RGI
Regulatory Governance Initiative

Regulation Papers

International Approaches to the Regulatory Governance of Nanotechnology

Jennifer Pelley and Marc Saner

April 2009

Carleton UNIVERSITY | School of Public Policy and Administration

Abstract

This report is an initial exploration into the question: "How have Canada and other jurisdictions reacted to the recent emergence of nanotechnology-based products in the marketplace (and what is the current state of affairs)?" undertaken from the perspective of regulatory governance.

The report is largely based on a literature review (up to March 2009) that has been corroborated with expert interviews. Our focus is on five jurisdictions (US, UK, EU, Australia and Canada) and we describe how the emergence of nanotechnology triggered activities in three domains: (a) public and stakeholder debate, (b) development of initial policy options, and (c) the management of regulatory development in a situation of scarce data.

On the basis of these up-to-date descriptions, we have selected a set of six regulatory governance principles and discuss the extent to which best practices are starting to emerge.

Acknowledgements

We thank the Centre of Regulatory Expertise at the Treasury Board of Canada Secretariat for funding this study. We are grateful to the following individuals for their willingness to be interviewed and for their generosity with their knowledge and time: Andy Atkinson (Environment Canada), Laurent Gémar (Health Canada), Andrew Maynard (Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, US), Kristen Kulinowski (International Council on Nanotechnology, US), Jo Anne Shatkin (CLF Ventures, US), Matthew Harvey (The Royal Society, UK), Steve Morgan (Department for Environment, Food, and Rural Affairs, UK), Geert van Calster and Joel D'Silva (Faculty of Law, KU Leuven, Belgium), and Diana Bowman (Monash University, Australia and KU Leuven, Belgium).

Available for download from www.regulatorygovernance.ca

ISBN # 978-0-7709-0530-9

Table of Contents

Glossary of Acronyms

AON = Australian Office of Nanotechnology

ASCC = Australian Safety and Compensation Council

BERR = United Kingdom Department for Business Enterprise & Regulatory Reform

CCA = Council of Canadian Academies

CEPA = *Canadian Environmental Protection Act 1999*

CIELAP = Canadian Institute for Environmental Law and Policy

CPSC = United States Consumer Product Safety Commission

CSOs = Civil Society Organizations

Defra = United Kingdom Department for Environment, Food and Rural Affairs

DIUS = United Kingdom Department for Innovation, Universities & Skills

DSL = Domestic Substances List (under CEPA in Canada)

DTSC = California Department of Toxic Substances Control

EC = European Commission

ECA = European Chemicals Agency

EFSA = European Food Safety Authority

EHS = Environmental, Health and Safety

ELSI = Ethical, Legal, and Social Issues (relating to nanotechnology)

EMEA = European Medicines Evaluation Agency

EPA = United States Environmental Protection Agency

ETC Group = Action Group on Erosion, Technology and Concentration (NGO based in Canada)

EU = European Union

FDA = United States Food and Drug Administration

FDCA = *Food, Drugs, and Cosmetics Act* (administered by the US FDA)

FIFRA = *Federal Insecticide, Fungicide and Rodenticide Act* (administered by the US EPA)

FoE = Friends of the Earth

FSA = United Kingdom Food Standards Agency

FSANZ = Food Standards Australia New Zealand

GMOs = Genetically Modified Organisms

HSE = United Kingdom Health and Safety Executive

ICON = International Council on Nanotechnology (a US-based partnership)

ICTA = International Center for Technology Assessment (a US-based non-profit organization)

IRGC = International Risk Governance Council

IRSST = Institut de recherche Robert-Sauvé en santé et en sécurité du travail (based in Quebec)

ISO = International Organization for Standardization

NEG = Nanotechnology Engagement Group (a UK initiative)

NGOs = Non-Governmental Organizations

NICNAS = Australian National Industrial Chemicals Notification and Assessment Scheme

NIOSH = United States National Institute for Occupational Health and Safety

NMSP = Nanoscale Materials Stewardship Program (administered by the US EPA)

NNI = US National Nanotechnology Initiative

NNST = Australian National Nanotechnology Strategy Taskforce

NSNR = New Substances Notification Regulations (under CEPA in Canada)

OECD = Organisation for Economic Co-operation and Development

OHS = Occupational Health and Safety

OSHA = US Occupational Safety and Health Administration

PEN = Project on Emerging Nanotechnologies (a think tank based in Washington, DC, USA)

PMSEIC = Australian Prime Minister's Science, Engineering and Innovation Council

RCEP = United Kingdom Royal Commission on Environmental Pollution

REACH = Registration, Evaluation, Authorisation and Restriction of Chemical Substances (EU)

RS-RAE = UK Royal Society and Royal Academy of Engineering

S&T = Science & Technology

SCCP = Scientific Committee on Consumer Products (EU)

SCENIHR = Scientific Committee on Emerging and Newly Identified Health Risks (EU)

SCHER = Scientific Committee on Health and Environmental Risks (EU)

SNAc = Significant New Activity (under the *Canadian Environmental Protection Act*)

SNURs = Significant New Use Rules (under the US Toxic Substances Control Act)

STIC = Science, Technology and Innovation Council (Canada)

TGA = Australian Therapeutic Goods Administration

TSCA = *Toxic Substances Control Act* (administered by the US EPA)

UK = United Kingdom

UNESCO = United Nations Educational, Scientific and Cultural Organization

US = United States

Which? = the UK-based Consumers' Association

WPMN = OECD Working Party on Manufactured Nanomaterials

WPN = OECD Working Party on Nanotechnology

About the Authors

Dr. Jennifer Pelley
Senior Researcher
Regulatory Governance Initiative

Jennifer Pelley is a Senior Researcher with the Regulatory Governance Initiative, in the School of Public Policy and Administration at Carleton University in Ottawa, Ontario, Canada. She brings to the RGI research team significant experience as a researcher, public affairs and government relations consultant, and analyst in the areas of health, health sciences, and pharmaceuticals. Jennifer holds a Ph.D. in Biochemistry and Molecular Biology from the University of Calgary (2006) and a B.Sc. in Biochemistry from Queen's University (1999).

Dr. Marc Saner
Executive Director
Regulatory Governance Initiative

Marc Saner is Executive Director of the Regulatory Governance Initiative. He has more than 15 years of experience carrying out assessments and conducting analytical work in the natural sciences and humanities. Prior to assuming his current position at Carleton, he was the Executive Vice President and Director of Assessments at the Council of Canadian Academies and a Director at the Institute On Governance. His research expertise is in the ethics, risk, and regulation of emerging technologies.

Marc holds a Ph.D. in Applied Ecology from the University of Basel, Switzerland (1991) and an M.A. in philosophy with a specialization in environmental ethics from Carleton University (1999). He is an Adjunct Research Professor in the Departments of Philosophy and Biology at Carleton University.

Introduction

In this report, we investigate the question: **"How have Canada and other jurisdictions reacted to the recent emergence of nanotechnology-based products in the marketplace (and what is the current state of affairs)?"** The perspective applied is that of *regulatory governance*, that is to say, the process whereby governments, industry and civil society make decisions about how to regulate (or otherwise influence the course of) nanotechnology, determine whom they involve, and how they render account.

The history of nanotechnology regulation is not only of interest in the context of the planning of emerging regulations, it can also provide clues on how to address novel technologies in a regulatory context *in general* (nanotechnology being neither the first nor last novel technology). Important questions from the perspective of regulatory governance are:

- Which key event or events triggered **debate**, stakeholder consultations or policy development and how did jurisdictions involve the public and stakeholders?
- How have countries dealt with **policy options**? For example, have they swiftly moved to the development of regulations or did they carefully consider or use other policy instruments? How have jurisdictions addressed the issue of regulatory impact?
- How have the various jurisdictions addressed the conundrum that evidence-based regulatory action should be based on safety **data** but that such safety data is hard to obtain in the absence of established regulations?

Methodologically, we approached these questions by reviewing the publicly available information and by corroborating results with selected expert interviews.

Our survey focuses on five key jurisdictions: the United States (US), the United Kingdom (UK), the European Union (EU), Australia, and Canada. These jurisdictions have been selected in collaboration with the Treasury Board of Canada Secretariat (the sponsor of the study); they represent a set of jurisdictions commonly monitored in regulatory policy development in Canada.

For each jurisdiction, we provide descriptions of the policy, regulatory and stewardship approaches undertaken to date in response to the emergence of nanotechnology onto the marketplace. Where known, we comment on the effectiveness of approaches utilized to date. We also discuss the strategies adopted in each jurisdiction to consult with stakeholders and also we outline key events and key players in the ongoing nanotechnology public policy debate. Where possible, we have taken care to include up-to-date information in our descriptions (up to March 2009) in order to provide the reader with an understanding of the current state of regulation in the five jurisdictions.

Finally, we provide a brief overview of international-level activities ongoing by member countries of the Organisation for Economic Co-operation and Development (OECD) relating to manufactured nanomaterials. The report ends with a comparison of regulatory governance approaches across jurisdictions and an analysis of the "best practices" that may be deduced from the experiences to date.

Nanotechnology: Basic Features and Regulatory Issues

Nanotechnology is a term used to describe the manipulation of matter on the molecular scale. It has been hailed as a "platform technology", meaning that it represents a significant scientific breakthrough with the potential to impact upon virtually every sector of the economy. Nobel laureate Richard Feynman is often credited with predicting the potential of nanotechnology in his December 1959 speech entitled "*There's Plenty of Room at the Bottom*"[1]. However, the term nanotechnology was not coined until 1974, when it was defined by Professor Norio Taniguchi as the "*processing of, separation, consolidation, and deformation of materials by one atom or by one molecule*"[2].

The term ***nanotechnology*** is used broadly to refer to particles, materials, and products at the ***nanoscale*** as well as the technologies (high-powered microscopes, for example) used to manipulate, visualize, and characterize materials on this scale. It is noteworthy that an internationally accepted definition for what constitutes the nanoscale does not yet exist, although the International Organization for Standardization (ISO) Technical Committee on Nanotechnology (TC229) has developed a working definition for nanotechnology. A majority of jurisdictions currently define the nanoscale as encompassing materials between 1 and 100 nanometres in size in at least one dimension. The term ***nanomaterial*** refers to any material having one or more dimensions in the nanoscale or a material that is itself nano-structured. The term ***nanoproduct*** refers to any product that incorporates nanotechnology.

Natural and incidental forms of nanomaterials have been around for a long time, but it is only relatively recently that scientists have developed ways to engineer and manipulate nanoscale particles for specific uses. In fact, it was not until the mid-1980's that scientists had developed the tools and techniques needed to facilitate the manipulation of individual atoms on a surface. The reporting of carbon fullerenes in 1985 was a significant breakthrough; so much so, in fact, that this discovery was eventually recognized with the 1996 Nobel Prize for Chemistry (awarded to Robert Curl, Harold Kroto, and Richard Smalley).

Applications of Nanotechnology

It is very likely that nanotechnology will be one of the defining technologies of the 21st century. What is particularly notable about nanotechnology is that it has potential applications in multiple sectors of the economy and industries, including manufacturing, health, the environment, energy, textiles, construction, mining, agriculture, and information and communications technologies. As of August 2008, the Consumer Products Inventory[3]—an inventory of nanotechnology-based consumer products maintained by the Project on Emerging Nanotechnologies (PEN), based in Washington D.C.—contained over 800 products or product lines. These products were being produced by 420 companies located in 21 different countries. To give some idea of the rapid rate at which nanotechnology-based applications are coming to market, it is noteworthy that the number of products listed in the database as of February 2008, a mere six months earlier, was just over 600 products.

---

[1] The transcript of Feynman's speech can be found at: http://www.its.caltech.edu/~feynman/plenty.html; accessed March 31, 2009.
[2] N. Taniguchi. (1974). "*On the Basic Concept of 'Nano-Technology'*". Proc. Intl. Conf. Prod. London, Part II, British Society of Precision Engineering.
[3] The methodology used to create the Consumer Products Inventory can be found at the following link: http://www.nanotechproject.org/inventories/consumer/background/methodology/.

Of the over 803 consumer products listed in the PEN consumer products inventory as of August 2008, 502 of these products fell into the category of "health and fitness products"—a category which includes personal care products, cosmetics, sunscreens, clothing, and sporting goods. Other categories of products included: "home and garden" (91 products), "food and beverage" (80 products), "electronics and computers" (56 products), and "goods for children" (18 products). Where products fell into more than one category, they were counted twice. A majority (more than one-half) of the nanotechnology-derived consumer products already on the market originate in the United States, whereas approximately 1 in 4 products hailed from East Asia, and 1 in 8 products were manufactured in Europe. Although Canadian-derived nanoproducts remain a relative scarcity in the marketplace, a 2007 report prepared by Industry Canada estimated that 517 nano-derived products were being sold in or imported into Canada at that time. A commonly cited estimate claims that by 2015, the worldwide market for nanotechnology-based products will be worth $1 trillion. Thus, it is plain to see that the potential impacts of nanotechnology will be both economically significant and far-reaching in terms of scope.

Issues Associated with Nanotechnology

Two main categories of issues have been associated with the development and proliferation of nanotechnology-based applications. Chief among the two is the consideration of potential risks that nanomaterials may pose to human health, the environment, and worker safety. The second category relates to concerns that have been raised regarding the ethical, legal, and social impacts of nanotechnology.

Environmental, Health and Safety Risks Associated with Nanotechnology

In the case of nanotechnology, there is currently only limited knowledge available regarding the potential health, safety, and environmental impacts of this technology. To date, development of the technology itself and of consumer applications has by far outpaced investments in the field of nanotechnology-related environmental, health and safety (EHS) research (Royal Commission on Environmental Pollution, 2008; US National Research Council, 2008).

Many members of the scientific community have been vocal in advocating for the cautious application of nanotechnologies. In 1986, Eric Drexler, a prominent US engineer, described a sci-fi version of nanotechnology in his book *Engines of Creation: The Coming Era of Nanotechnology*. In this book, Drexler proposed the idea of a nanoscale "assembler" that could copy itself, and coined the term "grey goo" to describe what might happen if such a hypothetical self-replicating version of nanotechnology went out of control. Also in 1986, Drexler co-founded the Foresight Institute, a California-based non-profit organization which sought to educate society about both the potential benefits and risks of nanotechnology. Drexler's gloomy predictions for the future of nanotechnology have been widely criticized by others in the scientific community. In fact, recently even Drexler himself concluded that the likelihood of a grey goo scenario was minimal at best. Yet the impacts of his early predictions remain in the collective conscious even today.

