in various ways, it is anticipated that the potential societal impacts will be magnified. Of nanobiotechnology, one commentator has stated:

> Nanobiotechnology is defined as a field that applies the nanoscale principles and techniques to understand and transform biosystems (living or non-living) and which uses biological principles and materials to create new devices and systems integrated from the nanoscale. The integration of nanotechnology with biotechnology, as well as with infotechnology and cognitive science, is expected to accelerate in the next decade. The convergence of nanoscale science with modern biology and medicine is a trend that should be reflected in science policy decisions.[84]

The discourse around human enhancement provides but one example of how convergent technologies may be disruptive to society and how nanotechnology might be implicated.[85] It is noteworthy that attendees of a 2001 workshop on

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University of Guelph, 2006), online: Joint Centre for Bioethics <http://www.utoronto.ca/jcb/genomics/documents/Convergent_Biotechnology.pdf>.

[84] *Ibid.* (Roco) at 337.

[85] G. Khushf, "Systems Theory and the Ethics of Human Enhancement: A Framework for NBIC Convergence" (2004) 1013 Annals of the New York Academy of Science 124; Gregor Wolbring, "Solutions Follow Perceptions: NBIC and the Concept of

nanotechnology hosted by the United States government concluded that national priority should be directed towards converging technologies and human enhancement.[86]

The convergence of technologies promises new ways to improve human performance – both physically and cognitively as well as individually and collectively. The integration of technologies may lead to a variety of benefits including: improved work force efficiency, enhanced sensory and cognitive abilities, heightened creativity, effective communication technologies (including brain to brain interactions), the perfection of human-machine interfaces and the amelioration of physical and cognitive decline due to aging.[87] Many concerns have been raised about human enhancement that suggest a distinct lack of consensus as to what comprises a benefit – either for individuals or for society.

Human enhancement is a much-debated topic in the biomedical literature. It has arisen in a variety of contexts including, among others, athletic enhancement[88],

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Health, Medicine, Disability and Disease" (2004) 12:3 Health L. Rev. 41; Tihamer Toth-Fejel, "Humanity and Nanotechnology: Judging Enhancements" (2004) 4:2 National Catholic Bioethics Quarterly 335.

[86] *Supra,* note 83 (Roco).

[87] *Supra*, note 32 (ETC Group) at 34.

[88] T.H. Murray, "The Bioengineered Competitor? Steroids, Hormones and Individual Rights" (1989) 69:4 National Forum 41.

genetic manipulation[89], pre-implantation genetic testing and selective implantation[90], life extension[91] and cognitive science[92]. Human enhancement and convergence raise several questions that society must answer:

- Though we possess technologies that can be used to engineer humans with desired traits, should we do so?
- Under what circumstances should enhancement be provided or permitted in society?
- If society opts to publicly provide certain enhancements, who will be eligible to receive them? How should allocation decisions about enhancement technologies be made?
- If certain enhancements are not available publicly, should they be attainable through the private market? If so, under what conditions?
- How should decisions be made about which enhancements are made publicly available?

[89] Ronald A. Lindsay "Enhancements and Justice: Problems in Determining the Requirements of Justice in a Genetically Transformed Society" (2005) 15:1 Kennedy Institute of Ethics Journal 3.

[90] W. Henn, "Consumerism in Prenatal Diagnosis. A Challenge for Ethical Guidelines" (2000) 26:6 J. Med. Ethics 444; D.S. King, "Preimplantation Genetic Diagnosis and the 'new' Eugenics" (1999) 25:2 J. Med. Ethics 176.

[91] Eric T. Juengst, Robert H. Binstock, Maxwell J. Mehlman, Stephen G. Post, "Anti-Aging Research and the Need for Public Dialogue" (2003) 299 Science 1323; Eric T. Juengst *et al* "Anti-Aging Medicine" and the Challenges of Human Enhancement" (2003) 33 Hastings Center Report 21.

[92] W. Glannon, "Psychopharmacology and Memory" (2006) 32 J. Med. Ethics 74.

- Will persons not eligible for or able to afford enhancement be viewed as less valuable in society?
- Will enhancement become a social imperative?
- Will the disabled in society become further marginalized if they decide not to be enhanced or "corrected"?

Many of these questions are reflected in the long-standing debate around genetic modification of organisms, including humans. Although the issues are not new they will likely become more acute as more nanotechnology-enabled enhancement innovations are developed. The ways in which nanotechnology can facilitate human enhancement and the effects of enhancement on society warrant proactive consideration. Similarly, other convergent technologies will warrant similar consideration. The enabling feature of nanotechnology will, in all likelihood, be an important consideration in the development of convergent technologies in society.

G. Military Uses of Nanotechnology

The use of nanotechnology for military purposes is an area that raises concern amongst members of the public. For example, the potential that nanotechnology will be used by rogue states or terrorist groups is a concern raised in the focus group work carried out by BMRB for the Royal Society.[93] It has also arisen in recently held Canadian and US focus group sessions.[94]

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[93] BMRB Social Research, "Nanotechnology: Views of the General Public", January 2004, report prepared for the Royal Society and Royal Academy of Engineering

This issue is significant because although medical applications of nanotechnology have the highest profile, the most significant early uses of nanotechnology are predicted to be in the military. An expanding body of academic writing is dedicated to military applications of nanotechnology.[95] In the post 9-11 era there is a newfound emphasis on technologically driven defense. It is suggested that nanotechnology will be key in determining the balance of global power in the future; this potential is reflected in government expenditures. After the National Science Foundation, the US Department of Defense is the largest recipient of public funds for nanoscience research.[96] Its stated objective is to exploit nanoscale phenomena "for the development of novel applications to enhance war fighter and battle systems

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Nanotechnology Working Group, online: BMRB <http://www.nanotec.org.uk/Market%20Research.pdf>.

[94] *Ibid.*

[95] See, for example, Jürgen Altmann, "Military Uses of Nanotechnology: Perspectives and Concerns" (2004) 35 Security Dialogue 61; John L. Petersen & Denis M.Egan, "Small Security: Nanotechnology and Future Defense" (2002) 8 Defense Horizons, online: National Defense University <http://www.ndu.edu/inss/DefHor/DH8/DH08.htm>; D.K. Kharat, H. Muthurajan, B. Praveenkumar, "Present and Futuristic Military Applications of Nanodevices" (2006) 36 Synthesis and Reactivity in Inorganic, Metal-Organic and Nano-Metal Chemistry 231.

[96] US, Nanoscale Science, Engineering, and Technology Subcommittee, *The National Nanotechnology Initiative: Research and Development Leading to a Revolution in Technology and Industry, Supplement to the President's FY 2007 Budget,* (Arlington, VA: National Nanotechnology Coordination Office, July 2006) online: National Nanotechnology Initiative <http://www.nano.gov/NNI_07Budget.pdf> at 35. In 2005, the Department of Defense actually received 29% of funds allocated to the NNI. The 2007 budget request for the Department of Defense is $345 M of the $1.2 B total budget request (27%). See also, Department of Defense, *Defense Nanotechnology Research and Development* (Washington: Department of Defense) 8 May 2006, online: NNI <http://www.nano.gov/html/res/DefenseNano2006.pdf>.

capabilities."[97] The creation of new institutes, including the MIT Institute for Soldier Nanotechnology[98] and the Centre for Nanoscience Innovation for Defense[99], are high profile examples of the US government commitment to defense.

It is hoped that nanotechnology will expand the range of defense options that are available to respond to aggression.[100] It may be used for military purposes in a variety of ways, including the development of:

- highly effective peacetime surveillance tools (networked sensing devices);
- intelligent sensors and barrier systems to be used in guerilla warfare;
- small, inexpensive weaponry;
- smart munitions and missiles; and
- 'smart' combat gear and protective clothing.

For Canadian policy-makers, it is important to recognise that military spending is inevitably a contentious issue. As in other areas of nanoscience research, public engagement and transparency in decision making processes will be key to maintaining public trust and confidence.

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[97] *Ibid.* (Department of Defense).

[98] Massachusetts Institute of Technology, Institute for Soldier Nanotechnologies, online: MIT <http://web.mit.edu/ISN/>.

[99] Center for Nanoscience Innovation for Defense, see: http://www.engineer.ucla.edu/stories/2002/cnid.htm

H. Public Engagement and Public Trust

The relevance of public attitudes in the realization of the potential of technological advances was crystallized in the debate over genetically modified (GM) crops and food both in the UK (and abroad).[101] Whether we are ready or not, nanotechnology is poised to emerge as yet another "public issue". The emergence of public opinion on nanotechnology is muddied for three main reasons: (1) People know very little about nanotechnology; (2) The actual risks associated with nanotechnology are, as yet, largely unknown and/or disputed and are difficult to assess in an objective manner; and (3) Portrayals of nanotechnology in the popular press (e.g. Michael Crichton's bestselling novel 'Prey'[102]) effectively blur the boundary between fact and fiction.

Like genetic technologies, nanotechnology may, to some extent, become a victim of the promise that it holds. There is concern that the benefits of nanotechnology are being hyped and that public expectations about nanotechnology are inflated. It is feared that, in the long term, the failure to meet expectations could

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[100] *Supra,* note 76 (Greenpeace) at s. 2.3.5.

[101] Michael D. Mehta "Regulating Biotechnology and Nanotechnology in Canada: A Post-Normal Science Approach for Inclusion of the Fourth Helix " (2005) 42 International Journal of Contemporary Sociology 107; Michael D. Mehta "From Biotechnology to Nanotechnology: What Can We Learn From Earlier Technologies?" (2004) 24 *Bulletin of Science, Technology and Society* 34.

[102] Michael Crichton, *Prey* (London: Harper Collins, 2002).

undermine public acceptance of nanotechnology and public trust in the broader scientific enterprise.

Scientists, industry leaders and the media all contribute to what the public hears and believes about new technologies. Each of these groups are obliged to communicate truthfully with the broader public and to engage in meaningful societal dialogue. Insofar as possible, efforts should be made to ensure that science communication is balanced and accurate. Meaningful societal dialogue about new technologies can only occur if the information relevant to weighing risks and benefits is communicated effectively.