Drexler was not alone in his cautious approach to nanotechnology. In an article published in *Wired* magazine in April 2000, Sun Microsystems co-founder and prominent American scientist Bill Joy argued that technological advances in the fields of genetic engineering, robotics, and nanotechnology posed

significant risks that threatened the very existence of the human species. The novel *Prey* by Michael Crichton, first published in November 2002, like his previous novel *Jurassic Park*, has been framed as a cautionary tale about technological advancement. Dealing with nano robotics, this novel has further popularized the idea of what might happen were nanotechnology to get out of control.

To date, there have been no documented cases of adverse health or environmental effects directly attributable to nanotechnology (Davies, 2009; Royal Commission on Environmental Pollution, 2008). However, numerous concerns have been raised by scientists, advocacy groups and the general public alike that the specific properties of nanomaterials arising from their small size – the same properties associated with their tremendous potential and numerous possible applications and benefits – may lead to different interactions in humans at the cellular level and with the environment. Because the properties of many nanomaterials differ significantly from the known properties of their non-nano counterparts, we do not yet know how this will affect the way they are transported, and hence their biological and environmental fate. The risk, therefore, is that these materials will have as yet unanticipated impacts on human health and the environment. Preliminary studies in the field of **nanotoxicology** (an emerging science which looks at the potential for nanotechnology to cause adverse effects) have indicated that some nanomaterials may have toxic effects. In particular, a number of studies have noted the potential for carbon nanotubes (cylindrical nanoforms of carbon which are characterized by their extraordinary strength and unique electrical properties) to exhibit toxic effects in the lung comparable to those of asbestos (UK RS-RAE, 2004). Such studies have raised serious concerns as well as recent calls for a moratorium (FoE Australia, 2008). However, it is important to note that the evidence on the toxic effects of carbon nanotubes is by no means conclusive at this point in time; other scientific studies have failed to reproduce such toxicity.

There is certainly evidence to suggest that some dimensions of nanotechnology may pose potential risks to human health, worker safety, and the environment. However, at this time we cannot yet fully appreciate the precise nature, magnitude or frequency of such risks. The burgeoning field of nanotoxicology has begun to address these questions; however there remains a substantial gap between this field of academic research and research which is of relevance to risk regulators and policy makers.

Ethical, Legal and Social Implications of Nanotechnology

In addition to the potential environmental, health and safety (EHS) impacts, concerns have also been raised about the ethical, legal and social issues (ELSI) associated with nanotechnology.

Much of the discussion on nanotechnology ELSI issues is coloured by the experience of the international debate on genetically modified organisms (GMOs); in fact, many of the players in the nanotechnology ELSI domain were recruited from the community that spent years debating biotechnology and the GMO file. This is true for scholars, civil society groups and, to a lesser extent, regulators. Despite this, the two files—GMOs and nanotech—only partially overlap with respect to their ELSI profiles.

Canadians played an important role in the early ELSI debate. In 2003, the Ottawa-based ETC Group (formerly known as RAFI and famous for coining the term “terminator technology” in the GMO context) published the report: *From Genomes to Atoms: The Big Down*. ETCs concerns spanned intellectual property rights, the concentration of corporate control, biological warfare, and the convergence of technology into synthetic biology; the group proposed a moratorium on nanotechnology (ETC, 2003).

Another Canadian group who was well established in the GMO debate, the Joint Centre for Bioethics (JCB) at the University of Toronto, responded to the need to discuss nanotechnology ELSI and the anti-nanotechnology analysis by the ETC Group with a call for increased investment in ELSI and regulatory research. For example, in their 2003 paper *Mind the Gap: Science and Ethics in Nanotechnology* (Mnyusiwalla *et al*., 2003), the JCB cautioned that there was a risk of derailing the potential benefits of nanotechnology, including for developing countries, if the study of ELSI did not catch up to the speed of technology development.

There was some media pick-up from these contributions and the positions of the ETC group and the JCB were usually juxtaposed in these reports. A number of contributions to nanotechnology ELSI research have been made since then, including a 2006 report by UNESCO. The key issue with ELSI content is the question of who both controls and benefits from the applications of nanotechnology. For example, who has the say in technology development, who holds intellectual property rights, to what extent do developing countries have access, and to what extent is there a potential for misuse (e.g., in terrorism). An overarching theme is the question: to what extent regulatory oversight is keeping pace with the technological advances?

In their 2006 report, UNESCO labelled two issues—the "grey goo" risk scenario proposed by Drexler and the use of nanotechnology to achieve post-humanism (or trans-humanism)—as "distractions" in the ELSI context (UNESCO, 2006). We should recognize, however, that the fields of biotechnology, neurobiology and synthetic biology increasingly converge with nanotechnology and are sometimes even considered a sub-category of nanotechnology. From this broad perspective, a number of novel and complex ELSI issues emerge. Within a more narrow focus on the nanomaterials in the marketplace, however, the relevant ELSI themes correspond more closely to well established topics that have already been discussed for decades in the context of the regulation of new chemicals.

Regulating Nanotechnology

In the current report, we will investigate the following question: *How have Canada and other jurisdictions reacted to the recent emergence of nanotechnology-based products in the marketplace?* Specifically, what policy, regulatory and stewardship initiatives have been undertaken in various jurisdictions in response to this important new emerging technology?

Awareness of nanotechnology has dramatically risen in recent years among lawmakers, regulators, and environmental activists alike. However, the question of whether, and how best, to regulate nanotechnology is not new. It was first raised in March 1989 by David Forrest in a paper originally written for a course on Law, Technology, and Public Policy at the Massachusetts Institute of Technology. As Forrest so elegantly stated two decades ago:

> "The emergence of new technologies continually forces us to ask whether our laws provide the proper balance between protecting us from potentially harmful consequences of those technologies, and allowing us to reap the benefits. The development of nanotechnology, a molecular-precision manufacturing technology which is surprisingly close to realization, will seriously challenge the ability of our regulatory system to respond quickly and to maintain the critical balance between dangers and benefits" (Forrest, 1989).

Forrest demonstrates an uncanny degree of foresight, especially given that nanotechnology was at a very early stage of development at the time it was written.

Twenty years after the publication of Forrest's 1989 paper, there is still much that we do not know about the potential impacts of nanotechnology, and this raises a number of regulatory issues. Questions arise as to which regulatory or policy instruments or approaches are most effective and appropriate for managing the categories of potential risk associated with nanotechnology. For example, should the applications of nanotechnology, either in whole or in part, rely solely on pre-market regulatory risk assessments? Should nanotechnology-derived products be subject to additional reporting or labelling requirements? On one extreme: should regulatory authorities adopt a wait and see stance, until further information regarding toxicity and exposure becomes available? Or, on the other extreme: should regulators impose product restrictions or even a moratorium until such a time as a full assessment of risk becomes possible?

Regulatory regimes designed to protect human health, consumer safety and the environment in many countries, including the US, EU, and Canada – were enacted long before the prospect of nanotechnology was yet on the horizon. Given the state of knowledge at the time, regulatory requirements were designed to assess the toxicity of bulk (macro and micro), not nano, materials. The issue is that the risk assessment criteria, regulatory oversight triggers, toxicity parameters, and threshold minimums outlined in health, safety and environmental regulations are no longer applicable (or less so, at the very least) in the context of nanotechnology-derived products.

Endpoints are an essential aspect in the assessment and management of risk because they define the scope of these activities. However, given limited information at this time, it is not immediately apparent which endpoints should be used to characterize and assess the biological and environmental fate and toxicity of nanomaterials; this issue is currently the subject of considerable debate at the international level. In 2008, the Organisation for Economic Co-operation and Development (OECD) released a list of nearly 60 endpoints that will be addressed during Phase I of the OECD testing programme (OECD, 2008a). In the words of the International Risk Governance Council (IRGC):

> "One of the risk governance challenges [related to nanotechnology] is to ensure that appropriate assessment methodologies are developed in line with the pace at which the applications themselves become reality" (IRGC, 2007).

The broader issues associated with nanotechnology relate to risk governance, which goes beyond the scope of risk assessment and risk management. The term ***risk management*** refers to the decision-making process regarding acceptable levels of risk. Traditionally, such decision-making relies heavily on technical evidence obtained through science-based ***risk assessments***.

In the area of environmental regulation, one of the key questions to be addressed pertains to the establishment of a regulatory definition for engineered nanomaterials. In other words, should nanoforms of well characterized materials, for example carbon or silver, be defined as "new" or "existing" chemicals? Individual jurisdictions' chemicals management frameworks are generally structured in such a way that health and environmental risk assessments must be conducted for any chemical with a new Chemical Abstract Service number (i.e. one which is not already included in the jurisdiction's chemical inventory). By this standard, a large number of engineered nanomaterials may be exempt from regulatory scrutiny, even though they may possess distinct properties that could impact upon their health, safety, and

potential environmental impacts. One issue therefore becomes the challenge of defining under which circumstances a nanomaterial should be considered, in regulatory terms, a new chemical, and then determining how such a chemical should be administratively handled.

Survey of International Regulatory Approaches to Nanotechnology

The United States

Some US Federal government agencies have been involved in the area of nanotechnology since at least the early 1980's, but we begin our narrative of nanotechnology regulation in the US context in the year 2000, with the announcement of the creation of the National Nanotechnology Initiative, as this event marks the beginning of serious attention given to nanotechnology innovation and regulation.

The US National Nanotechnology Initiative

In January 2000, United States President Bill Clinton announced the formation of a National Nanotechnology Initiative (NNI). This initiative, enacted by Congress in November 2000 and formally established in fiscal year 2001 with an initial investment of US $422 million (Roco, 2001), was intended to provide a formal sanctioned mechanism for the coordination of federal nanotechnology research and development activities. Note that the NNI does not directly fund research activities; rather, it informs and influences the budgetary and planning processes through its 25 member agencies in order to ensure that investments in nanotechnology are made in a coordinated and timely manner. In 2003, US President George W. Bush affirmed his own support for the continued development of nanotechnology by increasing federal funding for nanotechnology and signing into law the *21st Century Nanotechnology Research and Development Act*[4]. US Federal investment in nanotechnology research has increased steadily over the years: the 2009 budget for the NNI is US $1.5 billion. This represents the collective sum of the nanotechnology research and development budgets at the thirteen agencies with research mandates who participate in the NNI.

The National Nanotechnology Initiative has four main goals[5], which are as follows:

1. Advance a world-class nanotechnology research and development program.
2. Foster the transfer of new technologies into products for commercial and public benefit.
3. Develop and sustain educational resources, a skilled workforce, and the supporting infrastructure and tools to advance nanotechnology.
4. Support responsible development of nanotechnology.

The National Nanotechnology Initiative is managed within the framework of the National Science and Technology Council, a Cabinet-level council which is the primary mechanism within the executive branch to coordinate science, space, and technology policies across the Federal government. A sub-committee of the National Science and Technology Council known as the Nanoscale Science, Engineering and Technology Committee is the interagency body responsible for coordination of the NNI.

[4] The full text of this Act can be found online at: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_cong_public_laws&docid=f:publ153.108.
[5] http://www.nano.gov/html/about/home_about.html.

The interagency coordination activities of the Nanoscale Science, Engineering and Technology Committee are supported by the National Nanotechnology Coordination Office.

Policy Statements and Key Events Related to Nanotechnology

The US Federal government has not yet enacted any legislation directed specifically at the regulation of nanotechnology. A November 2007 memorandum jointly issued by the Director of the Office of Science and Technology Policy and Chairman of the Council on Environmental Quality states:

> "The Federal government's current understanding is that existing statutory authorities are adequate to address oversight of nanotechnology and its applications. As with any developing area, as new information becomes available the Federal government will adapt or develop additional oversight approaches, as necessary, to address the area of nanotechnology" (Marburger and Connaughton, 2007).

This memorandum further states that the "*Federal government should use standard oversight approaches to assess risks and benefits, and manage risks, considering safety, health and environmental impacts, and exposure mitigation*" and advocates for a proactive approach to international cooperation and information sharing. Of further note is the appearance of the following statements within this document: "*Where possible, regulatory approaches should enable rather than hinder innovation*" and "*Benefits of regulation should justify their costs*" (Marburger and Connaughton, 2007). In this regard, US Federal government policy on nanotechnology regulation differs significantly from that of the European Union, where a more precautionary approach has been adopted; this distinction will be discussed further later in this report.

In February 2009, the US House of Representatives passed the *National Nanotechnology Initiative Amendments Act of 2009*. This bill will reauthorize the National Nanotechnology Initiative, and additionally contains important measures that will result in increased funding for and emphasis on the potential environmental, health, and safety risks of nanotechnology. Such measures will address some of the concerns raised by a National Research Council panel in their December 2008 report *Review of the Federal Strategy for Nanotechnology-Related Environmental, Health and Safety Research*. The National Research Council panel was critical of the NNI approach to regulatory-relevant EHS research, as outlined in their February 2008 *National Nanotechnology Initiative Strategy for Nanotechnology-Related Environmental, Health and Safety Research*.

The US Nanotechnology Debate: Industry, Think Tanks, and Partnerships

There are a large number of stakeholders involved in the US nanotechnology debate, ranging from industry, non-governmental advocacy groups, and academics (in addition to governmental bodies), and it would be difficult to capture the full breadth of the ongoing debate. We therefore limit our scope below to a subset of those organizations outside of government who have had the greatest impact to date. US Government activities will be summarized in the section on regulation which follows.

The Project on Emerging Nanotechnologies (PEN), a US-based think tank established in April 2005 as a partnership between the Woodrow Wilson International Center for Scholars and the Pew Charitable Trusts, has been highly influential in the international nanotechnology policy debate. The overall objective of PEN is to inform and help businesses, governments, and the public to anticipate and manage the human and environmental risks of nanotechnology with a view to maximizing its potential benefits.

PEN maintains a comprehensive website on nanotechnology, and has published extensively on a number of topics related to nanotechnology, including regulation. For example, the January 2009 report *A Hard Pill to Swallow* outlines challenges facing the US Food and Drug Administration with regards to the regulation of nanomaterials in dietary supplements, and the July 2008 report *Nanotechnology Oversight* outlined a proposed regulatory agenda relating to nanotechnology for the incoming US President[6]. PEN is involved in a wide breadth of activities on nanotechnology – they regularly host Web-based seminars, are actively involved in partnerships, and engage a host of former regulatory experts in publishing and providing testimony on nanotechnology, among other activities. They have also contributed greatly to educating the public on nanotechnology, for example through initiatives such as the 2007 public dialogue on nanotechnology and the consumer (during which PEN's Chief Science Advisor Dr. Andrew Maynard described *The Twinkie Guide to Nanotechnology*[7]), and more notably, the Consumer Products Inventory[8], the oft-cited inventory of nanotechnology-based consumer products currently on the market that we have already referenced above.