In the dialogue about nanotechnology, extreme views are inevitable. We have seen this already with the ETC Group's call for a moratorium on the commercial production of new nanomaterials. Arguably, contrary voices play an important role in challenging society and the complacency that inherent in the status quo. Policy makers must be cautious not to dismiss extreme views. out of hand. Rather, thoughtful consideration of the bases of extremism is of critical importance. Given the lessons learned from the biotechnology arena and specifically those garnered from the GMO experience, failure to attempt to understand and address the opponents of nanotechnology head-on would be unwise.

Not surprisingly, recent quantitative and qualitative public opinion research in the UK, the US and Canada show that knowledge about nanotechnology is low.[103] Only about one third of survey respondents had heard of nanotechnology.[104] Fewer can offer a definition of nanotechnology. Most of these same people think nanotechnology will improve their life; only a small percentage thinks it will make their life worse.[105] Preliminary Canadian and US data reveal similar trends.[106] In all jurisdictions, focus group participants raise intelligent concerns including the potential long-term effects of medical applications, environmental risks associated with nanomaterials, the potential military uses of nanotechnology by states and terrorists and regulation of nanotechnology. Given the lack of direct knowledge about nanotechnology, the public's view remains speculative. Public opinion of the technologies will evolve over time and depend on individual perceptions about

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[103]Jane Macoubrie, Informed Public Perception of Nanotechnology and Trust in Government (8 September 2005) online: Pew Charitable Trusts <http://www.pewtrusts.com/pdf/Nanotech_0905.pdf>; BMRB Social Research, "Nanotechnology: Views of the General Public", report prepared for the Royal Society and Royal Academy of Engineering Nanotechnology Working Group (January 2004) online: BMRB <http://www.nanotec.org.uk/Market%20Research.pdf>; George Gaskell *et al*, "Europeans and Biotechnology in 2005: Patterns and Trends" A report to the European Commission Directorate-General for Research (May 2006) online: Europa <http://www.ec.europa.eu/research/press/2006/pdf/pr1906_eb_64_3_final_report-may2006_en.pdf; Edna Einsiedel, "In the Public Eye: The Early Landscape of Nanotechnology Among Canadian and US Publics", in *First Impressions: Understanding Public Views on Emerging Technologies*, Report Prepared for the Canadian Biotechnology Secretariat, September 2005, online: Bioportal <https://bioportal.gc.ca/CMFiles/CBS_Report_FINAL_ENGLISH249SFD-9222005-5696.pdf >.

[104] *Ibid*, (BMRB) at 4.

[105] *Ibid.*

[106] *Supra*, note 103 (Einsiedel).

specific nanotechnology applications once they developed and adopted by society. For now, people remain tentative; they see nanotechnology, correctly, as being "untried" but expect to see the potential benefits and drawbacks to become clear over time.[107]

The UK Royal Society views public open-mindedness towards nanotechnology as a golden opportunity to commence a proactive dialogue (using a variety of methods, led by numerous parties, and adequately funded) about the future of nanotechnology. It has recommended that the research councils in that country fund an extensive and sustained research programme focussing on public attitudes to nanotechnologies.[108] Qualitative work involving members of the general public as well as members of interested sections of society, such as the disabled should be undertaken.[109] Public dialogue around nanotechnology should be supported. Importantly, "[w]hether the public accepts the new technology and sees in it advantages for itself – or rejects it – will largely depend on how well informed it is and to what degree it is able to make objective judgments."[110] To this end, Greenpeace aptly warns that "dialogue between science and society must be more than a sophisticated means of engineering user acceptance."[111] There is a clear

[107] George Gaskell, Edna Einsiedel, William Hallman, Susanna Hornig Priest, Jonathan Jackson, Johannus Olstoorn, "Social Values and the Governance of Science" (2005) 310 Science 1908; Value-free Nanotech? (2005) 437 Nature 451.

[108] Supra, note 1 (Royal Society) at 62.

[109] *Ibid.*

[110] *Ibid.* at 44.

[111] *Supra*, note 76 (Greenpeace) at 5.

recognition that technological progress and progress in nanotechnology will depend on public approval. The "21st Century acceptance model" demands that technological advances are voluntarily adopted by the public and that the "perceptible usefulness of new technology products are balanced against associated risks that are shown to be manageable."[112]

It is important that Canada support the development of a transparent public consultation and education strategy around nanotechnology[113] though developing such a strategy will be a challenge. Where appropriate, the results of public consultation should be translated into tangible and visible action. The results of public consultation might, for example, be expected to underpin the development of position statements, guidance documents and best practices for academic institutes, government and industry participants. Developing an appropriate consultation and education strategy for Canada will be a challenging task. Careful thought must be given to the development of a bundle of strategies that will yield the best possible

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[112] *Ibid.* (Greenpeace) at 61. See also, D. Kennedy, "Risks and Risks" (2005) 309 Science 2137.

[113] Lorraine Sheremeta & Abdallah S. Daar, "The Case for Publicly Funded Research on the Ethical, Environmental, Economic, Legal and Social Issues Raised by Nanoscience and Nanotechnology (NE^{3}LS)" (2003) 12:3 Health L. Rev. 74.

understanding of public and stakeholder sentiment *in the Canadian context.* Appropriate and sustained levels of funding must be secured for these purposes.

Chapter 3

Canadian Environmental Policy & Nanotechnology

A. Introduction

In Canada, powers to protect the environment are shared between the federal, provincial and territorial, and local governments. The *Canadian Environmental Protection Act* (*CEPA, 1999*)[1] is Canada's main federal statute for protecting the environment and human health. The *Act* establishes a framework to manage environmental and human health impacts of the products of biotechnology, marine pollution, disposal at sea, vehicle, engine and equipment emissions, fuels, hazardous wastes, environmental emergencies and other sources of pollution. Pursuant to the *Act*, the Minister of the Environment must account to Parliament for the administration of *CEPA, 1999*. The Minister of the Environment and the Minister of Health jointly administer risk assessment and management issues associated with toxic substances. The preamble of the *Act* states:

> Whereas the Government of Canada is committed to implementing pollution prevention as a national goal and as the priority approach to environment protection;
>
> Whereas the Government of Canada acknowledges the need to virtually eliminate the most persistent and bioaccumulative toxic substances and the

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[1] S.C. 1999, c.33 [CEPA, 1999]. An earlier version of this chapter has been accepted for publication in a book that will be published by the Canadian Biotechnology Secretariat.

> need to control and manage pollutants and wastes if their release into the environment cannot be prevented;
>
> Whereas the Government of Canada is committed to implementing the precautionary principle that, 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;
>
> Whereas the Government of Canada recognizes that the risk of toxic substances in the environment is a matter of national concern and that toxic substances, once introduced into the environment, cannot always be contained within geographic boundaries.[2]

The drafters of *CEPA, 1999* recognised the importance of pollution prevention and the management and control of toxic substances and hazardous waste to reducing threats to Canada's ecosystems and biological diversity. The *Act* acknowledges the need to virtually eliminate the most persistent toxic substances that remain in the environment for extended periods of time before breaking down and toxic substances that accumulate within living organisms. It also recognizes the precautionary principle and the reality that pollution is a matter of both national and international concern. To this end, Health Canada and Environment Canada work together to assess potentially toxic substances and to develop regulations to control toxic

[2] *Ibid.*, Preamble.

substances. Nanoparticles and nanomaterials are potentially toxic substances and, therefore consideration of *CEPA, 1999* is critically important to this discussion.

There is concern about the adequacy of the existing legislative and regulatory framework to protect human health and the environment from harms arising from nanoparticles and nanomaterials.[3] There is an increasing sense of urgency on the part of some policy-makers about the appropriateness of standard risk assessment procedures to quantify all relevant risks. From the perspective of the federal government and its departments and agencies responsible for the oversight of nanotechnology, the challenges are particularly vexing and increasingly acute.

The objectives of this chapter are to: (1) provide an overview of the main policy challenges that nanotechnology raises in the context of environmental protection; and (2) to consider, through a short case study, the challenges of regulating fullerenes (C60) as "new substances" pursuant to *CEPA, 1999.* The main policy challenges that will be considered are: (1) Definitional and measurement issues; and (2) Lack of evidence of risk to inform regulatory decision-making; and (3) questionable applicability of existing laws and regulations.

For purposes of this Chapter, the choice to consider environmental regulation, as opposed to food and drug regulation is a deliberate one. Although there are

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[3]Karen Florini, Scott Walsh, John M. Balbus et al, "Nanotechnology: Getting it Right the First Time" (2006) 3:1 Nanotech. L. & Bus. 39.

concerns over the regulation of foods and drugs containing nanomaterials, the broad regulation of "substances" under *CEPA, 1999* is, at present, the primary avenue for nanotechnology regulation. Having said this, many of the issues offered for discussion in this chapter are relevant to, and will inform consideration of an expansive list of Canadian law and regulations (both federal and provincial) that purport to regulate, among other things, foods, drugs, hazardous materials, consumer products, air quality, water quality, occupational health and safety, transportation and others (see, Table 2-1, at 40).

At this time, it is salient to note that although this paper is focused on government regulation of nanotechnology pursuant to statutory authority and subordinate regulations, unless expressly avoided, courts are free to apply the common law to supplement statutory and regulatory controls. Accordingly, the common law relating to torts (e.g. strict liability[4], negligence, trespass and product liability), corporate-commercial law, and equity (e.g. the law of fiduciaries) may prove useful in determining the respective rights and obligations of nanotechnology producers and consumers with or without the existence of relevant and applicable statutory authority to act.

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[4] Of particular relevance to the discussion of nanotechnology is the 1866 House of Lords decision of *Rylands v. Fletcher* (1866), L.R. 3 H.L. 330, 37 L.J. Ex. 161. This case stands for the proposition that "those who engage for their own benefit in highly dangerous, although lawful, activities ought to bear the accident costs of those activities." See, Lewis Klar, Tort Law (3rd Ed) (Toronto: Thomson Carswell, 2003) at 555. See also *Cruise v. Niessen* (1977), 2 C.C.L.T. 53 (Man. Q.B.), reversed on other grounds (1978), 4 C.C.L.T. 58 (Man. C.A.); *Metson v. DeWolfe Ltd.* (1980), 14 C.C.L.T. 216 (N.S. T.D.).