In terms of non-governmental organizations (NGOs), the Environmental Defense Fund and the Natural Resources Defense Council (among others) have been actively involved in the nanotechnology debate. The International Center for Technology Assessment (ICTA), a non-profit organization dedicated to providing the public with information on the impacts of technology on society, is also highly engaged. Notably, the ICTA is leading, as part of their Nano Action project[9], a number of collaborative efforts relating to the regulation of nanotechnology such as the 2007 Declaration *Principles for the Oversight of Nanotechnologies and Nanomaterials*, which was signed by a broad coalition of civil society, public interest, environmental and labour organizations and which has since been endorsed by nearly 70 groups spread over six continents. In May 2008, ICTA led a coalition of consumer, health and environmental groups in filing a legal petition with the US Environmental Protection Agency (EPA) demanding that the regulatory agency exercise its authority pertaining to the regulation of pesticides to prevent the sale of consumer products containing nanoparticles of silver for antimicrobial purposes.

A rather unique NGO partnership with industry, the Environmental Defense – DuPont Nano Partnership, has also been highly influential. This partnership, established in 2005, culminated in June 2007 with the release of a *NANO Risk Framework* for ensuring the responsible development of nanoscale materials across the product lifecycle. The Framework was specifically designed (in consultation with a broad range of stakeholders) to be flexible, such that it could be readily adopted by other companies. This document outlines guidance on a number of key governance issues relating to the regulation of nanotechnology, including risk evaluations, risk management decisions and best practices, and communication of information and decisions to stakeholders. The Framework deals with nanomaterials over the complete product lifecycle, and discusses critical aspects of risk management including physicochemical properties, health and environmental hazard data, ecotoxicity, and environmental fate.

Scientists and researchers have also played a role in the US nanotechnology debate, and there are a number of university-based initiatives dealing with nanotechnology both in terms of its development and its policy and regulatory implications. The International Council on Nanotechnology (ICON) is a notable

[6] Both reports, as well as numerous others, are available from the PEN website: http://www.nanotechproject.org.
[7] http://www.nanotechproject.org/news/archive/the_twinkie_guide_to_nanotechnology/; accessed March 30, 2009.
[8] http://www.nanotechproject.org/inventories/consumer/; accessed March 30, 2009.
[9] http://www.nanoaction.org/nanoaction/index.cfm; accessed March 30, 2009.

partnership initiated by the Center for Biological and Environmental Nanotechnology at Rice University in Texas. Founded in 2004, ICON is a partnership between the nanotechnology industry, government, academia and select other organizations (for e.g., the Swiss Reinsurance Company and the Foresight Institute). ICON's activities are focused on the promotion of effective nanotechnology stewardship, and include the production and dissemination of information, outreach activities, the strategic identification of knowledge gaps, and research to fill such gaps.

Regulatory Developments on Nanotechnology

Two US regulatory agencies have taken leading roles thus far in terms of policy development around the regulation of nanotechnology: the US Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA). Both the EPA and the FDA have set up nanotechnology task forces, have held public stakeholder meetings with industry, academics and nanotechnology experts, and have published reviews of their regulatory capacity to address the risks of nanotechnology under current statutes. The EPA has been the first US regulatory agency to take formal regulatory action on nanotechnology.

Other US regulatory agencies, such as the Consumer Product Safety Commission (CPSC) and the Occupational Safety and Health Administration (OSHA) within the US Department of Labour have been notably more silent on the topic of nanotechnology regulation. The CPSC, which is the independent regulatory agency with jurisdiction over consumer products such as clothing, electronic devices, appliances, building materials, and toys, has only recently become involved in the nanotechnology policy debate. A three page *CPSC Nanomaterial Statement* can be accessed from their website[10]. OSHA, which is responsible for regulations pertaining to worker health and safety, has yet to become involved in the nanotechnology issue in any significant way – possibly due to limited resources and capacity issues. In contrast, the National Institute for Occupational Health and Safety (NIOSH), a research organization without any specific regulatory capacity, has been publishing documents on the risks and safe management practices for nanotechnology in the workplace for several years now. In February 2009, NIOSH released an *Interim Guidance for Medical Screening and Hazard Surveillance for Workers Potentially Exposed to Engineered Nanoparticles* (Department of Health and Human Services, 2009).

Below, we will detail regulatory and policy activities to date by the two main players in the US nanotechnology regulation debate – the EPA and the FDA.

The US Environmental Protection Agency (EPA)

In December 2004, the Environmental Protection Agency's Science Policy Council created a cross-Agency Nanotechnology Workgroup. This group was charged with examining the potential environmental applications and implications of nanotechnology. In February 2007, this group released the US EPA *Nanotechnology White Paper*, a document which outlines the potential benefits of nanotechnology for the environment, discusses the challenges inherent in the risk assessment of nanomaterials, and makes a number of recommendations with respect to future research needs, pollution prevention and environmental stewardship, collaborations, governance, and training. Prior to its finalization, a draft of the EPA White Paper was released and was subject to public consultation. Further

[10] http://www.cpsc.gov/library/cpscnanostatement.pdf; accessed March 30, 2009.

to the research recommendations outlined in the White Paper, the EPA Office of Research and Development released a Draft Nanomaterial Research Strategy in January 2008.

The Voluntary EPA Nanoscale Materials Stewardship Program (NMSP)

In January 2008, the US EPA officially launched its Nanoscale Materials Stewardship Program (NMSP). This voluntary program was developed in consultation with stakeholders and is intended to help provide a firmer scientific basis for future regulatory decisions related to nanotechnology. The NMSP is comprised of two sub-programs, the Basic Program and the In-Depth Program.

Under the Basic Program, the EPA invited industry to voluntarily report on the engineered nanoscale materials they were manufacturing, importing, processing, or using. As of December 8, 2008, a total of 29 companies or associations had submitted information to the EPA through the Basic Program and a further 7 companies had outstanding commitments. Thus, as of December 2008, the EPA had collected information on a total of only 123 nanoscale materials through the Basic Program, which very likely represents only a small fraction of the products currently under development in the US. Through the In-Depth stewardship program, the EPA invited participants to become involved in developing a plan for the gathering of data on certain representative nanoscale materials over a longer time frame. As of December 8, 2008, only 4 companies had agreed to participate in the In-Depth portion of the NMSP.

Although this voluntary initiative was developed in consultation with stakeholders during a series of public meetings, a primary criticism with respect to the NMSP is that stakeholder recommendations were not fully taken into consideration during development of the program. In particular, industry stakeholders had suggested that some form of incentive should be provided to encourage participation in the program, but no such incentives were included in the final program. In January 2009, the EPA released a mid-term report on progress with respect to the NMSP, claiming that the program to date has largely been a success, although "*a number of the environmental health and safety data gaps the Agency hoped to fill through the NMSP still exist*" (US EPA, 2009). Despite these claims of success by the EPA, many stakeholders have been critical of the voluntary approach to information gathering adopted by the EPA; the effectiveness of this initiative (and a similar effort in the UK, which will be described later) is the subject of much debate.

Other EPA Regulatory Activity on Nanotechnology

The official EPA position on nanotechnology regulation is that nanomaterials are currently covered under existing statutes. The EPA White Paper, in particular, outlines a number of possible regulatory options for nanotechnology. However, the EPA has also acknowledged that certain EPA policies and regulations, as well as the reporting tools under various statutes, may eventually need to be modified to accommodate nanoscale materials.

EPA exerts its regulatory authority under a broad range of statutes and programs. A subset of these statutes and programs has been identified as being particularly applicable to nanotechnology. These are as follows:

- The *Toxic Substances Control Act* (TSCA) – regulation of chemical substances;
- The *Federal Insecticide, Fungicide and Rodenticide Act* (FIFRA) – regulation of pesticides;
- The *Clean Air Act* – regulation of "hazardous air pollutants";

- The *Clean Water Act* – regulation of substances toxic to aquatic life;
- The *Safe Drinking Water Act* – regulates hazardous contaminants in drinking water;
- The *Comprehensive Environmental Response, Compensation, and Liability Act and the Resource Conservation and Recovery Act* – regulation of solid waste; and
- Toxics Release Inventory Program – a publicly available database containing information on toxic chemical releases and other waste management activities reported annually by manufacturing facilities and facilities in certain other sectors.

To date, regulatory action of nanomaterials by the US EPA has been primarily if not exclusively limited to the first two statutes – TSCA and FIFRA. Regulatory considerations under each of these two acts are described in the sections which follow.

The Toxic Substances Control Act (TSCA)

To date, the discussion around nanotechnology regulation in the US has focused primarily on the applicability of the *Toxic Substances Control Act* (TSCA) to the regulation of nanosubstances. TSCA is widely considered to be the only US law that can deal broadly with the regulation of nanotechnology. Unlike other statutes such as the *Clean Air Act* and *Clean Water Act*, which are limited to specific parts of the environment, TSCA is broadly applicable to all potentially toxic chemical substances. Statutes such as the *Food, Drug and Cosmetic Act* (FDCA) and the *Federal Insecticide, Fungicide and Rodenticide Act* (FIFRA)—both of which are administered by the US Food and Drug Administration—can potentially be applied to regulate the health and safety impacts of nanotechnology-based foods, drugs, cosmetics, and pesticides. Where nanomaterials are not covered by these other laws, TSCA applies.

There are many criticisms of TSCA as it applies both specifically to nanotechnology and more broadly to all chemical substances. TSCA was enacted in 1976, and there is "*a broad consensus among a diversity of stakeholders that TSCA needs to be re-examined*" (comments by Congressman Bobby Rush, February 2009[11]). Beginning in February 2009, TSCA is being revisited in a series of hearings by the Subcommittee on Committee, Trade, and Consumer Protection of the US House of Representatives Committee on Energy & Commerce. Among the first witnesses to appear before the Subcommittee was J. Clarence (Terry) Davies, a Senior Advisor to the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars. According to his testimony, TSCA has both strengths and weaknesses as it pertains to the regulation of nanotechnology.

Among the strengths of TSCA, Davies noted, are its broadness and potential flexibility; its reporting mechanisms, which allow the EPA to require manufacturers to immediately notify them of new information pertaining to substantial risks associated with a particular chemical; and the general cost-benefit framework of TSCA. However, Davies also noted that TSCA additionally contains a number of "*very difficult, perhaps impossible, requirements that must be met before a chemical can be regulated*" (Davies, 2009). This statement reflects the concerns of a number of stakeholders regarding the potential application of TSCA to nanotechnology regulation. For example, the EPA must satisfy stringent regulatory impact requirements for existing chemicals by demonstrating that a proposed regulation under TSCA is less burdensome than any other alternative, and that the risk they are proposing to regulate could

[11] http://energycommerce.house.gov/Press_111/20090226/rushopen.pdf, in a statement dated February 26, 2009; accessed March 31, 2009.

not be sufficiently reduced under another statute. Another widely reported criticism of TSCA is that the statute places the burden of proof on regulators to demonstrate harm rather than on manufacturers to demonstrate safety. In other words, the regulators can only delay or prohibit the manufacture of chemicals under TSCA if they can demonstrate that the chemical presents an "unreasonable risk". Thus, in the example of nanomaterials—where there is currently very little information available regarding the potential health and environmental impacts of these substances—it is extremely difficult for EPA regulators to restrict the entry of potentially toxic products onto the market.

Under TSCA, chemicals are defined by their molecular structures. Thus, the US EPA is faced with the same challenge facing many other jurisdictions like the EU, Canada, and Australia, namely which nanomaterials should be considered "new" and which should be considered "existing" chemical substances. In January 2008, the EPA issued a position statement describing their approach for determining whether a nanoscale substance is considered a "new" chemical under TSCA. According to this statement, a substance not already included on the TSCA Inventory is automatically considered a new chemical substance (under section 3(9) of TSCA). Under section 5(a) of TSCA, manufacturers are required to submit Premanufacture Notices to the EPA at least 90 days prior to the manufacture or importation, for commercial purposes, of new chemical substances. Following a review of Premanufacture Notices by regulators, a Notice of Commencement of Manufacture or Import may be issued by the EPA, and the substance thereby becomes and "existing" chemical substance on the TSCA Inventory. As of February 2009, the EPA estimated that is had received Premanufacture Notices for approximately 50 nanomaterials to date under the TSCA new chemical provisions (Davies, 2009).

However, not all nanomaterials will qualify as new substances under TSCA, as the bulk forms of many nanosubstances are already on the TSCA Inventory (for example, gold, silver, and titanium dioxide, all of which have nanoforms, are already on the TSCA Inventory). The EPA has stated its intention to determine whether nanosubstances are new or existing on a case-by-case basis, based on molecular structure (US EPA, 2008). Here, the EPA approach to distinguishing between new and existing chemicals becomes highly technical. A simplified version of their description is that different configurations of the same molecule are considered to be new chemicals under TSCA. As an example, graphite and diamonds, which are "allotropes" of carbon (in that the carbon atoms in each are arranged differently), are considered distinct substances. In contrast, molecules which differ only in terms of their particle size (e.g., gold and nanogold) are not considered to be new substances under TSCA.

Recent regulatory action by the EPA helps to clarify this point. On October 31, 2008, the EPA issued a Notice in the *Federal Register* stating that they consider carbon nanotubes to be a chemical substance distinct from graphite and other allotropes of carbon already listed on the TSCA Inventory. Thus, carbon nanotubes are considered new substances under TSCA, and become subject to the Premanufacture Notices reporting requirements described above.

In November of 2008, the EPA began to promulgate Significant New Use Rules (SNURs) under TSCA for nanoforms of certain "existing" substances, for example siloxane modified silica and alumina nanoparticles (which appeared in the November 5, 2008 *Federal Register*). Under the significant new use provisions of TSCA, such regulatory action by the EPA requires persons intending to manufacture, import, or process chemical substances for an activity that is designated as a significant new use under the statute to notify EPA of their intent at least 90 days prior to commencing that activity. SNURs provide the

EPA with an opportunity to evaluate the significant new use of a substance and, if necessary, give an opportunity for the EPA to prohibit or limit the new activity before it occurs. The significant new use provisions of TSCA thus provide regulators with a mechanism to evaluate the safety of nanoforms of existing substances; it is noteworthy that the EPA has recently begun to exercise its regulatory authority with respect to such substances.

The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

Regulation related to nanomaterials in the US has also occurred in the context of the *Federal Insecticide, Fungicide and Rodenticide Act* (FIFRA), which is also enforced by the EPA. Regulations under FIFRA require manufacturers to register all substances intended to destroy pests, including microbes. Registration of the substance may not be required unless the manufacturers of a given product make a specific claim about its antimicrobial properties.

Recently, the Samsung Silver Wash washing machine, which was claimed to release nanosilver ions during each wash with the intent of killing bacteria and other microbes in your laundry, presented an interesting challenge to US regulators. In 2007, the EPA issued a decision requiring the company to register this washing machine as a pesticide under FIFRA. Although this decision was widely touted in the press as US federal regulation of nanotechnology, the EPA has stated that they do not consider this activity to be related to nanotechnology. The primary reason for this is that there is some question as to whether such washing machines are actually releasing silver nanoparticles; instead, it may be the case that it is instead ionic silver particles which are being released by these devices (Kulinowski, 2008).

In March 2008, the EPA fined ATEN Technology Inc, manufacturers of IOGEAR computer peripherals, $208,000 over their failure to register several products being marketed as antimicrobial, and furthermore for making unsubstantiated claims about their effectiveness. The products which triggered this activity were a computer mouse and keyboard/mouse combination that had been treated with titanium dioxide-silver and which were claimed to be antibacterial. Once again, the EPA has stressed that this activity was unrelated to the issue of whether the product contained a nanomaterial. Instead, their concern was that a manufacturer was making an unproven health claim and had failed to register a product under FIFRA (Kulinowski, 2008).

The US Food and Drug Administration (FDA)

The US Food and Drug Administration (FDA) has been arguably slower than the EPA to wade into the nanotechnology regulation debate in the US. One could argue the issue may not have seemed as urgent for the FDA, as there are already strict pre-market requirements associated with many of the products that they regulate, including drugs, biological products, medical devices, and food and colour additives.

In August 2006, the Agency established the *FDA Nanotechnology Task Force*, which was charged with outlining regulatory approaches that would allow the continued development of nanotechnology while ensuring that FDA-regulated products containing nanotechnology were both safe and effective. In July 2007, the Task Force released a report which contained a review and analysis of nanotechnology-related science and policy issues falling under the FDA's jurisdiction. Among the recommendations contained in this report were recommendations to issue guidance to stakeholders, in order to provide greater predictability for industry and to ensure the protection of public health. The report was endorsed by the

Commissioner of Food and Drugs, and the Agency was instructed to move forward with implementation of the recommendations contained therein.

The FDA has broad regulatory authority over a wide range of product classes (e.g. pharmaceuticals, cosmetics, medical devices, etc...) where nanomaterials are already being used, or where nanomaterials are expected to play an increasing role in the coming years. Overall, the FDA believes that existing statutes will be sufficient to regulate nanotechnology, and that the regulatory challenges posed by nanotechnology will be similar to those previously posed by products manufactured using other emerging technologies, and particularly biotechnology. Given the extensive debate that took place in the mid-1980's surrounding the regulation of products of biotechnology, the agency appears content in large part to rely on the lessons learned from that public policy debate. One area where the FDA admits that nanotechnology may present unique regulatory challenges is in terms of the regulation of combination products containing nanomaterials. For example, highly integrated combinations of drugs, biological products and/or medical devices with combined diagnostic and therapeutic uses are predicted in the future development of nanotechnology. The question will no doubt one day arise as to how best to stream these combination products into the regulatory system. The FDA admits that its current mechanisms for selecting regulatory pathways may not be adequate (US FDA, 2007).

The primary statute applicable to the regulation of nanoproducts falling under FDA authority is the *Food, Drug and Cosmetic Act* (FDCA). For products subject to pre-market approval, which includes pharmaceuticals, high-risk medical devices, food additives, colours, and biological products, existing regulatory requirements are expected to be sufficiently stringent and flexible to accommodate the regulation of nanotechnology-containing products. That being said, the FDA does recognize that current data requirements, reporting and notification mechanisms do not contain specific information to allow for the assessment of nanomaterial safety.

Some products are subject only to post-market surveillance requirements, including foods and cosmetics. While manufacturers are nonetheless responsible for ensuring the continued safety of those products, this is one particular area where regulatory experts and stakeholders alike have called for increased regulatory scrutiny of products containing nanomaterials.

The specific example of sunscreens (sunscreens are classified as cosmetic products) containing engineered nanoparticles of titanium dioxide is frequently cited; the regulatory approach to such products has been widely criticized. In the regulatory context, it is notable that there is currently no mechanism to distinguish nano-containing sunscreens from sunscreens containing other forms of titanium dioxide. As is also the case with TSCA, nanoforms of titanium dioxide are considered to be "existing" materials. As such, regulators looking at the post-market safety of sunscreens would not be able to attribute any potential health or safety issues which might arise to the presence of nanoparticles.

Regulatory Developments in the US at the State and Municipal Levels

In the US, there has been a significant amount of legislative activity at both the state and municipal levels related to nanotechnology. As of October 2006, legislation with some reference to nanotechnology had been enacted or adopted in at least twenty-two states, and a July 2008 scan yielded further legislative activity. A list of nanotechnology-related legislation by State Legislatures has been created by the

National Conference of State Legislatures[12]. According to this list, as of July 2008 no state had yet enacted any laws aiming to regulate the potential health, safety, and environmental impacts of nanotechnology. For the most part, statutes enacted to date have focused on establishing study commissions, supporting educational initiatives through the funding of facilities and projects, and the provision of economic incentives including grants and tax credits. Thus, while the States have been active on nanotechnology, utilizing a number of different policy levers to date, there has been little or no formal activity pertaining to the regulation of nanotechnology-derived products.

Recently, however, the California Department of Toxic Substances Control (DTSC) announced its intention to exercise the regulatory authority granted to them through new sections of the *Health and Safety Code* adopted in 2006. These new sections granted powers to state agencies to issue mandatory requests for information on specific chemicals to manufacturers. Manufacturers are required to comply with these requests within one year. The 2006 amendments also contain provisions regarding trade secrets; the DTSC has stated their intent to work with manufacturers to respect trade secrets as required. In January 2009, the DTSC issued formal information request letters to a number of manufacturers producing or importing carbon nanotubes in California, or who may export them into the State. Copies of the formal request letter and a list of companies targeted through this initiative may be found on the DTSC website. The DTSC has further indicated that it is considering taking similar action for other nanomaterials, such as nanometals and quantum dots in 2009.

At the municipal level, two US municipalities – Berkeley, California and Cambridge, Massachusetts – have considered or adopted measures to date to regulate the health and safety impacts of nanomaterials. Notably, these two municipalities are both major centres for research activities. In December 2006, the Berkeley Municipal Code was amended to introduce new measures regarding manufactured nanomaterial health and safety. These amendments require facilities that manufacture or use nanomaterials to disclose in writing which nanomaterials are being used as well as the current toxicology of the materials reported (to the extent known) and to further describe how the facility will safely handle, monitor, contain, dispose, track inventory, prevent releases and mitigate such materials.

In January 2007, the Cambridge City Council also considered using regulation as a policy lever to address nanotechnology, directing their City Manager to examine Berkeley's nanotechnology ordinance and recommend an appropriate ordinance for Cambridge. However, in a July 2008 report, the Cambridge Public Health Department and Cambridge Nanomaterials Advisory Committee concluded that the municipality should not enact a new ordinance regulating nanotechnology at that time. Instead, they recommended that the City of Cambridge take steps to gain a better understanding of the nature and extent of nanotechnology-related activities.

[12] http://www.ncsl.org/programs/lis/legislation/NanoLegislation2006.htm.

The United Kingdom (UK)

Policy Statements and Key Events Related to Nanotechnology

Since 1997, the UK Government has been working to improve regulation by applying five principles identified by their **Better Regulation Taskforce**.[13] These five principles are: proportionality, accountability, consistency, transparency, and targeting. In January 2003, the Better Regulation Task Force released a report entitled *Scientific Research: Innovation with Controls*. This report recommended that the UK Government should encourage public debate regarding the risks posed by nanotechnologies and should take a lead over any issues of risk management to emerge from nanotechnologies.

The UK Government launched its nanotechnology strategy in 2003, pledging £45 million per year toward nanotechnology research for the period 2003 to 2009. In that same year, the UK Government, in response to the 2003 recommendations relating to nanotechnology by the Better Regulation Taskforce, commissioned its national academies of science and engineering to conduct an independent review that would outline any environmental, health, safety, ethical or societal implications that might be associated with the use of nanotechnology. This review was also intended to identify any further areas where regulatory action should be contemplated.

In response to this request, the UK Royal Society and Royal Academy of Engineering (RS-RAE) published a highly influential report on nanotechnologies in 2004 entitled: *Nanoscience and Nanotechnologies: Opportunities and Uncertainties*. This report highlighted a number of uncertainties associated with nanotechnology, called for public debate about development of the technology, and emphasized the need for immediate funding to support research into the potential human health and environmental risks posed by nanoparticles. This report was seminal not just in the UK, but internationally, and is widely credited with renewing debate regarding the need for nanotechnology regulation.

In their report, the RS-RAE explain that they carefully considered a number of policy options during their deliberations, including calls by the ETC Group, Greenpeace and other public interest groups to implement a moratorium on the development and release into the environment of manufactured nanoparticles or nanotubes. In response to calls for a moratorium on nanotechnology development, the RS-RAE panel concluded that a moratorium would not be an appropriate response to the challenges posed by the emergence of nanotechnology and its applications. This conclusion has since been supported by both the Council for Science and Technology and the Economic and Social Research Centre for Business Relationships, Sustainability and Society.

The panel also considered and ruled out the need to develop a separate nanotechnology-specific regulatory body or framework in the UK. The panel stated that regulatory frameworks already in place in the UK relating to the protection of human health and safety and the environment were sufficiently broad to extend to the regulation of nanotechnologies, although they did note the need to modify individual

[13] The Better Regulation Taskforce was replaced by the Better Regulation Commission in 2006, and this body was closed in turn following the establishment of the Risk and Regulation Advisory Council in January 2008.

regulations or standards within existing frameworks to reflect the specific properties of nanomaterials resulting from their nanoscale. Among a long list of other recommendations, the RS-RAE advised that all affected regulatory bodies in the UK undertake reviews of existing regulations and publish details on how they would address any regulatory gaps identified through this process[14].

In its 2005 response to the RS-RAE report, the UK Government committed to subjecting itself to an independent external review of progress on its policy commitments after two and five years. In March 2007, the Council for Science and Technology published its independent review titled *Nanosciences and Nanotechnologies: A Review of Government's Progress on its Policy Commitments*. In this report, the Council for Science and Technology concluded that progress on many commitments had been good, but criticized progress on governmental research commitments, particularly with regards to toxicology and the health and environmental impacts of nanomaterials. In that regard, the Council for Science and Technology did not feel the government was living up to its commitment to ensure an understanding of potential risks to human health and the environment and thereby promote the responsible development of nanotechnology. It recommended a more targeted approach to research funding going forward.

In November 2008, the UK Royal Commission on Environmental Pollution (RCEP) published a report entitled *Novel Materials in the Environment: The case of nanotechnology*. This work by the RCEP was originally prompted by broad concerns surrounding potential environmental releases of novel materials from industrial applications. Due to the preponderance of evidence focused on nanomaterials, this became a focus of the report. This report contains a number of observations regarding the toxicology and fate of nanomaterials, functionality, and adaptive governance. Chapter 4 considers options for the regulatory governance of emerging technologies under challenging circumstances. Overall, the Commission recommended that governance approaches to the regulation of nanotechnology should be based on the functionality of materials, rather than particle size or mode of production, as this is the key consideration when evaluating potential environmental and health impacts (RCEP, 2008).

More recently, in February 2009, the British House of Lords Select Committee on Science and Technology launched an inquiry on the use of nanotechnologies and nanomaterials in the food sector[15].

Nanotechnology Strategy and Governance

In 2007, in response to a recommendation made by the Council for Science and Technology in their review of government progress on policy commitments, a **Ministerial Group on Nanotechnologies** was established. This group is currently chaired by the Minister of State for Science and Innovation, Lord Drayson, and also includes Ministers with responsibility for the Environment (Department for Environment and Rural Affairs), Public Health (Department of Health), Health and Safety (Department of Work and Pensions), and Business and Competitiveness (Department for Business Enterprise & Regulatory Reform). Since its creation, the Ministerial Group has engaged with stakeholders and coordinated progress by Government Departments on policy, regulation, and research.

[14] Regulatory bodies in the UK took this advice to heart and undertook or commissioned reviews of the adequacy of existing legislation. Refer, for example, to Chaudhry *et al*. (2006) (report commissioned by Defra), and the FSA report (2008).

[15] Details of the Nanotechnologies and Food inquiry can be found on the following website: http://www.parliament.uk/parliamentary_committees/lords_s_t_select/nanotechfood.cfm; accessed March 31, 2009.

In February 2008, this Ministerial group issued a *Statement by the UK Government about Nanotechnologies*. This document outlined a vision for nanotechnologies, as follows:

> "The vision of the UK Government for nanotechnologies is for the UK to derive maximum economic, environmental and societal benefit from the development and commercialisation of nanotechnologies, and to be in the forefront of international activity to ensure there is appropriate control of potential risks to health, safety and the environment."

Furthermore, the Government committed to openness regarding its activities and transparency regarding any uncertainties in the science. With respect to the regulation of nanotechnology, the Government noted the need to manage the potential risks associated with nanotechnology within the context of a "proportionate regulatory framework". Although they did not rule out the possibility of eventually developing new nano-specific regulatory frameworks or legislation, the Government stated that existing legislation currently offered sufficient protection in areas as diverse as environmental protection, health and safety, food safety, medicines and medical devices, cosmetics, and consumer products, enabling a prompt response should products be found to pose a risk to health, safety, or the environment (UK Government, 2008).

In January 2009, this Ministerial group reiterated their commitment to the responsible development of nanotechnology in the UK and outlined seven deliverables[16]. These seven specific commitments, which are as follows, will be carried out by the Departments represented on the group.

1. Respond (in Spring 2009) to the recommendations outlined in the November 2008 report by the Royal Commission on Environmental Pollution.
2. Develop a better understanding of UK industry sectors (their objectives and needs) that are likely to make use of nanotechnologies and nanomaterials.
3. Work with industry to develop a workable reporting scheme for nanomaterials.
4. Involve the spectrum of interested parties (academia, industry, NGOs, and the general public) in the development of a strategy.
5. Improve the targeting and prioritisation of UK research devoted to understanding and managing the health risks associated with nanotechnologies.
6. Ensure that appropriate action is taken whenever there is evidence that products containing nanoparticles may pose a risk to workers, consumers or the environment.
7. Work with industry to develop a workable way of providing information about products that are being developed and brought to market.

The UK government has also established two groups, with the responsibility for coordinating policy and research activities, respectively, across Government departments, agencies, and research councils. These groups are the Nanotechnology Issues Dialogue Group and the Nanotechnology Research Coordination Group. These two bodies report directly to the Ministerial Group on Nanotechnologies.