B. Defining and Measuring Nanotechnology

Nanoscience and nanotechnology are characterized by the unique elements of size and scale, and also of complexity. These characteristics lead to profound challenges in the characterization, measurement and definition of the outcomes of nanotechnology research. From a policy perspective that which is inherently hard to characterize and measure will inevitably be difficult to regulate. Measurement challenges are a particular problem for international coordination and for the development of appropriate occupational health and safety norms.

i) Definitional Challenge

The most frequently cited definition of nanotechnology is that of the U.S. National Nanotechnology Initiative (NNI) which defines nanotechnology as:

> the understanding and control of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications. Encompassing nanoscale science, engineering and technology, nanotechnology involves imaging, measuring, modeling, and manipulating matter at this length scale. **At the nanoscale, the physical, chemical, and biological properties of materials differ in fundamental and valuable ways from the properties of individual atoms and molecules or bulk matter.** Nanotechnology R&D is directed toward understanding and creating

> improved materials, devices, and systems that exploit these new properties.[5] [Emphasis added].

The NNI distinguishes nanotechnology research and development from other types of scientific research which simply operate at the nanometer scale but do not exploit novel properties arising at that scale. The distinction between what is, and what is not, considered nanotechnology is particularly challenging at the intersection of nanotechnology and biotechnology. In light of this, the U.S. National Institutes of Health has attempted to clarify the situation by taking the position that:

> [w]hile much of biology is grounded in nanoscale phenomena, NIH has not re-classified most of its basic research portfolio as nanotechnology. Only those studies that use nanotechnology tools and concepts to study biology; that propose to engineer biological molecules towards functions very different from those they have in nature; or that manipulate biological systems by methods more precise than can be done by using molecular biological, synthetic chemical, or biochemical approaches that have been used for years in the biology research community are classified as nanotechnology projects.[6]

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[5] National Nanotechnology Initiative, "What is Nanotechnology?" online: NNI <http://www.nano.gov/html/facts/whatIsNano.html>.

[6] National Institutes of Health, National Institutes of Health Bioengineering Consortium, online: NIH <http://www.becon.nih.gov/nano.htm>.

In a similar vein, Canada's National Research Council defines nanotechnology as:

> the application of science and engineering at the atomic scale. It facilitates the construction of new materials and devices by manipulating individual atoms and molecules, the building blocks of nature. Nanotechnology enables the atom-by-atom design and fabrication of tiny structures that are very small, typically 1-100 nanometres, and which have **new properties** and powerful application in medicine and biotechnology, in energy and the environment, and in computing and telecommunications.[7] [Emphasis added].

In its first request for nanomedicine funding proposals, the Canadian Institutes of Health Research defined nanotechnology as: "the design, synthesis or application of materials, devices or technologies in the nanometer scale for the basic understanding, diagnosis, and/or treatment of disease."[8] However, "many current research initiatives in the development of novel techniques and methodologies relevant to biomedical research and clinical practice [did] not necessarily fit within this strict definition."[9] For purposes of the second announcement the CIHR recognized that microscale technologies, though not meeting the strict size definition,

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[7] National Institute for Nanotechnology, "About Nano", online: NINT <http://nint-innt.nrc-cnrc.gc.ca/nano/index_e.html>.

[8] Canadian Institutes of Health Research, "Regenerative Medicine and Nanomedicine: Innovative Approaches in Health Research" online: CIHR <http://www.cihr-irsc.gc.ca/e/22842.html#4>.

[9] *Ibid.*

are relevant for nanomedicine and regenerative medicine and were deemed potentially fundable. Specific categories of applications falling into this category include cellular imaging, biophotonics, drug delivery and targeting, and molecular characterization of cellular processes. The CIHR's expanded definition also includes the application to health of existing technologies and methodologies not traditionally associated with the life sciences. Relevant disciplines could include, for example, mathematics, computational sciences, chemistry, physics, and engineering and applied sciences. The definitional incoherence around the terms "nanoscience" and "nanotechnology" raises administrative challenges and is confusing to potential funding recipients.

In addition to creating administrative challenges for research funding agencies, the definitional issues described above also create challenges for governments, market analysts and others who seek to quantify how much nanotechnology research and development is being done in a given region, and what is the likely commercial potential of the developments associated with nanoscience research. Given the acutely competitive nature of nanotechnology research and development, there will inevitably be inconsistencies, both intentional and unintentional, in the definition and/or the application of the definition of nanotechnology when attempting to measure current investment and to attract future investment. A common definition applied in a standardized fashion by all funding agencies and investors would facilitate more accurate comparisons of relative research and development expenditures both within and between nations. The issue has arisen in Canada, for example, where two provinces, Québec and Alberta, have sought to quantify their nanotechnology research and development capacity using markedly different definitions.[10] At issue is whether research investment that does not support areas traditionally recognised as nanotechnology – for example, molecular biology and synthetic biology – should be counted as investment in nanotechnology. Given the current degree of definitional ambiguity, the solution to this problem logically resides in the development of standard definitions and standard measures of science and technology investment. A consistent schema should be developed and followed by industry, academia and government so as to avoid double counting and the intentional skewing of the overall investment profile.

In a recent report authored by J. Clarence Davies and published by the Project on Emerging Technologies at the Woodrow Wilson International Center for Scholars, Davies, questions whether it makes sense to regulate nanotechnology on the basis of size and whether a definition can be found that will facilitate certainty between manufacturers and regulators.[11] Other commentators in the U.S. and elsewhere have raised these same questions.[12] They are salient for Canadian policy-makers given that

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[10] Personal Communication, Richard Brommeland, Director of Business Development, National Institute for Nanotechnology, Edmonton, Alberta, Canada.

[11] Davies, J. Clarence "Managing the Effects of Nanotechnology" January 2006, online: Project on Emerging Technologies <www.nanotechproject.org/index.php?id=39> at 7.

[12] *Supra*, note 3 (Florini).

that the ability to regulate effectively in this area will depend on a clear definition of nanotechnology and appropriate standards to apply.[13]

ii) Challenges Relating to Standards and Metrology

An issue related to the definitional challenge is the need to develop common terminology and formalisms that will appropriately describe nanotechnology to enable scientists from diverse disciplines to communicate and collaborate. Nomenclature conventions are necessary to eliminate ambiguity when communicating differences between nanomaterials and bulk materials and in reporting for regulatory purposes. To that end, Canada is leading the International Organization for Standardization (ISO) working group on terminology and nomenclature (ISO TC229). Two additional working groups have also been created under TC299: metrology and characterization (led by Japan); and health, safety and the environment (led by the United States). ISO/TC 229 will produce standards for classification, terminology and nomenclature, basic metrology, calibration and certification, and environmental issues related to nanotechnology. It will also develop standardized test methods that will focus on physical, chemical, structural and biological properties of materials or devices whose performance is critically dependent on one or more dimension of less than 100 nm.[14] Other organizations are

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[13] *Ibid.* at 8.

[14] International Standards Organisation (ISO), New ISO Committee Will Develop Standards for Nanotechnology" (10 November 2005) online: ISO <http://www.iso.org/iso/en/commcentre/pressreleases/archives/2005/Ref978.html>; 2005; Peter Hatto, "Recommendations for Risk Governance for Nanotechnology"

also working towards developing a common nomenclature for nanotechnology. These include, among others, the American National Standards Institute (ANSI), the American Society for Testing and Materials (ASTM), the American Chemical Society (ACS), the Chemical Abstract Service (CAS), the Institute of Electrical and Electronics Engineers (IEEE) and the International Engineering Consortium (IEC).

C. A Need for Scientific Evidence to Inform Regulatory Decision-Making

In addition to the definitional and measurement challenges described above, nanotechnology policy development is plagued with a lack of scientific evidence to inform regulatory decision-making. This will be discussed from two perspectives -- of nanomaterials and human health and nanomaterials and the environment.

Presentation, IRGC Workshop on Risk Governance for Nanotechnology" Zurich, Switzerland (30 January 2006) [unpublished].

i) Nanomaterials and Human Health

Though nascent, the emerging body of evidence on the impact of nanoparticles and nanomaterials is sufficient to raise genuine concern about potential harm to human health and the environment.[15] Engineered nanomaterials are defined as "materials designed and produced to have structural features with at least one dimension of 100 nanometres or less."[16] Size-related properties that make them ideal for use in a variety of applications [17] may confer biological activity that differs from

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[15] Vicki Colvin "The Potential Environmental Impact of Engineered Nanomaterials" (2003) 21 Nature Biotechnology 1166.; Andrew D. Maynard and Eileen D. Kuempel "Airborne Nanostructured Particles and Occupational Health" (2005) 7 J. Nanoparticle Res. 587-614; Eva Oberdörster "Manufactured Nanomaterials (Fullerenes, C_{60}) Induce Oxidative Stress in Brain of Juvenile Largemouth Bass", (2004) 112 Environmental Health Perspectives 1058, online: Environmental Health Perspective <ehp.niehs.nih.gov/docs/2004/7021/abstract.html>; Peter H. Hoet, Abderrahim Nemmar & Benoit Nemery, "Health Impact of Nanomaterials?" (2004) 22 Nat. Biotechnol. 19.; A.A. Shvedova, E.R. Kisin, A.R. Murray, V.Z. Gandelsman, A.D. Maynard, P.A. Baron and V. Castranova "Exposure to Carbon Nanotube Material II: Assessment of the Biological Effects of Nanotube Materials Using Human Keratinocyte Cells" (2003) 66 J. Toxicol. Environ. Health Part A 1901-1918.

[16] Günter Oberdörster, Eva Oberdörster, and Jon Oberdörster "Nanotoxicology: An Emerging Discipline Evolving from Studies of Ultrafine Particles," (2005) 113 Environmental Health Perspectives 823, online: EHP <http://www.ehponline.org/docs/2005/7339/abstract.html>.