[16] http://nds.coi.gov.uk/environment/fullDetail.asp?ReleaseID=391430&NewsAreaID=2&NavigatedFromDepartment=False

The UK Nanotechnology Debate: National Academies and Royal Commissions

An aspect of the nanotechnology debate in the United Kingdom, which arguably distinguishes the UK from other jurisdictions, has been the ongoing involvement of its national academies: the Royal Society and the Royal Academy of Engineering. The national academies were commissioned in 2003 to write the independent report which catalyzed discussions both within the UK and internationally on the need for nanotechnology regulation. The Royal Society has remained actively engaged in the nanotechnology debate since the publication of this seminal report in 2004, and maintains a comprehensive website on nanoscience and nanotechnology[17] targeted at educating the general population.

Another group which has been influential and actively involved in the debate on nanotechnology has been the UK Consumers' Association, which goes by the quizzical name of "Which?". This group has a long history of campaigning on behalf of consumers in the UK to ensure the protection of consumer rights, and also conducts product reviews and offers independent advice on a number of subjects. Which? has developed a 10 Point Action Plan which outlines a set of key actions they would like to see guide the nanotechnology debate. Those 10 points are as follows: Co-ordination, Definitions, Products, Research, Assessment, Precaution, Transparency, Regulation, Information, and Engagement; the Action Plan is described in further detail in a November 2008 policy briefing prepared by Which? on the topic of nanomaterials in cosmetic products (Which?, 2008).

Both the UK Government and the EU have placed great emphasis on the aspect of public engagement in the nanotechnology debate. Their proactive approach to public engagement has very likely been informed by their recent experience in the context of Genetically Modified Organisms (GMOs). In the case of GMOs, a substantial public outcry regarding environmental aspects of this technology essentially halted the progress of GM crops through the regulatory system back in 1998. As such, the UK and the rest of Europe have arguably not yet been able to realize the same benefits from GM crops as other countries.

Based on this prior experience, there have been a number of initiatives undertaken in both the UK and the EU to foster public engagement in the nanotechnology debate. Public engagement and communication are two very important aspects of regulatory governance, as will be discussed later; however is it outside the scope of the current report to summarize all such initiatives to date. The 2007 report from the Nanotechnology Engagement Group (NEG), discussed in the next section, provides a good overview of some of the public engagement initiatives previously undertaken in the UK.

Public Engagement and the Nanotechnology Engagement Group

In 2005, the NEG was established to document the learning from a series of United Kingdom initiatives attempting to involve the general public in discussions regarding the development and governance of nanotechnologies. The NEG was convened by Involve, a not-for-profit organization specializing in public participation and analysis into which processes work best for public engagement, with support from the UK Government and universities. The final report of the NEG, entitled *Democratic Technologies?*, was published in 2007 (Gavelin and Wilson, 2007). This report looks at six projects in the UK that sought to engage the general public in a dialogue on nanotechnology. Based on their analysis of these projects, the

[17] The Royal Society's webpage on Nanoscience and nanotechnology is located at the following link: http://royalsociety.org/landing.asp?id=1210; accessed March 31, 2009.

NEG concluded that upstream public engagement on issues of science and technology was beneficial because it:

- informed and aligned science policy and research with public needs and aspirations;
- made science governance more transparent;
- put science into context by encouraging reflection by scientists on the broader implications of their work;
- created more active and scientifically aware citizens; and
- helped to overcome negative preconceptions and to break down cultural barriers between scientists, the general public, and decision makers.

The NEG report also outlines a number of recommendations emerging from their analysis, intended to inform the UK Government's science and public engagement policies.

The UK Government has also undertaken a number of public engagement initiatives. For example, Defra—the Department for Environment, Food and Rural Affairs in the UK—regularly convenes meetings with stakeholders through their *Nanotechnologies Stakeholder Forum*. The eleventh such stakeholder meeting on nanotechnologies through this forum took place in September 2008[18].

Regulatory Developments on Nanotechnology

In terms of activity on nanotechnology research and policy development by Government departments in the UK, a few of the key players to date have been:

- the Department for Environment, Food and Rural Affairs (Defra);
- the Food Standards Agency (FSA);
- the Department for Business Enterprise & Regulatory Reform (BERR);
- the Department of Health (DH);
- the Health and Safety Executive (HSE); and
- the Department for Innovation, Universities & Skills (DIUS).

Defra has played a leading role on the development of nanotechnology policy and regulation in the UK. Defra plays an oversight role for the regulation of the food industries, and is the government department responsible for environmental protection in the United Kingdom (among other responsibilities, including fisheries and rural communities). Notably, Defra leads for the UK at the EU level on the environment file (with the exception of climate change) and has thus also been actively involved in the nanotechnology debate at the EU and international levels. As its name implies, the Food Standards Agency also has a role in the regulation of food products – it is an independent regulatory agency with the mandate to protect the public's health and consumer interests in relation to food in the UK. The Department of Health has responsibility for the regulation and medicinal products, through the Medicines and Healthcare products Regulatory Agency, an executive agency of the DH. The Health and Safety Executive, an agency of the Department for Work and Pensions, has a mandate over the regulation of nanotechnology as it relates to worker safety. The Department for Innovation, Universities & Skills is also heavily involved in the

[18] http://www.defra.gov.uk/environment/nanotech/research/meetings/index.htm; accessed March 17, 2009.

nanotechnology policy debate, but it is not a regulatory department; DIUS is mainly involved with the innovation and research aspects of nanotechnology. The Ministerial Group on Nanotechnologies is currently chaired by the Minister of State for Science and Innovation from DIUS. Finally, the Department for Business Enterprise & Regulatory Reform (BERR) has responsibility for broad oversight over regulation in general. BERR houses the Better Regulation Executive, and leads the regulatory reform agenda across government.

To assess whether existing regulatory frameworks were sufficiently rigorous to deal with the potential risks posed by nanomaterials, the UK Government has previously commissioned reviews of the adequacy of existing legislation in the context of each of its key regulatory departments (Chaudhry *et al*., 2006 (report commissioned by Defra); FSA, 2008). In addition, an independent overview was carried out to identify any existing or potential gaps, inadequacies or inconsistencies (Frater *et al*., 2006). By and large, these reports have all concluded that the existing regulatory framework is broadly adequate, although they also note the potential for nanomaterials to fall outside of regulatory controls in certain circumstances. Such loopholes include the potential for nanoscale materials to fall outside of threshold amounts originally developed in the context of macroscale materials and the possibility that certain consumer products containing nanomaterials may be found safe to market but that risk assessments may not consider the full product lifecycle, including their disposal.

Formerly known as the Department of Trade and Industry, it was BERR who commissioned the independent regulatory gaps analysis for nanotechnology completed by Cardiff University in December 2006 (Frater *et al*., 2006). Entitled *An Overview of the Framework of Current Regulation affecting the Development and Marketing of Nanomaterials*, this comprehensive report took the approach of mapping current and future foreseeable applications of nanomaterials against existing UK regulatory frameworks that might govern the lifecycle of nanomaterials. In this report, the authors noted two main regulatory issues (Frater *et al*., 2006). The first issue was that of regulatory gaps arising in situations where thresholds have previously been established to govern whether or not materials or products fall within the scope of the regulation (the issue here is that since nanoparticles have a substantially increased surface area relative to bulk materials, they are active at lower overall masses and volumes and therefore such thresholds may be too high to appropriately regulate the risks of the products of nanotechnology). The second regulatory issue noted is the question of what to do when a nanomaterial represents a variation of a bulk substance that is already well regulated and understood (e.g. nanosilver versus silver)—an issue which has been previously described in the current report in the context of the US EPA and TSCA.

An interesting aspect of the Cardiff report was their approach of examining a lifecycle approach to the regulation of nanomaterials. As has been noted by others, the authors state that many of the regulatory gaps currently associated with nanotechnology arise from a lack of existing data on the potential health and environmental effects of nanomaterials. In their own words, "*this report demonstrates how effective regulation will depend on moving to a position of greater certainty*" on outstanding questions related to nanomaterials; they emphasize that "*better research and better regulation ought to move hand in hand*". Related to the lifecycle of nanomaterials, the authors note that "*often the regulation will govern the generation of further data as part of a system of risk governance*" (Frater *et al*., 2006). The example cited is the classification of substances by regulators as hazardous, a classification which then requires manufacturers to provide additional information relating to risks and hazards of the material. In essence, the authors suggest that classification of substances as being of priority interest can serve as a "*trigger for*

effective risk management programmes" and helps to ensure that the substance is tracked by regulators throughout its lifecycle (Frater *et al*., 2006). The authors emphasize the need for an integrated regulatory governance approach to the regulation of nanotechnology.

The example provided in the Cardiff report is of particular interest given recent regulatory activity by Defra and the HSE. In a May 2008 letter to the Nanotechnologies Industries Association and the UK Research Councils, Defra advised that waste containing free (unbound) carbon nanotubes would be classified as hazardous, with immediate effect. They have also issued guidance on how best to dispose of waste containing unbound carbon nanotubes. Similarly, the HSE has also taken regulatory action on carbon nanotubes relating to worker safety, advising users to treat carbon nanotubes as substances of very high concern in the absence of scientific evidence that this is not the case (OECD, 2008b). These moves can be seen as an attempt by the UK Government to generate further health, environmental, and safety data on carbon nanotubes, a substance that is currently seen as a substance of priority interest among nanomaterials. As noted above, regulatory action on carbon nanotubes has also been taken by the US EPA and California DTSC.

In addition to regulation, the UK Government has previously noted that guidance and advice, for example the provision of guidance to industry by regulatory departments on the methodologies to be used for risk assessments, are tools that can be used to respond to the potential risks posed by nanotechnologies (UK Government, 2008). Guidance documents, a form of non-legislative control, are inherently more flexible than regulatory approaches, and in 2008 the UK Government signalled their commitment to regularly updating such documents based on the best available research.

As a Member State of the European Union, no discussion on the regulation of nanotechnology in the UK would be complete without a discussion of regulatory initiatives by the EU. In fact, the bulk of the current discussion in the UK on issues related to nanotechnology is focused on EU Regulations such as REACH and the EU's Novel Food Regulation and Directives such as the *Cosmetics Directive*. We turn next to a discussion of nanotechnology in the context of the full European Union, where we will elaborate upon these three specific examples.

The European Union (EU)

EU Approach to Emerging Technologies: the Precautionary Principle

One area where the European Union and its Member States differ from other jurisdictions (most notably the United States) in terms of their approach to the regulation of emerging technologies has been their definition and application of the precautionary principle to the management of risks.

In February 2000, the European Commission (EC) adopted the *Communication from the Commission on the Precautionary Principle*, a document which aimed to build a common understanding among EU Member States of governance approaches to the assessment, appraisal, management and communication of risks in situations (such as the regulation of emerging technologies) where full scientific evaluations are not yet possible. Notably, this Communication was designed (at least in part) with the intent of easing trade tensions with the United States. This document outlines five guiding principles for the application of

precaution: proportionality, non-discrimination, consistency, examination of the benefits and costs of action and lack of action, and examination of scientific developments (European Commission, 2000).

The precautionary approach to nanotechnology in the EU is summarized as follows: "*Where the full extent of a risk is unknown, but concerns are so high that risk management measures are considered necessary, as is currently the case for nanomaterials, measures must be based on the precautionary principle*" (EC, 2008a).

It has been argued that the EU and its Member States also take a somewhat different approach to risk analysis as compared with other jurisdictions (van Calster, 2008). Risk analysis can be thought of as a process involving four components: risk identification, risk assessment, risk management, and risk communication. In the EU, each of these components is seen as a distinct step, and the EU assigns responsibility for each of the four stages to different professional groupings. For example, the risk assessment process is seen to be the responsibility of scientists, whereas risk management is very clearly the domain of the politicians. Critics have argued that this deliberate delineation of responsibility in the EU context can result in excessive recourse to the precautionary principle in response to public outcry and political pressure, and that this has in particular occurred in response to emerging technologies such as genetically modified foods and nanotechnologies.

Policy Statements and Key Events Related to Nanotechnology

The European Union, like the United States, has indicated in no uncertain terms that it wishes to pursue the development of nanotechnology applications, with a view to the realization of important benefits. However, the EU approach to developing a regulatory framework for nanotechnology has been relatively cautious; in no other jurisdiction has there arguably been such an emphasis placed on public engagement and consultation. The 'safe, integrated, and responsible' approach is a central and defining feature of EU policy on nanotechnology.

The European Commission formally announced its intention to develop an integrated nanotechnology strategy for Europe in May 2004 in its Communication *Towards a European Strategy for Nanotechnology*. In a foreword to the Communication, then Commissioner for Research Phillipe Busquin noted it was "*essential that [European] industry can bring nanotechnology-based products and services to the market, so as to generate wealth, employment and sustainable growth*". However, he further noted that "*any negative impacts on public health, safety or the environment must be addressed upfront and as an integral part of the technological development process*" (EC, 2004).

The proposed strategy outlined in the 2004 Communication was subsequently reviewed and supported by the Competitiveness Council and the European Economic and Social Committee. In addition, all stakeholders were invited to provide their opinion on the Commission's proposed strategy via an open survey organizing by Nanoforum and the European Commission which ended in October 2004. Over 750 responses were received through this process, and the results are summarized in a January 2005 report *Outcome of the Open Consultation on the European Strategy for Nanotechnology*.

Following the public consultation, the European Commission adopted the Communication *Nanosciences and nanotechnologies: An action plan for Europe 2005-2009* in June 2005, which outlines a number of commitments with respect to nanotechnology research and development and establishing an effective

dialogue with stakeholders. The Action Plan also underlines a number of commitments with respect to international collaboration on nanosciences and nanotechnologies. In the interests of protecting public health, safety, the environment and consumers, the Action Plan states that "*risk assessment related to human health, the environment, consumer and workers should be responsibly integrated at all stages of the life cycle of the technology, starting at the point of conception and including R&D, manufacturing, distribution, use and disposal or recycling*" (EC, 2005).

The Action Plan also called on the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) to provide an opinion on the ability of existing risk assessment methodologies to extend to nanotechnology. The SCENIHR Opinion, entitled *The appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies*, was adopted in September 2005. Following public consultation, this opinion was subsequently revised, and a modified version adopted in March 2006.

The Action Plan also called upon the European Group on Ethics in Science and New Technologies to examine the ethical aspects of nanomedicine, a commitment that was fulfilled in January 2007.

A first implementation report on the EU Nanosciences and Nanotechnologies Action Plan was produced and adopted in September 2007, wherein the EC reports on progress in areas identified in the 2005 Action Plan. A second implementation report is expected in late 2009.

In February 2008, the EC produced a Recommendation on a *Code of Conduct for Responsible Nanosciences and Nanotechnologies Research* that was circulated to all Member States. Consistent with the EU approach, this Recommendation was developed in consultation with the public. The stated aim of this Code of Conduct is to "*promote integrated, safe and responsible nanosciences and nanotechnologies research in Europe for the benefit of society as a whole*" (EC, 2008b). The Code is underpinned by the principles of: meaning, sustainability, precaution, inclusiveness, excellence, innovation, and accountability. The intention of this document is to guide the actions of Member States in the formulation and implementation of both innovation and regulatory research strategies in individual jurisdictions. The Recommendation also suggests that research funding schemes should be tied to the guiding principles therein, and that Member States should encourage the voluntary adoption of the Code of Conduct by all bodies with an interest in nanotechnology research. The Recommendation will be reviewed every two years, and efforts will be made to monitor the extent to which stakeholders adopt and apply the Code of Conduct. Member States are also asked to report annually to the Commission any measures taken pursuant to the Recommendation and to communicate any results and best practices.

In January 2009, Member of the European Parliament (MEP) Carl Schlyter brought forward a *Draft Report on regulatory aspects of nanomaterials (2008/2208(INI))* to the Committee on the Environment, Public Health and Safety of the European Parliament. This draft Report, brought forward of the MEP's own initiative, contains the text of a "*Motion for a European Parliament Resolution on regulatory aspects of nanomaterials*" (Schlyter, 2009). The Motion contained within this draft Report calls for labelling of consumer products containing nanomaterials, the urgent development of adequate testing protocols to assess the hazards of and exposure to nanomaterials over their entire lifecycle, the development of ethical guidelines, a potential limitation of patent rights in order to avoid stifling innovation, among other aspects. As of the time of writing of this report (March 2009), a finalized version of the Report was not

yet available, and the report had not yet by the European Parliament. If endorsed, this would be a highly significant statement of policy on nanotechnology by the European Parliament.

The EU Nanotechnology Debate: Public Engagement and Expert Opinions

There are a few aspects which distinguish the nanotechnology debate in the European Union from that in other jurisdictions. First and foremost, there is a continuous emphasis in government-led initiatives on ensuring transparent public engagement and consultation. As discussed above for the UK, this emphasis stems from lessons learned from prior examples of the regulation of emerging technologies such as genetically modified foods. It also stems in part from some prominent past regulatory failures which drew a lot of media attention and elicited a public outcry, notably the 1996 BSE crisis in the United Kingdom and the 1999 dioxin contamination scandal in Belgium (van Calster, 2008). As both situations were related to the regulation of food products, there also remains a lingering risk aversion among the general public associated with the modification or possible contamination of food products, as was recently illustrated in the context of the genetically modified foods debate. Thus, a second unique aspect is that it is practically impossible to discuss nanotechnology in the European context without making some reference to GMOs and foods.

A third aspect is the pre-existence of dedicated independent scientific committees. These committees serve to provide the European Commission (EC) with scientific advice to inform policy development on issues related to public health, consumer safety, and environmental protection. The committees also play a role in alerting the EC to potential risks associated with emerging technologies. In the EU, there exist three such independent committees of external experts – the Scientific Committee on Consumer Products (SCCP), the Scientific Committee on Health and Environmental Risks (SCHER), and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). To date, two of these committees – SCENIHR and SCCP – have released opinions on aspects of nanotechnology.

SCENIHR has taken a leading role on the consideration of policy issues relating to the potential risks associated with nanotechnology. To date, they have released four Opinions and one modified (i.e. updated and revised) opinion on nanotechnology[19]. Their first Opinion, originally released in 2005 and modified in 2006, has already been referenced above. In their most recent Opinion, adopted in January 2009, SCENIHR addresses the *Risk Assessment of Products of Nanotechnologies*. In this document, they recommend adopting a case-by-case approach to the risk assessment of nanomaterials until such a time as a general approach to the identification of hazards associated with nanomaterials is within reach (SCENIHR, 2009).

In March 2008, SCCP released a document entitled *Opinion on Safety of Nanomaterials in Cosmetic Products*. This Opinion outlined a number of areas where, at the time, there remained inadequate information on the risks associated with nanoparticle use in cosmetic applications. In addition, SCCP recommended that the safety of insoluble nanomaterials in sunscreens should be evaluated.

The social, ethical, and legal implications of nanotechnology are also being debated within the European Union, and here stakeholder involvement has also been a key aspect of the debate. As an example, the

[19] All of the SCENIHR opinions on nanotechnology can be accessed through the following link: http://ec.europa.eu/health/ph_risk/committees/04_scenihr/scenihr_opinions_en.htm#nano.

EU-funded Nanologue project aimed to help establish a common understanding concerning ELSI aspects of nanotechnology and to facilitate a Europe-wide dialogue among science, business and civil society. Based on extensive research and stakeholder consultations, the 21-month collaborative project (now complete) developed several products to enhance the dialogue about ELSI aspects of nanotechnology applications, including the pamphlet *The Future of Nanotechnology: We Need to Talk*[20].

Regulatory Developments on Nanotechnology

On June 17, 2008, the European Commission issued a Communication on *Regulatory Aspects of Nanomaterials*. This Communication was prepared in response to a commitment by the EC to conduct a regulatory review of EU legislation in relevant sectors of relevance to nanotechnology. As outlined in this document, "*the regulatory challenge is therefore to ensure that society can benefit from novel applications of nanotechnology, whilst a high level of protection of health, safety and the environment is maintained*" (EC, 2008a). The Commission concludes that, overall, risks related to nanotechnology can be dealt with under the current legislative framework, but that certain modifications may be required in light of new information becoming available, for example with regards to the threshold volumes applicable in certain legislative documents (EC, 2008a).

The Communication then discusses the legislative instruments of relevance to the health, safety and environmental aspects of nanomaterials, according to whether the instrument governs: (1) chemicals, (2) worker protection, (3) products, or (4) environmental protection.

In the European Union, a **Regulation** is defined as a legislative act which becomes immediately enforceable as law in all member states simultaneously. Regulations differ from another regulatory instrument, **Directives**, in that directives are required to be transposed onto national law (at least in principle) by each Member State. Enforcement of directives becomes the responsibility of each Member State, and authority for this function is assigned to a **competent body**, which is essentially the regulatory body responsible for implementation and enforcement of the directive in each jurisdiction.

In addition to competent bodies in Member States, the EU has its own regulatory bodies. EU regulatory agencies generally possess limited powers as compared with regulatory bodies at the national level in Member States. Instead, EU-level regulatory bodies play a primarily advisory and/or consultative role, particularly in highly technical or scientific areas. Regulatory agencies in the EU with mandates of relevance to nanotechnology include:

- the European Chemicals Agency;
- the European Food Safety Authority (EFSA); and
- the European Medicines Evaluation Agency (EMEA).

Consider, for example, the work of the European Food Safety Authority. EFSA is the EU risk assessment body for food and feed safety. One of its roles is to provide independent scientific advice to EU risk managers (note the deliberation separation of the task of risk assessment from that of risk management in this description). Following decision-making, EFSA is also involved in the communication of risks relating to food and feed safety. EFSA works in close collaboration with the food and feed authorities in

[20] Pamphlet available from: http://www.nanologue.net/custom/user/Downloads/Nanologue_we-need-to-talk.pdf; accessed March 30, 2009.

EU member states – for example, the Food Standards Agency in the United Kingdom – since ultimately responsibility for the implementation and enforcement of regulations is at the national level.

Due to this complexity, we will simplify the discussion of nanotechnology below by discussing regulation from the standpoint of categories of products rather than that of regulatory authorities. The categories of products that will be discussed in depth below are: chemicals, cosmetics, novel foods and workplace safety, as these offer important insights into the regulation of nanotechnology in the EU context.

Regulating Chemicals in the EU – the REACH Regulation

On June 1, 2007, a new regulation on chemicals and their safe use (EC 1907/2006) came into effect in the European Union. Known as REACH, the new EU chemicals policy deals with the **R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emical Substances. The two most important aims of REACH are to "*improve protection of human health and the environment from the risks of chemicals while enhancing the competitiveness of the EU chemicals industry*" (European Commission, 2007). One characteristic feature of the REACH regulation is that it places greater responsibility on industry to manage the risks from chemicals by requiring manufacturers and importers to provide safety information on substances. Eventually, information from industry on chemical substances will need to be registered in a central database which will be run by the European Chemicals Agency (ECA). The provisions of REACH are underpinned by the precautionary principle.

The REACH Regulation was developed in consultation with stakeholders, and its provisions will be phased in over an 11 year period. Another key feature of REACH is that it mandates the progressive substitution of the most dangerous chemicals in situations where suitable alternatives to such chemicals have been identified. Guidance documents have been made available for industry.

There are no provisions in REACH referring specifically to nanomaterials. In October 2006, while the REACH Regulation was under development, the Environment Committee of the European Parliament proposed an amendment requiring that all "nanoparticles" be authorized and registered, irrespective of their chemical properties. However, this amendment was voted down, and the final version of the REACH Regulation that was adopted in December 2006 does not contain any specific requirements relating to nanomaterials. Nanomaterials are essentially treated like any other chemical substance under REACH and are subject to all of the same requirements.

The adequacy of REACH to deal with the regulation of nanomaterials has been the subject of extensive debate among stakeholders in recent years. The UK Government, stakeholder organizations, and others have commissioned or produced reports assessing the adequacy of REACH to manage the potential risks of nanomaterials. One issue that has been highlighted regarding the applicability of REACH is that of regulatory triggers. Under REACH, manufacturers and importers are required to submit a registration dossier for substances that are manufactured or imported at levels above 1 tonne per year. Chemical safety reports are required above the 10 tonnes per year threshold. As noted by Frater *et al*. (2006), "*given that some nanomaterials have different properties to their non-nanomaterial counterparts, it is conceivable that these thresholds are inappropriately set for the inclusion in products of nanoparticles*".

Annex IV to the REACH Regulation contains a list of substances considered to be of minimum risk due to their intrinsic properties and where sufficient information is known about these substances to justify

their inclusion in the Annex. When the REACH Regulation was originally adopted in 2006, it contained the requirement that the Commission must review the list of substances included in Annex IV (as well as Annex V, which represents a list of substances exempted from the registration requirements under REACH) by June 1, 2008. Pursuant to the mandated review exercise, Commission Regulation (EC) No 987/2008 (adopted on October 8, 2008) formally amends the two Annexes. Of significance to nanotechnology, through the amendment exercise, both carbon and graphite were removed from the list of substances in Annex IV. This amendment was "*due to the fact that the concerned Einecs and/or CAS numbers are used to identify forms of carbon or graphite at the nano-scale, which do not meet the criteria for inclusion in this Annex*" (EC, 2008c). Through this regulatory amendment exercise, the European Commission rescinded an exemption which had previously applied to carbon nanotubes and other nanoforms of carbon and graphite through REACH. Note that the text of Regulation (EC) No 987/2008 does not explicitly state that carbon nanotubes are considered as distinct from carbon (which was the US EPA approach). However, it does open the door to regulatory action on carbon nanotubes under the REACH Regulation, and in this regard the EU and US approaches arguably have the same end result.

A European Commission document dated December 16, 2008 reflects current thinking on how REACH applies to nanomaterials by the REACH Competent Authorities (Competent Authorities are those government bodies or departments responsible for the implementation of REACH within each EU Member State) and its subgroup on nanomaterials. The Commission has pledged to update this document as required, pursuant to ongoing discussions on this topic. According to this document, the burden for demonstrating that nanomaterials do not adversely affect human health or the environment in the EU falls to manufacturers, importers and downstream users of specific nanomaterials.

The Cosmetics Directive Recast and its Relevance to Nanomaterials

The constituent ingredients of cosmetic products, as chemical substances, fall under the scope of the REACH Regulation. However, they are additionally governed under a separate regulatory framework specific to cosmetics, the details of which are outlined in the Cosmetics Directive. The Cosmetics Directive (Council Directive 76/768/EEC), which was originally adopted by the European Economic Community in 1976, states that cosmetic products marketed within the European Community may not result in damage to human health when applied under normal or foreseeable conditions of use.

Recently, the European Commission has put forth a proposal to simplify the 1976 Cosmetics Directive though a process known as a "recast". Recasting is similar to the process of codification, in that it is intended to pull a piece of legislation and all subsequent amendments together into a single new document. Unlike codification, the process of recasting legislation involves new substantive changes to content, as further amendments are made to the original Act during preparation of the recast text[21].

The proposed simplification of the Cosmetics Directive recasts the Directive into a Regulation (EC, 2008d), a move supported by the Regulatory Impact Assessment Report by Commission staff. According to the impact assessment, "*the Cosmetics Directive is very detailed and frequently amended*" and minor differences between the approaches taken in 27 jurisdictions to transposing the directive onto national laws has created "*additional costs for industry without contributing to product safety*" (EC, 2008e).

[21] For further information on the EU recast process, see http://ec.europa.eu/dgs/legal_service/recasting_en.htm; accessed March 21, 2009.

Of note to nanoscale materials are the two following observations. First, the proposed Cosmetics Regulation does not explicitly refer to nanoscale materials at any point in the text. As such, there are no separate regulatory requirements applying specifically to nanomaterials. However, the recast Cosmetics Regulation states that "*particular consideration shall be given to any possible impacts*" on both exposure and toxicological profile "*due to particle sizes*" (EC, 2008d).

Should there be any doubt as to the intent behind the inclusion of language pertaining to particle size in the proposed Cosmetics Regulation, the Committee on the Environment, Public Health and Food Safety recently proposed amendments to the proposal which would see this made explicit. Among the proposed amendments is the insertion of a new Article clearly articulating that a high level of protection of consumers and human health shall be ensured in the case of cosmetic products containing nanomaterials. Should these proposed amendments be adopted, then manufacturers / importers would be required to report all existing cosmetic products containing nanomaterials to the Commission at least 12 months prior to the date of application of the Regulation. The Commission would then have six months in which to publish a report on all nanomaterials already in use in cosmetic products.

Debate regarding the applicability of the proposed Cosmetics Directive recast to nanotechnology is ongoing in the European Union and has drawn international attention. Environmental NGOs such as Friends of the Earth Europe and the UK Consumer Association "Which?" are attempting to influence the outcomes of the debate and final shape of the Cosmetics Regulation through influential educational campaigns on the topic of nanomaterials in cosmetics. It will be interesting to see how the recast Cosmetics Regulation, once approved in its final form, approaches the regulation of nanotechnology[22].

Regulating the Presence of Nanomaterials in Food Products

There is currently no designed regulatory regime in the European Union which applies specifically to the applications of nanotechnology in food products. Regulation (EC) No 178/2002, the General Food Law, outlines the general principles and requirements of food law in the EU and established the European Food Safety Authority. This Regulation provides for general food safety requirements and establishes the principles underpinning scientific risk assessments undertaken by EFSA in relation to food products. As with REACH, this Regulation places responsibility for ensuring the safety of food products on the food industry.