[17] United States Environmental Protection Agency, "Nanotechnology White Paper" External Review Draft, (2 December 2005) online: EPA <http://www.epa.gov/osa/nanotech.htm> at 34. Chemical properties that are important in the characterization of chemical substances include, but are not limited to, molecular weight, melting point, boiling point, vapour pressure, octanol-water partition coefficient, water solubility, reactivity and stability. Chemical properties such as those listed above may be important for nanomaterials, but other properties such as particle size and distribution, surface/volume ratio, magnetic properties, coatings, and conductivity are expected to be more important for the majority of nanoparticles.

and is not predicted by the bulk properties of the constituent chemicals or compounds."[18] Generally, nanomaterials are categorized into four basic types:[19]

- *Carbon-based materials* - nanoparticles composed entirely of carbon and taking the form of a sphere (buckyball, fullerene, nano-onion), ellipsoid or nano-tube (single or multi-walled). These particles have many potential applications including improved films and coatings and stronger, lighter materials.
- *Metal-based materials* - these materials include metal oxides like titanium dioxide, quantum dots, nano-gold and nano-silver.
- *Dendrimers* - nano-sized polymers built up from branched units called monomers. Technically, a dendrimer is a branched polymer. Its surface has numerous chain ends that can be tailored to perform specific chemical functions and cavities that may be useful for drug delivery or other delivery applications.
- *Nanocomposites* – combination materials that contain nanoparticles or nanomaterials to confer enhanced properties (i.e. enhanced mechanical, thermal, barrier or flame-retardant properties).[20]

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[18] *Supra*, note 16 (Oberdörster, 2005).

[19] *Supra*, note 17 (EPA).

[20] *Ibid.* at 6.

Despite the fact that the scientific data concerning risk is incomplete, many products employing nanoparticles and nanomaterials have been launched into consumer markets following a relatively short research and development phase. Currently, engineered nanoparticles, including carbon nanotubes, buckyballs and metal oxides are currently used in a variety of applications including sunscreens, cosmetics, anti-bacterial wound dressings, sports equipment, high strength composites, resins, surface coatings, sensors, probes and semiconductor devices.[21] The lack of risk data relevant to these products is of particular concern to insurers and re-insurers who, due to a lack of exposure and toxicity data, are unable to assess the associated risks to human health and the environment.[22] Increasingly, this lack of scientific evidence is creating uncertainty in the minds of regulators[23], industry

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[21] Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies, "A Nanotechnology Consumer Products Inventory" online: Woodrow Wilson International Center < http://www.nanotechproject.org/index.php?id=44>; See also, Ray H. Baughman, Anvar A. Zakhidov, Walt A. de Heer, "Carbon Nanotubes – The Route Toward Applications" (2002) 297 Science 787.

[22] Swiss Re, *Nanotechnology – Small Matter, Many Unknowns*, (Rüschlikon: Swiss Reinsurance Company, 2004) online: Swiss Re <www.swissre.com/INTERNET/pwswpspr.nsf/fmBookMarkFrameSet?ReadForm&BM=../vwAllbyIDKeyLu/ULUR-5YAFFS?OpenDocument>; Christine Ogilvie Robichaud, Dicksen Tanzil, Ulrich Weilenmann *et al*, "Relative Risk Analysis of Several Manufactured Nanomaterials: An Insurance Industry Context" (2005) 39 Envir. Sci. Technol. 8985.

[23] *Supra*, note 17 (EPA). Qasim Chaudhry, James Blackburn, Peter Floyd *et al*, *A Regulatory Gaps Study for the Products and Applications of Nanotechnology: Final Report* (March 2006) online: DEFRA <http://www2.defra.gov.uk/research/project_data/More.asp?I=CB01075&M=KWS&V=Nanotech&SUBMIT1=Search&SCOPE=0>.

experts[24] and the broader publics. Public action groups have been quick to latch onto potential risk and some have mobilized with overt anti-nanotechnology messages.[25] Others, including Greenpeace International and Environmental Defense have maintained a healthy skepticism about the governance of nanotechnology whilst recognizing its potential to benefit society.

Figure 2 outlines four general stages of nanotechnology development. We are currently positioned well within the second generation and advances directed towards third and fourth generation nanotechnologies including systems of nanosystems and molecular nanosystems between now and 2015.[26] This predictive timeline suggests that nanotechnology development will occur very quickly and will have the potential to effect significant societal change in the relative near-term.

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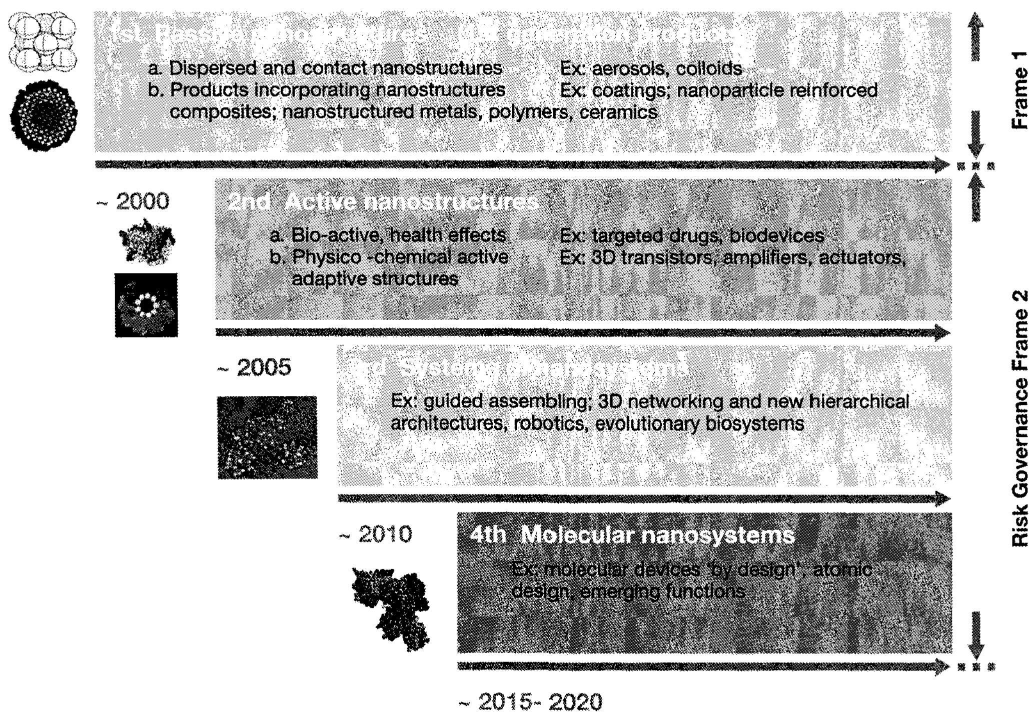
[24] *Ibid*; Nanobusiness Alliance, "Nanotechnology EH&S: A Roadmap for Responsible Innovation" Public Policy Tour" (15-17 February 2006) online: NanoBusiness Alliance <http://nanobusiness.org/Members/sean/EHSPolicyDocument.pdf>.

[25] ETC Group, *From Genomes to Atoms: The Big Down: Atomtech – Technologies Converging on the Nano-scale* (Winnipeg: ETC Group, January 2003) online: ETC Group <www.etcgroup.org/documents/TheBigDown.pdf>; Friends of the Earth (Australia), "Nanotechnology Policy Statement" May 2006, online: FOE <http://nano.foe.org.au/filestore2/download/94/FoEA%20Nanotechnology%20Policy %20May%202006.pdf>; Friends of the Earth, "Nanomaterials, Sunscreens and Cosmetics: Small Ingredients Big Risks" May 2006, online: FOE <http://www.foe.org/camps/comm/nanotech/nanocosmetics.pdf>.

[26] *Supra*, note 17 (EPA).

Figure 3-1: Stages of Nanotechnology Development[27]



a) Nanotoxicology

Few studies that evaluate the effects of nanomaterials on human health or the environment have been published to date[28] though there is an growing corpus of

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[27] IRGC, *White Paper on Nanotechnology Risk Governance*, White Paper No. 2 (Geneva: IRGC, 2006) [unpublished paper, on file with the author]; see also, IRGC, *White Paper on Risk Governance: Towards an Integrative Approach* (Geneva: Swiss Reinsurance Company, 2005) online: IRGC <http://http://www.irgc.org/irgc/projects/risk_characterisation/_b/contentFiles/IRGC_WP_No_1_Risk_Governance_(reprinted_version).pdf> at 22 (used with permission).

[28] ILSI Research Foundation/Risk Science Institute Nanomaterial Toxicity Screening Working Group, "Principles for Characterizing the Potential Human Health Effects from Exposure to Nanomaterials: Elements of a Screening Strategy" (2005) 2(8) Particle and Fibre Toxicology, online: Pub Med Central <www.pubmedcentral.nih.gov/picrender.fcgi?artid=1260029&blobtype=pdf>; Supra, note 15 (Maynard & Kuempel).

published in-vitro and in-vivo animal studies.[29] In 2004, a highly influential report of preliminary data was published by Eva Oberdörster, a nanotoxicologist and lecturer at Southern Methodist University. She has demonstrated, through her work, that carbon buckyballs (C60)[30] can make their way from a water environment into the brains of juvenile largemouth bass.[31] Whereas the ability for small molecules to cross the blood brain barrier may be desirable in the context of certain drug treatments, there may be significant adverse health effects if certain materials with neurotoxic effects are released into the environment and accumulate in animal species, including humans. Yet another recent article suggests that C_{60} can bind to and deform DNA nucleotides. The authors speculate that the molecular interactions may negatively impact the structure and biologic functioning of DNA.[32] These data are preliminary and it is not yet known if or how they might translate to broader human health and environmental risks. In response to the concerns a new field of "nanotoxicology" has emerged to study the effects of nanomaterials in biologic systems. The term "nano-

[29] *Supra*, note 15 (Oberdörster, 2004)

[30] H.W. Kroto, J.R. Health, S.C. O'Brien *et al* "C_{60}: Buckminsterfullerene" (1985) 318 Nature 162. This seminal paper describes the vaporization of graphite and the spontaneous synthesis of a 60-carbon molecule configured in the shape of a soccer ball. Three authors of this paper (R.F. Curl, H.W. Kroto, and R.E. Smalley) were awarded the 1996 Nobel Prize for Chemistry for their discovery.

[31] *Supra,* note 15 (Oberdörster, 2004); See also, S. Bosi, T. Feruglio, G. Da Ros *et al,* "Hemolytic effects of water-soluble fullerene derivatives" (2004) 47 J. Med. Chem. 6711.