Of particular relevance to the case of nanotechnology in the food sector is the EU's Novel Food Regulation – Regulation (EC) No 258/1997. This Regulation, adopted in 1997, applies to novel foods and food ingredients that were not consumed to any significant degree prior to May 15, 1997. All such "novel foods" (this term is used to refer to newly developed innovative foods, foods produced by new

[22] **Note added in proof**: On March 24, 2009, the European Parliament adopted a legislative resolution amending the proposed regulation of the European Parliament and of the Council on cosmetic products recast. The amendments, as adopted, contain a definition of 'nanomaterial' as an "insoluble or bio-persistent and intentionally manufactured materials with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm. The amendments also call for a nano-specific safety assessment procedure for all products containing nanomaterials. In the absence of such a procedure, this could lead to a ban on a substance if there is a risk to human health (van Calster, Bowman, and D'Silva, personal communication). As of March 31, 2009, while political agreement had been reached on the final act, it was still awaiting final decision by the Council. As such, this significant development on the nanotechnology regulation has not been captured in the current report. Further information regarding this legislative action can be found online at the following link: http://www.europarl.europa.eu/oeil/file.jsp?id=5598862.

technologies, and exotic traditional foods from outside of the European Union) are required to undergo a pre-market safety assessment and authorisation before they can be marketed in the European Union. When originally adopted, this Regulation was applicable to genetically modified foods. However, since 2004 GM foods are now separately regulated in the EU under Regulation (EC) No 1829/2003 on genetically modified food and feed.

Recently, a revision of the Novel Food Regulation was deemed necessary, to reflect the fact that GM foods no longer fall under the scope of the Regulation. A proposed revision was presented in 2007 adopted by the European Commission in January 2008; this proposal aims to ensure food safety and a high level of consumer health protection while improving access to new and innovative foods within the EU market. Under the draft revised Regulation, novel foods will remain subject to pre-market authorisation; applications for authorisation must be submitted to EFSA, who will carry out independent scientific risk assessments related to the health and safety of such products. Responsibility for product approvals falls to the EC and Member States.

With GM foods no longer encompassed under the revised Novel Food Regulation, applications of nanotechnology to food production become a prime example of "novel foods" in the EU context. Importantly, the January 2008 EC proposal specifically states that the definition of novel foods under the revised Novel Food Regulation would include "*foods modified by new production processes, such as nanotechnology and nanoscience, which might have an impact on food*" (EC, 2008f). If the revised Regulation as eventually adopted includes an explicit definition including the application of nanotechnology to foods, then this would be a significant legislative precedent in the area of nanotechnology regulation. As such, there is great interest in the precise final form that the amended Novel Food Regulation will take[23].

In the EU, the regulation of food packaging materials is distinct from that of foods and food ingredients. Regulation (EC) 1935/2004 covers materials and articles that are, are intended to be, or can reasonably be expected to be brought into contact with food and which might transfer their constituents to food. Thus, the regulation of nanotechnology applications in food packaging would be through this Regulation. A recent review of regulatory issues and gaps conducted by the UK Food Standards Agency concluded that Regulation (EC) 1935/2004 was "drawn widely enough to deal with the migration of 'nanocomponents' into food from food contact materials and articles" (FSA, 2008). The basis for this conclusion is that regulators are mandated to assess the material or article coming into contact with food and its components in general, rather than any one component or type of component in particular. In plain language, the

[23] **Further note added in proof**: Following the action taken by the European Parliament on nanotechnology in the context of the Cosmetics Directive recast on March 24, 2009, the European Parliament also adopted a legislative resolution amending, under first reading, the proposal for a revised Novel Food Regulation. The proposed amendments call for the development of nano-specific test methodologies as a matter of urgency, and further specify that novel foods containing nanomaterials should not be allowed to enter the market until such a time as these test methodologies have been developed. Given that such methodologies do not yet exist, should these amendments be adopted, this would essentially amount to a moratorium on nanomaterials in food products (van Calster, Bowman, and D'Silva, personal communication) – the first moratorium on nanomaterials to be seriously considered in any of the five jurisdictions examined in the current report. As of the time of finalization of our report (March 31, 2009), the Novel Food Regulation as amended was still at the first reading stage. This will be an important development to track over the coming weeks and months. The status of this legislative procedure can be tracked online at the following link: http://www.europarl.europa.eu/oeil/file.jsp?id=5583302.

Regulation states that food packaging materials may not transfer components to foods (under normal and foreseeable conditions of use) in quantities that could endanger human health. Notwithstanding this, the FSA noted that the future possibility of developing rules to deal with 'nanocomponents' on their own "*should not be ruled out*" and would make explicit that the EU regulatory framework for food contact materials and articles extends to nanotechnology.

With respect to the risk assessment of food products containing nanomaterials, on March 5, 2009, the European Food Safety Authority released the *Scientific Opinion of the Scientific Committee on a request from the European Commission on the Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety* (EFSA, 2009). In this report, the EFSA Scientific Committee concludes that while it is currently possible to apply internationally accepted risk management approaches to the case of engineered nanomaterials, that in the short term future it will nonetheless be necessary to assess each nanomaterial on a case-by-case basis. The basis for this opinion was that current data gaps and a lack of validated assessment methodologies are such that the risk assessment of specific nano products is subject to a high degree of uncertainty.

Codes of Conduct for Workplace Safety

In the European Union, two distinct (and presumably competing) codes of conduct have been adopted – one which was developed by the European Commission through a process of stakeholder consultation, and one which was developed specifically for businesses by a multi-stakeholder group of international businesses, academics and NGOs run from the United Kingdom. Both voluntary codes are intended as complementary approaches to government-led regulation of workplace health and safety issues.

In November 2006, a partnership formed between the UK Royal Society, Insight Investment, and the Nanotechnology Industries Association. A workshop convened by the three organizations resulted in a unanimous agreement on the requirements for a voluntary principles-based Code of Conduct for businesses engaged in nanotechnology. Following the workshop, the three organizations, joined by the UK-based Nanotechnology Knowledge Transfer Network, worked to facilitate development of this voluntary code, which is known as the *Responsible Nano Code*. This Code is based on the following seven principles:

Principle One – Board Accountability;

Principle Two – Stakeholder Involvement;

Principle Three – Worker Health & Safety;

Principle Four – Public Health, Safety & Environmental Risks;

Principle Five – Wider Social, Environmental, Health and Ethical Implications and Impacts;

Principle Six – Engaging with Business Partners; and

Principle Seven – Transparency and Disclosure.

The Code, once fully developed, will also contain examples of good practice and a detailed Benchworking Framework for evaluating the compliance of companies with the code, even companies who have not adopted the Code. This Responsible Nano Code offers an alternative approach to that taken by the European Commission.

In February 2008, the European Commission adopted a Recommendation on a *Code of Conduct for Responsible Nanoscience and Nanotechnologies Research* (EC, 2008b). This Recommendation was the culmination of a stakeholder consultation process launched in July 2007. Like the Responsible Nano Code described above, the Commission's Recommendation includes seven guiding principles, as follows:

Principle One – Meaning;

Principle Two – Sustainability;

Principle Three – Precaution;

Principle Four – Inclusiveness;

Principle Five – Excellence;

Principle Six – Innovation; and

Principle Seven – Accountability.

The Commission's Code of Conduct also provides guidelines for implementation of these 7 principles under good governance of research, due respect of precaution, and dissemination and monitoring of the Code of Conduct. In contrast to the *Responsible Nano Code*, the European Commission's code of conduct extends only to worker health and safety in the context of nanotechnology and nanoscience research activities; as such its scope is somewhat limited. In the context of nanotechnology regulation, it is interesting that the European Commission has limited its choice of policy instruments for the oversight of worker safety to a voluntary code of conduct only at this time. Note that adherence to voluntary codes by Member States is entirely voluntary. The Recommendation will be reviewed in 2010; it will be interesting to see at that time to what extent Member States have adopted and implemented the voluntary code.

A comparison of these two voluntary initiatives (as well as the Dupont / Environmental Defense Nano Risk Framework and the Global Core Principles of Responsible Care developed by the International Council of Chemical Associations) has previously been conducted by Grobe *et al*. (2008), on behalf of the International Risk Governance Council (IRGC). Although the two EU-based initiatives have similar objectives and a number of commonalities (see Grobe *et al*., 2008, page 41), there are also distinct differences between the two codes of conduct.

Whether there is in fact a need for two codes of conduct in the same jurisdiction is highly debatable. As noted in the report prepared for the IRGC: "*In an ideal world, there should be only one such code*" and "*In the long run, it is in the interest of all players to reduce the variability of codes or at least the heterogeneity of performance standards in order to avoid being arbitrarily held responsible by courts or other actors*" (Grobe *et al*., 2008). It is perhaps for this very reason that a December 2007 workshop was organized where both proposed codes of conduct were presented in order to encourage discussion and debate[24].

[24] The agenda for this December 2007 Debate can be found online on the European Commission website at: http://ec.europa.eu/nanotechnology/pdf/agenda_codevent.pdf; accessed March 30, 2009.

Australia

Policy Statements and Key Events Related to Nanotechnology

In a March 2005 report, the Australian Prime Minister's Science, Engineering and Innovation Council (PMSEIC) provided an overview of nanotechnology and its potential benefits, including potential future gains for the Australian economy. In this report, PMSEIC outlined their key findings and recommended that the Australian Government should examine options for implementation of a national strategy regarding nanotechnology that would ensure "*an appropriate regulatory framework which safeguards the health and safety of Australians*" (PMSEIC, 2005).

Later in 2005, an inquiry into the health impacts of workplace exposure to toxic dust and the adequacy of regulations governing workplace exposures also had a substantial impact on the nanotechnology debate. Among the terms of reference of the Senate Community Affairs References Committee inquiry on toxic dust was a mandate to investigate "the potential of emerging technologies, including nanoparticles, to result in workplace related harm". This last term of reference drew the attention of stakeholder groups. The submission from Friends of the Earth (FoE) Australia, for example, branded nanoparticles as the "new asbestos" and called for a moratorium on the commercial production of nanoparticles until such a time as regulations could be finalized to protect worker health (FoE Australia, 2005). The final report from the Senate Committee provided further support for the 2005 PMSEIC recommendations, additionally calling for the formation of a working party on nanotechnology regulation to consider the impacts of nanotechnology on the Australian regulatory framework including whether existing regulations were appropriate to the regulation of nanotechnology, options to address regulatory gaps and uncertainties and to ensure the comprehensive risk management of nanoparticle exposure through regulation, and whether there was a need to establish a permanent body to regulate nanotechnology (Australian Senate Community Affairs References Committee, 2006).

A National Nanotechnology Strategy Taskforce (NNST) was established within the Department of Industry, Tourism and Resources in July 2005. The NNST taskforce delivered their report outlining *Options for a National Nanotechnology Strategy* to the Australian Government in June 2006. Among the recommendations outlined therein were governance options for overseeing the implementation of the strategy and coordination across government departments, establishment of a forum to look at health, safety, and environmental issues, and a recommendation that the Government should undertake an assessment and gaps analysis of current regulatory frameworks.

The Australian Office of Nanotechnology (AON) was subsequently created to drive implementation of the National Nanotechnology Strategy. The AON, which is based within the Department of Innovation, Industry, Science and Research, is the coordinating body charged with ensuring a consistent approach to nanotechnology issues across government departments. In addition, the AON works with industry, NGO's and the State and Territorial Governments in Australia on projects related to the responsible development and regulation of nanotechnology as well as the coordination of nanotechnology policies and industry development activities. The broad objective of the National Nanotechnology Strategy, as outlined in the 2008 implementation plan developed by the AON, is to "*capture the potential benefits of nanotechnology while effectively addressing the issues impacting on the successful and responsible development of the technology*" (AON, 2008).

Following on from the NNST recommendation regarding nanotechnology regulation, a contract to conduct an independent study of the possible impacts of nanotechnology on regulatory frameworks was awarded in January 2007 to members of the Monash Centre for Regulatory Studies within the Faculty of Law at Monash University. The final report from Monash University, *Review of Possible Impacts of Nanotechnology on Australia's Regulatory Frameworks*, was delivered to the Government in June 2007.

The Monash Report was released broadly to the public in July 2008. As part and parcel of the public announcement, the Australian Government also released a position statement on nanotechnology. Entitled *Australian Government Approach to the Responsible Management of Nanotechnology*, this statement provides an overview of Government policy regarding nanotechnology development and regulation. Noting that the existence of "*established and robust regulatory arrangements...to address human health and environmental safety issues associated with these materials and products, as well as manufacturers' and suppliers' liability obligations*", the Government concludes that "*there has so far been no demonstrated need for a specific regulatory system for engineered nanomaterials*". Consistent with the approaches taken in most jurisdictions described above, these statements are tempered somewhat by a pledge to continually review existing regulatory schemes and to implement reform initiatives as required. The Government also outlines three high level objectives to guide the responsible management and oversight of nanotechnology, which are as follows: (1) Protect the health and safety of humans and the environment; (2) Foster informed community debate; and (3) Achieve economic and social benefits.

The Monash Report also concludes that "*there is no immediate need for major changes to the regulatory regimes*", however further to this, the study's author identified six areas of potential concern regarding "regulatory triggers" for nanomaterials (Ludlow *et al*., 2007). These areas are:

1. A regulatory gap surrounding uncertainty as to whether new nanoforms of conventional products would be classified as "new" or "existing".
2. The dependence of many regulatory triggers on a threshold weight or volume, because such thresholds may not be meaningful in the context of nanomaterials.
3. Appropriate regulation, in some instances, requires specific knowledge of either the presence of nanomaterials and/or the risk posed by those materials. The authors point out that knowledge gaps relating to nanotechnology are such that these regulatory triggers are unlikely to be met.
4. The reliance of current regulatory frameworks ensuring health and safety (both human and environmental) on risk assessment protocols and methodologies which may not be appropriate for determining the potential risks of nanomaterials.
5. Regulatory exemptions for research and development uses of chemicals may pose threats to worker safety for those handling potentially hazardous nanomaterials and nanoproducts; such research and development exemptions are also based on weight thresholds.
6. Many of Australia's regulatory frameworks refer to international documents or documents sourced outside regulators. The authors point out that gaps occurring in such documents may lead to a further potential regulatory gaps in the Australian context.

It is noteworthy that many of the areas of concern noted in the Monash Report have also been noted in other jurisdictions. For example, the first two points noted above (i.e. the classification of "new" vs. existing substances and the issue of threshold weights or volumes) were also identified as primary regulatory issues in regulatory studies prepared for the UK Government (Chaudhry *et al*., 2006; Frater *et*

al., 2006). The lack of specific knowledge on the risks posed by nanomaterials and inadequacy of current risk assessment protocols and methodologies is also a recurring theme. Thus, with the possible exception of point #6 above, the areas of potential concern outlined by the Monash group could easily be extended to other jurisdictions.