[32] X. Zhao, A. Striolo, P.T. Cummings, "C_{60} Binds to and Deforms Nucleotides" (2005) 89 Biophysical Journal 3856. Importantly, interactions of this nature were predicted by modeling techniques. See, for example, H.J. Gao, Y Kong, "Simulation of DNA-nanotube interactions" (2004) Annu. Rev. Mater. Res. 123; H.J. Gao, Y Kong, "Spontaneous Insertion of DNA Oligonucleotides into Carbon Nanotubes (2003) 3:4 Nano Letters 2003.

ecotoxicology" is increasingly used to describe the study of the effects of nanomaterials in and on the environment.[33]

Determining the toxicological effects of nanoparticles and materials raises a variety of scientific challenges. For example, there exists a huge potential complement of materials containing nanoparticles – some of which are already commercially available; many others are under development. Not unlike other chemical substances, nanoparticles or nanomaterials may often be produced by several different processes. Production by different processes may lead to identical materials or variants of the material. The EPA notes that single-walled carbon nanotubes, for example, can be mass-produced by four different processes, each generating carbon nanotubes with a specific size, shape and composition.[34] These differences may lead to different toxicological profiles for each species of nanotube produced.[35] It cannot be predicted, at least until more data is amassed, whether toxicity data pertaining to one source material will be relevant to similar source materials produced by different methods. Rapid screening methods are needed to predict the toxicity of engineered nanomaterials in a standardized, rapid, and cost

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[33] *Supra*, note 16 (Oberdörster, 2005); *Supra*, note 28 (ILSI); A. Seaton & K. Donaldson, "Nanoscience, Nanotechnology and the Need to think Small" (2005) 365 Lancet 923; K. Donaldson, V. Stone, C.L. Tran, "Nanotoxicology" (2004) 61 Occupational & Environmental Medicine 727.

[34] *Supra*, note 17 (EPA) at 42.

[35] *Ibid.*

effective manner.[36] In addition, methods are needed to obtain accurate health risk assessment information on the diverse complement of nanomaterials currently used in consumer products."[37]

b) Workplace Safety

In the near-term, public exposure to nanomaterials is most likely to arise from two main sources – either from workplace exposures or from the use of cosmetics, sunscreens and other commercial products that contain nanoparticles.[38] Measurement devices and standards for measuring and monitoring workplace exposures to nanoparticles are urgently needed. In the meantime, it is unclear if currently available protective equipment, designed to block larger particles, is effective at limiting worker exposure to nanoparticles.[39]

The Royal Society has recommended that in light of previous experience with asbestos, carbon nanotubes (and other nanoparticles) warrant special toxicological attention. They have gone so far as to recommend that until proven otherwise, nanoparticles should be presumed hazardous.[40] From the lay perspective this seems a

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[36] Andrew Nel, Tian Xia, Lutz Madler et al, "Toxic Potential of Materials at the Nanolevel" (2006) 311 Science 622.

[37] *Supra*, note 28 (ILSI).

[38] Royal Society and the Royal Academy of Engineering, *Nanoscience and Nanotechnologies: Opportunities and Uncertainties* (London: Royal Society, August 2004) at 70, online: Royal Society and Royal Academy of Engineering <http://www.nanotec.org.uk/finalReport.htm>.

[39] *Supra*, note 15 (Maynard & Kuempel).

[40] *Supra*, note 38 (Royal Society).

perfectly reasonable thing to. From the regulatory perspective, the approach is inconsistent with the general approach adopted by Canadian regulators when dealing with traditional new chemical substances. In addition, the implications of the "presume hazardous" approach may have far reaching and unduly harsh implications for nanotechnology business development. In its 2003 report on nanotechnology, Swiss Re, a Swiss reinsurance company recommended that "no reasonable expense should be spared in clarifying the current uncertainties associated with nanotechnological risks."[41] These conclusions, if heeded, would have direct implications for Canadian regulators;[42] adherence would lead to regulatory inconsistency and discriminatory practices, outcomes that Environment Canada and Health Canada aim to avoid.[43]

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[41] *Supra*, note 22 (Swiss Re).

[42] Though outside the purview of this paper, the issue of state jurisdiction over conduct of individuals in society raises complex philosophical questions. For one perspective, see, J.S. Mill, "On Liberty" in *On Liberty and Other Essays*, John Gray, ed. (New York: Oxford University Press, 1991). Mill's position is that "as soon as any part of a person's conduct affects prejudicially the interests of others, society has jusrisdiction over it, and the question whether the general welfare will or will not be promoted by interfering with it, becomes open to discussion" (at 82-83). With respect to nanotechnology, it is arguably unclear whether the conduct (nanotechnology research and development) is prejudicially affecting the interests of others. There are many opinions about how the state should determine the appropriate time for state intervention. To a large extent, it depends on society's tolerance for risk.

[43] Environment Canada & Health Canada, "Internal Guidance Document on the Canadian Environmental Protection Act 1999 and the Precautionary Principle: Improved Decision Making Under Uncertainty" September 2005 [unpublished]. Decisions based on the precautionary principle should be: "non-discriminatory, in that similar situations should not be treated substantially differently; consistent with other risk management measures taken in similar circumstance; and the least trade-restrictive means of attaining the desired environmental or human health objective" (at 10).

ii) Nanomaterials and the Environment

It is anticipated that nanotechnology will provide tools that will enhance environmental quality and sustainability through pollution prevention, detection and remediation.[44] Research and development efforts are being directed towards new "green" applications for nanotechnology. Highly sensitive nanotechnology-enabled sensing devices, including micro and nanofluidic devices, devices employing engineered nanoparticles, nanostructures and nanoprobes, can be used to detect the presence of pollutants or pathogens in the environment in real-time.[45]

It is envisioned that nanotechnology may enable the development of environmentally friendly substances and processes that will replace toxic substances currently in use, reduce harmful emissions and waste products from industrial processes, provide clean energy sources, lead to the production of products that utilize fewer natural resources and use less fuel to operate.[46] For example, non-toxic, energy-

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[44] W. Zhang "Nanoscale Iron Particles for Environmental Remediation: An Overview" (2003) 5 J. Nanoparticle Res. 323-332; T. Masciangioli & Wei-Xian Zhang, "Environmental Technologies at the Nanoscale" (2003) Environmental Science and Technology" March 1, 102A-108A; P.V. Kamat, R. Huehn, R. Nicolaescu, "A Sense and Shoot Approach for Photocatalytic Degradation of Organic Contamination in Water" (2002) 106 J. Phys. Chem. 788.

[45] L.M. Pilarski, M.D. Mehta, T. Caulfield *et al*, "Microsystems and Nanoscience for Biomedical Applications: A View to the Future" (2004) 24 Bull. of Sci. Technol. & Sociol. 40. See also, Jan C. Eijkel & Albert van den Berg "Nanofluidics: What is it and What Can We Expect From It? (2005) 1 Microfluidics and Nanofluidics 249.

[46] Science-Metrix, *Canadian Stewardship Practices for Environmental Nanotechnology*, Report prepared for Environment Canada, March 2005, online: Science-Metrix <http://www.science-metrix.com/pdf/SM_2004_016_EC_Report_Stewarship_Nanotechnology_Environment.pdf>.

efficient computer monitors are replacing older models. New liquid crystal display monitors are smaller, do not contain lead and consume significantly less power than previous generation monitors.[47]

In addition to facilitating the development of products that are indirectly beneficial to the environment, nanotechnology is expected to facilitate the development of chemical tools that will be useful for direct remediation or removal of contamination. In situ field research performed on contaminated sites has demonstrated promising results using nanoscale bimetallic particles for treating a variety of common environmental contaminants in groundwater.[48] Field studies undertaken in New Jersey and North Carolina have shown nanoscale iron particles to be both effective and adaptable for the treatment of environmental contamination. Iron particles can be injected into the ground subsurface or deployed in off-site slurry reactors for treating contaminated soil, sediment and solid wastes. Alternatively, they can be mounted a solid matrix such as activated carbon for treatment of water, wastewater or gaseous process streams.[49]

Though substantial benefits are expected accrue to the environmental arena from nanotechnology, very little is currently known about the potential long-term impact of nanomaterials on the environment. The increasing manufacture of

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[47] *Ibid.* (Masciangioli & Zhang).

[48] R. Glazier *et al* "Nanotechnology Takes Root" (May 2003) Civil Engineering 64.

[49] *Ibid.*

nanoparticles for use in industrial and medical applications translates into an increased potential for unintended environmental release. The release of nanoscale pollutants into the air, water, soil and groundwater may occur as a manufacturing by-product or as end-of-life pollution as products containing nanomaterials are discarded or recycled.[50] More knowledge about the environmental impact of nanomaterials is needed. Life cycle assessments aimed at demonstrating a net savings in consumption for nanotechnology applications and product "to ensure that savings in resource consumption during the use of the product are not offset by increased consumption during manufacture and disposal have been suggested as a useful tool to quantify the environmental impact of nanomaterials."[51]

It remains a daunting challenge for Environment Canada and other government agencies with environmental oversight responsibilities is to facilitate the realization of the societal benefits of nanotechnology, while identifying and minimizing any adverse impacts to humans or ecosystems from exposure to nanomaterials.[52]

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[50] Kevin L. Dreher, "Health and Environmental Impact of Nanotechnology: Toxicological Assessment of Manufactured Nanoparticles" (2004) 77 Toxicological Sciences 3-5; See also, Leonard Sweet & Bradford Strohm, "Nanotechnology—Life Cycle Risk Management" (2006) Human Ecological Risk Assessment 528.

[51] *Supra*, note 38 (Royal Society) at 85.

[52] *Supra,* note 17, (EPA) at 10.

D. Towards Regulatory Clarity

Currently, the overall ability of Canada's legal framework to adequately regulate nanotechnology is unclear. The legal framework that governs "health" and "the environment" is complex. The subject matters are diffuse and cut across many different areas of constitutional responsibility, some federal, some provincial.[53] Both areas may be regulated using valid federal or provincial legislation depending on the circumstances and nature and scope of the problem in question. In Canada there are many laws and regulations, some overlapping, promulgated by both the federal and provincial governments that are potentially relevant to the regulation of nanotechnology (see Table 2-1, at page 40). One specific example is the existence of federal and provincial environmental protection laws which both have implications for the regulation of chemical substances.[54]

In addition, to the overall complexity of "health" and the "environment" as subject matters for legislative and regulatory oversight, existing national and international governance systems that cover human health and the environment, including Canada's, reflect the scientific understanding of bulk and macro-scale materials. For this reason, the existing potentially relevant statutes and regulations may have limited relevance due to the unique size-related risks posed by nanoscale

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[53] *R. v. Hydro Québec* [1997] 3 S.C.R. 213.

[54] See, for example, *Environmental Protection and Enhancement Act*, S.A. c. E-12; and see the related *Substance Release Regulations*, Alta. Reg. 124/93.

materials.[55] Canadian statutes that warrant urgent evaluation for their applicability and relevance to nanomaterials include, among others, *CEPA 1999*, *Hazardous Products Act*, *Pesticides Act*, *Feeds Act*, *Fertilizers Act*, the *Food and Drugs Act* and their relevant regulations. Provincial statutes and regulations covering these subject matters must also be evaluated.

In 2004, the UK Royal Society recommended that government regulatory bodies consider the appropriateness of the legislative framework in that country. They also recommended that the results of the review and that detailed plans to address any regulatory gaps identified during the review be made public."[56] In 2005 DEFRA (the UK government Department for Environment, Food and Rural Affairs) awarded a scoping study to researchers at the Central Science Laboratory (Chaudhry *et al*) who completed the project in March 2006. The scoping paper and the agency final report have been made publicly available.[57]

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[55] For a discussion of this issue from the U.S. perspective, see, *supra*, note 11 (Davies); Lynn L. Bergeson and Bethami Auerbach, "The Environmental Regulatory Implications of Nanotechnology" (2004) 71 Daily Environment Report BNA 4-14-04; Ahson Wardak, "Nanotechnology and Regulation: A Case Study Using the Toxic Substance Control Act" Woodrow Wilson International Center for Scholars, Foresight and Governance Project, Publication 2003-6, online: International Association of Nanotechnology <http://nanotechcongress.com/Nanotech-Regulation.pdf>.

[56] *Supra*, note 38 (Royal Society, 2004) at 85.

[57] Qasim Chaudhry, James Blackburn, Peter Floyd *et al*, *A Regulatory Gaps Study for the Products and Applications of Nanotechnology: Final Report* (March 2006) online: DEFRA <http://www2.defra.gov.uk/research/project_data/More.asp?I=CB01075&M=KWS&V=Nanotech&SUBMIT1=Search&SCOPE=0>; See also, DEFRA, Research Project Final Report, CB01075, online: DEFRA

The main regulatory gaps identified in the scoping paper relate to reporting thresholds and exemptions under relevant regulation, definitional issues, lack of information about hazards and risks, lack of validated methods for monitoring exposure to nanomaterials and lack of information with respect to the potential impacts of nanomaterials on human health and the environment. DEFRA recognizes that much work is needed to reduce the uncertainties highlighted in the scoping paper and they note that there is

> an urgent need for setting clear, authoritative definitions for nanotechnologies and nanomaterials, and achieving a scientific consensus to categorise different types of nanomaterials into new (or different form), or existing substances, as this will have a major bearing on the appropriateness and applicability of current and future legislation.[58]

DEFRA has expressed a desire for this study to be reviewed and updated as more information becomes available.

The American Bar Association, Section of Environment, Energy and Resources (SEER) published a series of seven papers assessing the EPA's environmental mandate to regulate nanotechnology in that country.[59] One paper was

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<http://www2.defra.gov.uk/research/project_data/More.asp?I=CB01075&M=KWS&V=Nanotech&SUBMIT1=Search&SCOPE=0>.

[58] *Ibid.* (Chaudhry) at 13.

[59] American Bar Association, Section of Environment, Energy and Resources, Regulation of Nanoscale Materials Under the Toxic Substances Control Act" (June

prepared for each of the main federal environmental statutes, including the Clean Air Act (CAA), the Comprehensive Environmental Response Compensation Liability Act (CERCLA), the Clean Water Act (CWA), The Environmental Management System (EMS), the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the Resource Conservation and Recovery Act (RCRA) and the Toxic Substances Control Act (TSCA). These papers provide a comprehensive, review of the core federal environmental statutes with a view toward assessing the utility of each in addressing the legal and regulatory issues relevant to EPA's jurisdiction. In general, the papers conclude that the core environmental statutes provide EPA with sufficient legal authority to address adequately the challenges EPA is expected to encounter as it assesses the risks and benefits associated with nanotechnology.[60]

2006) online: ABA <http://www.abanet.org/environ/nanotech/pdf/TSCA.pdf>; American Bar Association, Section of Environment, Energy and Resources, "CAA Nanotechnology Briefing Paper" (June 2006) online: ABA <http://www.abanet.org/environ/nanotech/pdf/CAA.pdf>; American Bar Association, Section of Environment, Energy and Resources, "CERCA Nanotechnology Issues" (June 2006) online: ABA < http://www.abanet.org/environ/nanotech/pdf/CERCLA.pdf>; American Bar Association, Section of Environment, Energy and Resources, "Nanotechnology Briefing Paper: Clean Water Act" (June 2006) online: <http://www.abanet.org/environ/nanotech/pdf/CWA.pdf>; American Bar Association, Section of Environment, Energy and Resources, The Adequacy of FIFRA to Regulate Nanotechnology-Based Pesticides" (May 2006) online: ABA <http://www.abanet.org/environ/nanotech/pdf/FIFRA.pdf>; American Bar Association, Section of Environment, Energy and Resources, "RCRA Regulation of Wastes from the Production, Use and Disposal of Nanomaterials" (June 2006) online: ABA <http://www.abanet.org/environ/nanotech/pdf/RCRA.pdf>; American Bar Association, Section of Environment, Energy and Resources, "EMS/Innovative Regulatory Approaches" (June 2006) online: ABA <http://www.abanet.org/environ/nanotech/pdf/EMS.pdf>.

[60] Online: American Bar Association <http://www.abanet.org/environ/nanotech/>.

To date, no comprehensive legal analysis has been performed in Canada to evaluate the overall framework as it relates to nanotechnology. It remains unclear, therefore, whether existing Canadian laws concerning human health and the environment can, even with regulatory adjustment, adequately protect the public and the environment from the risks that nanoparticles and nanomaterials may pose. As will become clear from the case-study on Canada's *New Substances Notification Regulations*[61] presented in the next section of this paper, it is this author's position that some degree of statutory and/or regulatory modification will ultimately be needed.

In the meantime we can expect that regulatory uncertainty will become increasingly costly to industry and may be fatal to some private firms.

> We have moved into a world which is, as David Rejeski [Director, Foresight and Governance Project of the Woodrow Wilson International Center for Scholars] states, "dominated by rapid improvements in products, processes and organizations, all moving at rates that exceed the ability of our traditional governing institutions to adapt or shape outcomes." He warns, "If you think that any existing regulatory framework can keep pace with this rate of change, think again.[62]

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[61] S.O.R./2005-247.

[62] *Supra*, note 11 (Davies, 2005 at 9) citing Rejeski.

Clarence Davies, Senior Advisor to the Woodrow Wilson International Center for Scholars Project on Nanotechnologies, suggests that the U.S. should consider a new law that would require manufacturers to submit a sustainability plan to show that the product will not present an unacceptable risk.[63] In support of this approach, Paul Glover, Director of Health Canada's Safe Environments programme, is quoted as stating that:

> [n]anomaterials involve multiple chemicals and mixtures used over varying periods of time with varying levels of intensity. Therefore, a chemical-by-chemical risk assessment approach will not be effective. Thus, there is a need for government to update risk assessment methodologies via multidisciplinary approach with industry, different levels of government, and broad scientific input.[64]

i) ***Case Study: The Manufacture of C_{60} as a Research and Development Substance and the Applicability Canada's New Substances Notification Regulations***

The purpose of this section is to examine the applicability of the *New Substances Notification Regulations*[65] (enacted pursuant to *CEPA, 1999*) to nanotechnology research and development in the specific, albeit hypothetical, context

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[63] *Ibid.*

[64] Institute of Medicine (IOM), Implications of Nanotechnology for Environmental Health Research, Lynn Goldman & Christine Coussens, Eds. (Washington: National Academies Press, 2005) at 39.

[65] *Supra*, note 61.

of the production of C_{60} (fullerenes) for research and development in Canada. The main questions to be answered are: (1) Does C_{60} manufactured for research purposes potentially fall under the ambit of this Regulation? (2) If so, under what circumstances is there an obligation for researchers to report to the Minister of the Environment that they are manufacturing C_{60} for research use[66]? (3) Is the requirement for reporting logically consistent with what is currently known about C_{60} (and other nanoparticles or nanomaterials)?

In sum, it appears that C_{60} does potentially fall under the ambit of this regulation. There is no obligation for researchers to report manufacturing of C_{60} for research purposes unless the quantity manufactured is over 1000 kg/year. A second report to the Minister would be required if the quantity manufactured in a given year exceeds 10,000 kg. These requirements for reporting under the *New Substances Notification Regulations* are inconsistent with what is currently known about C_{60} and other nanoscale substances. The basis for these conclusions will be explained in the sections that follow.

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[66] Pursuant to *CEPA, 1999* a "research and development substance" is defined as a substance that is undergoing systematic investigation or research, by means of experimentation or analysis other than test marketing, whose primary objective is any of the following: (a) to create or improve a product or process; (b) to determine the technical viability or performance characteristics of a product or process; or (c) to evaluate the substance prior to its commercialization, by pilot, plant trials, production trials, including scale-up, or customer plant trials, so that technical specifications can be modified in response to the performance requirements of potential customers.

a.) Why Focus on C_{60}*?*

C_{60} fullerenes are molecules comprising 60 carbon atoms in the configuration of a soccer ball – "a truncated icosahedron, a polygon with 60 vertices and 32 faces, 23 of which are pentagonal and 20 hexagonal."[67] Kroto et al first reported the existence of fullerenes in 1985.[68] Of their discovery, the authors suggested, "[i]f a large-scale synthetic route to this C_{60}species [could] be found, the chemical and practical value of the substance may prove extremely high.[69]

Three named authors on the 1985 publication (R.E. Smalley, H.W. Kroto & R.F. Curl) were awarded the Noble Prize in Chemistry in 1996 for their achievement. C_{60} quickly became somewhat of a Rosetta Stone leading to the discovery of a series of new geodesic structures of pure carbon built on the nanometer scale. Carbon is unique in that it has "this genius of making a chemically stable two-dimensional, one-atom thick membrane in a three-dimensional world".[70] Smalley and colleagues accurately predicted that the discovery would be "very important in the future of chemistry and technology in general."[71] Since their discovery in 1985, C_{60} (and other

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[67] *Supra*, note 30 (Kroto).

[68] *Ibid.*

[69] *Ibid.*

[70] Richard E. Smalley, "Discovering the Fullerenes", Nobel Lecture (7 December 1996) online: Nobel.org <http://nobelprize.org/nobel_prizes/chemistry/laureates/1996/smalley-lecture.pdf>.

[71] *Ibid.*

geodesic carbon molecules) have been the subject of much research effort; their potential utility for a variety of applications continues to be aggressively pursued.[72]

Evidence is, however, emerging that suggests C_{60} is not a biologically inert and may pose risks to human health and to the environment. Studies referenced earlier in this paper suggest that C_{60} has previously unexpected properties that raise concerns about its potential toxicity and that of other nanoscale carbon molecules, including carbon nanotubes.[73]

b.) Determining the Applicability of the New Substances Notification Regulations to C_{60}

There is no overt reference to nanoscale substances in *CEPA, 1999* or the subordinate *New Substances Notification Regulations (Chemicals and Polymers)*[74] the stated purpose of the latter being:

> These Regulations set out the information that a person must provide to the Minister of the Environment under subsection 81(1) of the Act before manufacturing or importing a **chemical** or polymer that is **not the [Domestic Substance List (DSL)]**. The information is required so that the Minister may

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[72] S.B. Sinnott & R. Andrews, "Carbon Nanotubes: Synthesis, Properties and Applications" (2001) 26 Crit. Rev. Solid State Mat. 145; Shekhar Subramoney, "Nanocarbons- Structure, Properties and Potential Applications" (1998) 10 Adv. Mater. 1157.

[73] *Supra*, note 15 (Oberdörster, 2004); *Supra*, note 44 (Zhang).

[74] *Supra*, note 61.

determine whether the chemical or polymer is **toxic or capable of becoming toxic** within the meaning of section 64 of the Act. These Regulations set out the periods within which the Minister must assess the information received and the conditions under which the Minister of the Environment must add a chemical or polymer to the DSL under section 87 of the Act. [75] [Emphasis added].

Canada's Domestic Substance List (DSL) is a registry of approximately 25,000 substances[76] that are currently or have been previously used in Canada. Pursuant to subsection 66(1) of *CEPA, 1999*, the DSL includes substances that were, between January 1984 and December 1986, in commercial use in Canada or were used for commercial manufacturing purposes, or were manufactured or imported into Canada in a quantity of 100 kg or more in any one calendar year. All substances on the DSL are to be classified to identify those that require further screening or assessment as Priority Substances because of concerns about exposure, inherent toxicity, persistence or bioaccumulation. Certain listed substances have already been designated as Priority Substances and they must undergo further assessment within a defined time period. In addition to the DSL, there is a Non-Domestic Substances List (NDSL) that lists chemicals that are recognized to be used commercially in the international arena.

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[75] *Ibid*, s. 2(1).

[76] *Ibid.* at interpretation. "Substances" are defined to include any distinguishable kind of organic or inorganic matter, whether animate or inanimate that is capable of being

Chemical substances are listed on the DSL or NDSL by their Chemical Abstract Service (CAS) number. The CAS registry number is the identification number assigned to a substance by the Chemical Abstracts Service Division of the American Chemical Society. CAS numbers are assigned when a molecule is newly identified in the peer-reviewed literature by CAS. The molecule is catalogued in the CAS registry with its molecular structure diagram, systematic chemical name, molecular formula, and other identifying information. Substances not appearing on the DSL are considered new substances pursuant to the *New Substances Notification Regulations*.

Once notified that a new substance is being used or will be used in Canada, Environment Canada and Health Canada work together to evaluate new substances for risks to the environment and human health. Depending on the results, a new substance evaluation will result in one of the following outcomes:

- If the substance is not suspected to be toxic, the notifier may import or manufacture the substance after the assessment period has expired;
- If the substance is suspected of being toxic or becoming toxic, the government may take risk management measures;

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released into the environment as a single substance, an effluent, emission, waste or mixture. A "chemical substance" is defined as a substance that is not a polymer.

- If the substance is not suspected of being toxic but a significant new activity could result in the substance becoming toxic, the substance can be subject to re-notification under certain conditions.[77]

Given the lack of scientific evidence about the effect of C_{60} (and nanomaterials generally) on human health and the environment, the question of inherent toxicity is important. Section 64 of *CEPA, 1999* defines a substance as "inherently toxic" if:

> it is entering or may enter the environment in a quantity or concentration or under conditions that:
>
> (a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;
>
> (b) exposure to the substance may constitute a danger to the environment on which life depends; or
>
> (c) it may constitute a danger in Canada to human life or health.[78]

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[77] Environment Canada, *A Guide to Understanding the Canadian Environmental Protection Act*, December 2004, online: Environment Canada <http://www.ec.gc.ca/CEPARegistry/the_act/guide04/toc.cfm> at 16.

[78] *Supra*, note 1 (*CEPA, 1999) s. 64.*

Whether C_{60}, or any nanomaterials for that matter, will meet this regulatory definition of remains to be seen. If a substance is deemed toxic or inherently toxic, the government can, at its discretion, take the following risk management measures:

- Permit the manufacture or import of the substance subject to specified conditions;
- Prohibit the manufacture or import of the substance for a period not exceeding two years unless replaced by regulation; or
- Prohibit the manufacture or import of the substance until supplementary information or test results have been submitted and assessed.[79]

c) Procedure to Determine the Reporting Requirements for the Research Manufacture of C60

In the hypothetical case of a Canadian research laboratory seeking to manufacture C_{60} (or other new substance) for research purposes the following process would be followed in order to determine the reporting requirements, if any:

Question : Is the C_{60} fullerene as described by Kroto et al in 1985 a "new substance" in Canada?

- ***Step 1:*** Determine whether C_{60}, as described by Kroto *et al* in 1985 has a unique Chemical Abstract Service (CAS) registry number

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[79] *Ibid.*

  - The C_{60} fullerene as described by Kroto *et al* is registered under CAS# 99685-96-8

- ***Step 2:*** Determine if CAS# 99685-96-8 appears on the DSL or the NDSL
  - It does not appear on either registry maintained by Environment Canada
  - CAS# 99685-96-8
- ***Conclusion:*** C_{60} (CAS# 99685-96-8) is a new chemical for purposes of the *New Substances Notification Regulation.*

d) Reporting Requirements for New Research and Development Substances in Canada

In the case of a new research and development substances, the information, set out in Schedule 1 of the regulations (below), must be reported to the Minister of the Environment at least 30 days before the day on which the quantity of the chemical produced exceeds 1000 kg in a calendar year.[80] **There is no duty to report if the amount produced does not exceed 1000 kg/year.** If larger quantities will be manufactured, the person must also report to the Minister at least 30 days before the day on which the quantity of the chemical exceeds 10,000 kg in a calendar year.[81] At the second reporting, the person must submit an update of the information previously provided or indication that there has been no change in the information reported.

[80] *Ibid.* s 5(1)

[81] *Ibid.* s 5(5)

SCHEDULE 1 – Information respecting chemicals and biochemicals that are **research and development substances**[82], contained site-limited intermediate substances or contained export-only substances [emphasis added]

1. The type of substance: (research and development)
2. The new substances pre-notification consultation number if it has been assigned and if known.
3. The chemical name of the chemical, established in accordance with the chemical nomenclature rules of the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service.
4. The trade names of the chemical and the synonyms of its chemical name, if known.
5. The CAS registry number of the chemical, if such a number can be assigned.
6. The following information in respect of the chemical:
    a. its molecular formula;
    b. its structural formula;
    c. its gram molecular weight;
    d. the degree of purity in its technical grade composition, if applicable;
    e. known impurities present and their concentration by weight;

[82] *Supra*, note 61.

   f. any additives, stabilizers and solvents present when the chemical is tested and their concentration by weight.

7. A material safety data sheet in respect of the chemical, if available;
8. The following exposure information respecting the chemical:
   a. the anticipated annual quantity to be manufactured, if applicable;
   b. the anticipated annual quantity to be imported, if applicable;
   c. the anticipated uses;
   d. its anticipated concentration in products and, if known, in end-use products;
   e. a description of the expected modes for its transportation and storage;
   f. a description of the size and type of container used for its transportation and storage;
   g. an identification of the components of the environment into which it is anticipated to be released;
   h. its anticipated releases into municipal wastewater systems;
   i. a description of the methods recommended for its destruction or disposal;
   j. whether the public is anticipated to be significantly exposed to the chemical in a product taking into account factors including its concentration, duration, frequency and circumstances of exposure and factors that may limit direct human exposure and, if not,

information substantiating that the public is not anticipated to be significantly exposed; and

k. for site-limited intermediate substances, the location of use.[83]

The research and development reporting triggers of 1000 kg/year and 10,000 kg/year pursuant to the *New Substances Notification Regulations* are extremely high. The result being that nanoparticles and nanomaterials will likely escape regulation because of low production quantities. The fact that existing regulations are based on bulk quantity assessment, raises important questions about appropriate interim procedures used to assess toxicity. While analogues may be relevant in the regulatory context (e.g. microorganisms and ultra-fine particles) there is insufficient empirical data demonstrating the effect of nano-particles on plants, animals and the ambient environment. There also appears to be some confusion as to the applicability of *CEPA, 1999* to manufacturers whose end products will be incorporated into products that are regulated pursuant to other Canadian statutes. Clarification on this specific point is needed. *CEPA, 1999* provides a federal benchmark for the notification of new substances. Schedule 2 of the Act exempts products manufactured under the *Pest Control Products Act*[84], the *Feeds Act*[85] and the *Fertilizer Act*[86] on the basis that notification and assessment requirements are met under those acts. Products manufactured for use in drug products and other products regulated under the *Food*

[83] *Supra*, note 46, Schedule 1.

[84] R.S.C. 1985, c.P-9.

[85] R.S. 1985, c. F-9.

and Drugs Act[87] are not exempted from the notification requirements pursuant to *CEPA, 1999.*

Though the present discussion is limited to *CEPA, 1999*, the approval processes for foods, drugs, medical devices and cosmetics and other consumer products are similarly hampered by lack of empirical data and may, therefore, be inadequate to protect the public from hazards associated with nanomaterials. There is a clear need to review existing hazard, exposure and risk assessment tools to determine their applicability to nanomaterials and to develop risk mitigation strategies that are appropriately tailored to nanomaterials.

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[86] R.S. 1985, c. F-10.

[87] R.S., c. F-27.

Chapter 4

Future Priorities:

Stewardship Through Risk Governance

At present, Canada remains without a national nanotechnology strategy. In 2005 it was noted by a team of international experts, that Canada has a burgeoning nanotechnology talent but it must act strategically to enable it to compete in those areas where it has demonstrated strength and expertise. At this juncture, the nature, purpose, scope and ambit of a national strategy remain elusive. 2007 is nearly upon us and no strategy has materialized. Canada needs a nanotechnology strategy to ensure that significant past investments in people, research and infrastructure are not wasted and to ensure that the future benefits of nanotechnology are realized by Canadian society.

It is well recognized by those in industry, academia, government (and increasingly the broader publics) that, given the potential impact of nanotechnologies, it is necessary to proactively consider the economic, environmental, ethical, legal and social issues (NE^3LS) in conjunction with the science and the development of emerging technologies.[1] The need is heightened given that potential risks to human

[1] The Royal Society and the Royal Academy of Engineering, *Nanoscience and Nanotechnologies: Opportunities and Uncertainties* (London: Royal Society, August 2004), online: The Royal Society <http://www.nanotec.org.uk/finalReport.htm>; Mihail C. Roco, "Broader Societal Issues of Nanotechnology" (2003) 5 J. Nanoparticle Res. 181, online: National Science Foundation <http://www.nsf.gov/crssprgm/nano/reports/BroaderSocIssue.pdf>; Alexander Huw Arnall, *Future Technologies, Today's Choices* (London: Greenpeace Environmental

health and the environment and gaps in the regulatory oversight of nanotechnology have been identified. The C_{60} example presented in this paper is but one illustration of this point. The complexity of the issues raised by nanotechnology highlight the need for interdisciplinary collaborations between scientists, clinicians, engineers, social scientists and regulators and civil society to address the concerns and to forge a scientifically, ethically and legally sound approach to nanotechnology.

Policy decisions about nanotechnology must be based on the best available scientific information and in combination with the proactive consideration of the many ethical, environmental, economic, legal and social issues that will inevitably arise. Despite increasing expenditures on nanotechnology research and development, it is now a matter of societal urgency that sufficient funds be dedicated to the examination of the risks and benefits of nanotechnology to the environment, human health and society writ large. Failure to act quickly to fill this gap will undermine public trust in the scientific enterprise and may well spell disaster for the broad development and introduction of nanotechnology products in the long term.

Trust, 2003), online: Greenpeace.org <http://www.greenpeace.org.uk/MultimediaFiles/Live/FullReport/5886.pdf >; ETC Group, *From Genomes to Atoms: The Big Down: Atomtech – Technologies Converging at the Nano-scale* (Winnipeg: ETC Group, January, 2003) online: ETC Group <http://www.etcgroup.org/documents/TheBigDown.pdf>; Fabio Salamanca-Buentello, Deepa L. Persad, Erin B. Court *et al*, "Nanotechnology and the Developing World" (2005) 2:4 PloS Medicine e97, online: Joint Centre for Bioethics <http://www.utoronto.ca/jcb/home/documents/PLoS_nanotech.pdf>

The Federal Government, in cooperation with the governments of all Canadian provinces and territories must joint with industry to support the development of a research agenda that will address the unique issues, both foreseen and unexpected, that nanoscience and nanotechnology will raise. Failure of Canada to support a robust NE^{3}LS research agenda will increase the potential that nanotechnology will be derailed.[2]

The concept of stewardship is one that is frequently invoked by Canadian policy-makers.[3] It implies overarching ethical management and the reaping of benefit from innovation while avoiding societal risk. It is commonly, though not exclusively, used in the context of "environmental stewardship". The U.S. EPA includes "Principles of Environmental Stewardship" as an appendix to its White Paper on nanotechnology.[4] To be effective, stewardship demands multiple stewards at various levels including international organizations, state governments, regional and local

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[2] A. Mnyusiwalla, A.S. Daar & P.A. Singer, "'Mind the Gap': Science and Ethics in Nanotechnology" (2003) 14 Nanotechnology R9.

[3] John Capelli & Marc Saner, "Current Uses of the Notion of 'Stewardship': Survey and Preliminary Analysis in the Canadian Biotechnology Context" March 2003, online: < http://www.iog.ca/publications/biotech_stewardship.pdf>. See, also

[4] United States Environmental Protection Agency, Nanotechnology Workgroup, *Nanotechnology White Paper (External Review Draft)* (2 December 2005) online: EPA <http://www.epa.gov/osa/pdfs/EPA_nanotechnology_white_paper_external_review_draft_12-02-2005.pdf> at 101. The principles of environmental stewardship include: (1) Exceeds required compliance; (2) Makes environment a key part of internal priorities, values and ethics, and leads by example; (3) Holds oneself accountable; (4) Believes in shared responsibility; and (5) Invests in the future.

governments, industry leaders, public action groups and individuals.[5] The notion of stewardship is related to the concept of risk governance, which has been described by the IRGC as:

> Involv[ing] the totality of actors, rules, conventions, processes, and mechanisms concerned with how risk information is collected, analysed and communicated and management decisions are taken. It is of particular importance in situations where there is no single authority to take a binding risk management decision and where the nature of the risk requires the collaboration and co-ordination between a range of different stakeholders [e.g. nanotechnology]. It includes a multi-faceted, multi-actor risk process and calls for the consideration of contextual factors such as institutional arrangements (e.g. the regulatory and legal framework that determines the relationship, roles and responsibilities of the actors and coordination mechanisms such as markets, incentives or self-imposed norms) and political culture, including different perceptions of risk. [Emphasis added]. [6] [7]

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[5] *Supra,* note 3 (Capelli & Saner).

[6] IRGC, *White Paper on Nanotechnology Risk Governance,* White Paper No. 2 (Geneva: IRGC, 2006) [unpublished paper, on file with the author]; see also, IRGC, *White Paper on Risk Governance: Towards an Integrative Approach* (Geneva: Swiss Reinsurance Company, 2005) online: IRGC <http://http://www.irgc.org/irgc/projects/risk_characterisation/_b/contentFiles/IRGC_WP_No_1_Risk_Governance_(reprinted_version).pdf>. Although unofficial, there is an intention by Canadian policy-makers to use the IRCG risk governance model in

It is this author's position that the concepts of stewardship and risk governance are logically connected and should be embodied in a uniquely Canadian national strategy for nanotechnology. The recently published IRGC Risk Governance Framework for Nanotechnology is directed to policy-makers. The framework is comprehensive and includes proactive and ongoing consideration of NE^3LS issues.

A. IRGC Risk Governance Framework

Although a detailed analysis of the IRGC risk governance framework is beyond the scope of this paper, what the IRGC proposes is a conceptual framework for use by decision makers that will provide a "systematic and integrated approach to analyzing and managing the anticipated risks, challenges and opportunities of nanotechnology".[8] The framework conceptually categorizes nanotechnology into four generations of nanotechnology product development and their expected characteristics; and two broad frames of reference (Frames 1 and 2) based on the evolution of knowledge, level of complexity and anticipated social and ethical consequences of the developments (Frame 1 focuses on simple, passive nanostructures; Frame 2 focuses on active, complex or evolving nanostructures and nanosystems) (see Figure 3-1 at 85). The framework also integrates a science-based risk assessment and an assessment of risk perception and the societal context of risk

development of its nanotechnology stewardship plan. Personal Communication, Dr. Nigel Skipper, Director, Departmental Biotechnology Office, Health Canada.

[7] *Ibid.*

[8] *Ibid.* at 12.

(the so-called "concern assessment"). The framework also addresses the educational gap, political and security issues, and longer term human development issues. The risk management strategies elaborated take into account the relative state of scientific information and societal balancing of perceived risks and benefits and aim to be both corrective and adaptive. The framework demands that:

> All interested parties [are] to be effectively engaged, for risk to be suitably and efficiently communicated by and to the different actors, for decision-makers to be open to public concerns and, in cases of high ambiguity, for upstream public engagement to be an integral part of the decision-making process.

For Canada, there are many benefits of adopting the IRGC framework. Firstly, it would position Canadian policy-makers to collaborate with the interdisciplinary team of international experts who conceived of the framework.[9] It would spur the performance of strategically planned, well-coordinated scientific research to better define the risks associated with nanoparticles and nanomaterials and would facilitate the international coordination of activities by individuals and groups who are already working on the toxicological profiling of nanomaterials. For Canada, integration at this level will facilitate a much more direct route to understanding the issues than

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9 *Supra*, note 6 (IRGC White Paper 2) at 4. The interdisciplinary team of experts is led by Mihail Roco (U.S. NNI) and Ortwin Renn (Germany, Dialogik).

would otherwise be possible. As a result of participation, Canada will be prepared to address regulatory gaps more quickly than would otherwise be possible.

While Canada decides on its nanotechnology strategy – whether formal or informal – it should consider adopting voluntary reporting mechanisms intended to facilitate the collection and dissemination of safety and toxicity data to the broader community.[10] Canada is well advised to participate in these efforts in its attempt to avoid or mitigate adverse impacts of nanotechnology on human health, the environment in a timely manner.

An editorial published in the Wall Street Journal is insightful. The piece, co-authored by Fred Krupp, the president of Environmental Defense, a U.S. nonprofit organization and Chad Holliday, the President and CEO of Dupont reveals the need for the diverse elements that exist in civil society to come together to address issues that nanotechnology raises. They poignantly conclude that "we" indeed can inspire the responsible development of nanotechnology. "In the end" they say:

> It all comes down to this: Can we reap the benefits while minimizing the risks? We believe we can. The key steps are identifying and addressing the risks. We encourage those with an interest and a stake in nanotech to collaborate in the development of responsible safety

[10] *Supra*, note 4 (EPA) at 27. EPA is working to develop voluntary and regulatory measures to evaluate nanomaterials.

standards and to exercise great care in the launch of new materials. We urge the federal government to adequately fund the agencies that need to understand nanotechnology so they can create thoughtful and informed regulations for this exciting field of scientific discovery and commercial promise.[11]

[11] Fred Krupp and Chad Holliday, "Let's Get Nanotech Right" Wall Street Journal, 14 June 2005, B2. Mr. Krupp is president of Environmental Defense an Mr. Holliday is Chairman and CEO of Dupont.