The Australian Nanotechnology Debate: Influential NGOs and Labour Unions

Stakeholders, particularly NGOs and labour unions, have played a key role in driving the debate in Australia surrounding the regulation of nanotechnology. FoE Australia has been involved with the Australian debate on nanotechnology since 2005, and has arguably been the most vocal and active of all the Australian NGO projects on this issue. In addition, they have collaborated with FoE Europe and FoE US on a number of nanotechnology-related projects and reports. In Australia, FoE has launched a number of targeted initiatives, including campaigns on nanomaterials in cosmetics and sunscreens, nanotechnology in food and agriculture, and raising concerns among the public regarding carbon nanotubes by drawing analogies to asbestos. Asbestos exposure has been a significant political and social issue in Australia for decades; the town of Wittenoom in Western Australia, where asbestos was mined for many years, was ravaged by the effects of diseases attributed to asbestos, and Australia has the highest per capita rates of mesothelioma (a form of cancer associated with asbestos exposure) in the world. Sunscreens are another hot button issue for Australians, since Australia also has the highest rates of skin cancer in the world, and public education campaigns around sunscreen are prevalent. The high profile achieved by FoE in Australia might therefore be attributable to the targeted approach adopted in relation to their campaigns (Diana Bowman, personal communication).

The labour unions in Australia are also active in the nanotechnology debate, particularly with respect to occupational health and safety issues. Here too, public awareness around asbestos and particularly resulting from a lawsuit by victims of asbestos against the mining company James Hardie in Australia has been an influential factor. In addition, the Senate Committee inquiry referenced above resulted from worker exposure to crystalline silica in the Australian sandblasting industry. These two examples have likely resulted in an elevated importance of occupational health and safety issues in the Australian public policy debate surrounding nanotechnology, as compared with other jurisdictions. The Australian Council of Trade Unions in particular has been highly active on nanotechnology policy issues.

The Australian Government is still in the early stages of developing a strategy on stakeholder involvement in the nanotechnology debate. The Australian Office of Nanotechnology has recently embarked on a project to strengthen its social inclusion and stakeholder engagement policy and practices. As a first step in this process, AON invited participants from Government, industry, researchers, community, and so-called 'change agents' to attend a workshop in December 2008[25]. The process is ongoing at the time of writing of this report.

[25] A report summarizing outcomes from the December 2008 workshop, entitled *Social Inclusion and Engagement Workshop Report*, may be found at the following link: http://www.innovation.gov.au/Section/Innovation/Documents/SocialInclusionandEngagementWorkshopFinalReport.pdf; accessed March 31, 2009.

Regulatory Developments on Nanotechnology

The Regulation of Nanotechnology at the Federal Level

In Australia, the federal regulatory agencies with jurisdiction over areas of particular relevance to the nanotechnology debate are as follows:

- The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) – responsible for the regulation of industrial chemicals;
- Food Standards Australia New Zealand (FSANZ) – governmental body responsible for developing food standards for both Australia and New Zealand; and
- The Therapeutic Goods Administration (TGA) – the regulatory body for therapeutic goods (including prescription, over-the-counter, and complementary medicines; medical devices; blood and tissues; and other therapeutic goods) in Australia.

Occupational health and safety (OHS) in Australia is regulated at the State level rather than federal level. However, a federal body – the Australian Safety and Compensation Council (ASCC) – is charged with leading and coordinating national efforts to promote best practice in OHS and with developing national policy on OHS issues and matters of worker compensation.

The 2007 Monash Report on nanotechnology regulation recommended that all federal regulatory agencies should undertake to conduct their own in-house regulatory assessments to identify potential gaps in the regulation of products falling under their oversight. To date, both NICNAS and TGA have undertaken this activity, although the results of these evaluations are not yet publicly available. In the case of NICNAS, representatives from industry, the community and academia make up the Nanotechnology Advisory Group, which has been established to advise on strategies for addressing the regulatory and safety impacts of nanomaterials. The work of this Advisory Group is ongoing.

On the TGA website, a question and answer section on *Nanotechnology and therapeutic products*[26] indicates that while the existing regulatory framework of the TGA has been adequate to date to identify, assess and manage the risks associated with therapeutic products incorporating nanotechnologies, the continued development of nanotechnologies will likely pose regulatory challenges in the future. The TGA response to nanotechnology has been to undertake an in-house, science-based review of the capacity of their regulatory framework to deal with future generations of nanotechnologies. The results of this in-house review are not yet publicly available.

In Australia, the responsibility for regulation of food products is shared with New Zealand. In these jurisdictions, all food supplied must comply with the *Australia New Zealand Food Standards Code* (the Code). New food substances require pre-market approval, involving a rigorous science-based safety assessment, before they can be legally supplied. Applications for approval of food substances must follow a set of standards which are outlined in the FSANZ *Application Handbook*. The Code also sets out the regulations with respect to food labelling. Responsibility for ensuring the compliance of manufactured foods with the Code in Australia falls to the State and Territorial governments, whereas imported foods are monitored by the Australian Quarantine and Inspection Service. With respect to nanotechnology, FSANZ has also set up an in-house steering group to advise on nanotechnology and has indicated that it will make adjustments to existing regulatory frameworks as required. In October 2008, FSANZ proposed

[26] http://www.tga.gov.au/meds/qanano.htm; accessed March 15, 2009.

amendments to the FSANZ *Application Handbook* that would require applicants to provide information on particle size and morphology "*in cases where these characteristics may relate to the toxicity of a food contaminant*"[27], stating the proliferation of nanotechnology in industrial applications could result in an increase of nanoparticles entering the food chain in the future. This amendment would provide a mechanism for FSANZ to gather additional information on nanoparticles in the future, and may be viewed as a mandatory reporting regulation related to nanotechnology.

The Australian Government has also undertaken voluntary reporting initiatives related to nanotechnology, as summarized below.

Voluntary Reporting – The Australian Experience

In February 2006, NICNAS (located in the Australian Government Department of Health and Ageing) issued a voluntary Call for Information to industry to provide information on the uses and quantities of nanomaterials being manufactured or imported for industrial purposes, or for use in cosmetics and personal care products (NICNAS, 2007). The Australian Government thereby became the first international government to undertake a voluntary reporting scheme. However, very few companies responded to this call for information. With some additional prodding from the regulatory authority, a total of only about 20 companies eventually responded to this voluntary initiative. Approximately one-third of those surveyed indicated that the nanomaterial(s) were only being used for research purposes. Although NICNAS concluded that the information collected through this voluntary initiative was valuable, this project is not generally perceived among the international nanotechnology policy community to have been successful.

A second Voluntary Call for Information was initiated by NICNAS in October 2008, targeted at all manufacturers or importers of nanomaterials or products (mixtures) containing nanomaterials for commercial or research and development purposes in 2008 (the first call excluded the use of nanomaterials for R&D purposes). NICNAS is seeking to ascertain: what industrial nanomaterials are being introduced and used in Australia, the volumes of nanomaterials used, what categories of physicochemical and toxicological data are held by companies, and how these materials are being used in industry and in public sector research. The call stipulates that actual data need not be submitted, and that no new data need be generated. Under this call, information was due to NICNAS by the end of January 2009. The results of this call have not yet been made public.

The Regulation of Nanotechnology by State and Territorial Governments

There are a number of State-level nanotechnology initiatives currently ongoing. Among the most active states in the area of nanotechnology are the governments of Victoria and New South Wales.

Victoria has been very active in the area of nanotechnology. February 2008 saw the release of the *Victorian Nanotechnology Statement: Taking Leadership in Innovations in Technology*, which noted national regulation (collaboration with the Federal Government and other States in the development and introduction of a regulatory framework to protect workers, customers, the community and the

27 http://www.foodstandards.gov.au/_srcfiles/Proposed%20Amendments%20to%20Application%20Handbookoct%2020081.pdf; accessed March 15, 2009.

environment from the potential dangers of nanomaterials) and industry self-regulation (encouraging the development of industry-designed and led protocols for the responsible management of nanotechnologies) among its four areas of focus within their priority of ensuring the responsible development of nanotechnologies (State Government of Victoria, 2008).

In New South Wales, the Legislative Council Standing Committee on State Development recently undertook an inquiry into nanotechnology, including the health, safety and environmental risks and benefits of nanotechnology, the appropriateness of the current regulatory frameworks for the life-cycle management of nanomaterials, and options to improve public awareness of nanotechnology issues. The Committee released its comprehensive report in October 2008. Given the States mandate in Australia to regulate occupational health and safety issues, it is not surprising that OHS issues were a prominent feature of the Committee's report. Among the recommendations contained in the report was a recommendation that New South Wales should advocate for development of a national mandatory labelling scheme for engineered nanomaterials used in the workplace, or alternatively, that New South Wales should proceed with developing its own mandatory labelling scheme. This recommendation in particular, if adopted and pursued, would represent an international first in terms of mandatory labelling requirements for nanomaterials. The New South Wales Government will respond to this report in the coming months.

If the history of the regulation of GMOs is any indication, then the role of States and Territories in Australia could become very important. For GMOs, national policies and national regulatory approvals did not prevent moratoria at the state levels. It is, however, difficult to predict if similar events could occur with respect to the products of nanotechnology.

Canada

Policy Statements and Key Events Related to Nanotechnology

Among the five jurisdictions examined in the current report, Canada is unique in that no overall national vision or strategy with regards to nanotechnology has yet been articulated. In this regard, the Canadian Federal government lags behind a number of provincial governments – notably Alberta[28] and Quebec – who have developed provincial strategies regarding the development of nanotechnology.

In 2005, the Prime Minister's Advisory Council on Science and Technology produced a series of four reports on the topic of nanotechnology. These reports dealt with Canadian research strengths in nanotechnology, an environmental scan of nanotechnology in Canada, the industrial capacity to absorb nanotechnology, and a review and analysis of foreign nanotechnology strategies. In October of 2005, an official from the Office of the National Science Advisor presented a presentation at a Workshop on Nanotechnology and the Environment in Arlington, Virginia entitled *Towards a National Nanotechnology Strategy for Canada*[29]. This presentation notes that a sustained Canadian investment in

[28] The *Alberta Nanotechnology Strategy: Unleashing Alberta's Potential* may be found online at: http://www.technology.gov.ab.ca/en/documents/Nanotechnology_Strategy_Complete.pdf; accessed March 11, 2009.
[29] The presentation by Paul Dufour of the Office of the National Science Advisor may be accessed through the US EPA website: http://es.epa.gov/ncer/publications/workshop/10_26_05/p2dufour.pdf; accessed March 11, 2009.

nanotechnology, though necessary, would not be effective without an integrated national strategy incorporating several aspects, including regulatory considerations.

Despite this initial leadership by the Office of the National Science Advisor, Canada does not yet have a national strategy in place to guide the development of nanotechnology or to manage the issues associated with EHS risks and ELSI issues surrounding the technology. The Office of the National Science Advisor was phased out in 2008, and no longer exists.

In 2007, the Government of Canada released its comprehensive Science & Technology (S&T) Strategy, entitled *Mobilizing Science & Technology to Canada's Advantage*. With respect to nanotechnology, the S&T Strategy notes that "*the challenges and opportunities [of nanotechnology] are yet to be fully realized*". The Strategy calls for support of nanotechnology by "*strong science and effective regulation to protect human health and the environment while supporting Canadian competitiveness*" (Government of Canada, 2007a).

With respect to the regulation of nanotechnology, the S&T strategy calls for "*an effective, forward-looking, and responsive regulatory environment that promotes a competitive marketplace and protects the health and safety of Canadians and the environment*" (Government of Canada, 2007a). The Strategy commits federal regulatory departments and agencies to developing a plan to ensure the responsible and timely regulation of a spectrum of technologies, including biotechnology, nanotechnology, and ICT products, services and technologies. Further to this commitment, the S&T Strategy notes the Government of Canada's $9 million investment (announced in Budget 2007) in making Canada a best-in-class regulator by ensuring efficiency and effectiveness in regulation through the new *Cabinet Directive on Streamlining Regulation*.

The provision of advice on policy issues surrounding biotechnology, an emerging technology which became the focus of considerable attention and debate in the 1980s, was previously the mandate of the Canadian Biotechnology Advisory Committee. This Advisory Committee was established in September 1999 as part of the Government of Canada's 1998 *Canadian Biotechnology Strategy*. No similar governance structure for nanotechnology has yet been established. Instead, the 2007 S&T Strategy consolidated the roles and responsibilities of CBAC and other advisory bodies into the Science, Technology and Innovation Council (STIC), reporting to the Minister of Industry. It would in theory fall under the mandate of STIC to provide evidence-based advice on issues relating to nanotechnology, provided that such a request was forwarded to it by the Government of Canada.

A February 2008 report, *Nanotechnology and Its Impact on Consumers*[30], prepared for the Consumers Council of Canada with support from Industry Canada Office of Consumer Affairs, was prepared with the intention of providing consumers in Canada with objective information on nanotechnology. A key aspect of this study was a survey of the Canadian public and consumer representatives. This survey found that 70% of those survey lacked awareness of nanotechnology, although a majority of Canadians (despite their lack of awareness) were generally optimistic regarding the technology and had few concerns about risks.

[30] The full report is available from the Consumers Council of Canada website at: http://www.consumerscouncil.com/site/Consumers_Council_of_Canada_69/pdf/Nanotech%20report.pdf; accessed March 31, 2009.

In July 2008, the Council of Canadian Academies (CCA) released a report entitled *Small is Different: A Science Perspective on the Regulatory Challenges of the Nanoscale*. This report from the CCA Expert Panel on Nanotechnology was prepared for the Government of Canada in response to a request originating from the Minister of Health. This report concludes that existing Canadian regulatory approaches and risk management strategies are sufficient to deal with the assessment of nanomaterials, with a few caveats. For example, the expert panel noted the need for greater investment in regulatory-relevant research, particularly research associated with the risk assessment of nanomaterials. In addition, the panel stated that attention should be paid to addressing outstanding regulatory issues such as: regulatory triggers, regulatory capacity, and governance models for the coordination of nanotechnology-related activities among federal regulatory agencies, between the federal and provincial levels of government, and among international regulatory agencies. According to the report, the panel specifically avoided making specific recommendations regarding the best regulatory tools to manage the potential risks associated with nanotechnology or next steps for Canadian regulatory agencies—instead, its conclusions are presented in the form of "findings". This approach aimed to provide flexibility to the sponsoring agencies to proceed with developing their own strategies, following appropriate consultation.

The Government of Canada has not yet responded to the report produced by the CCA Expert Panel on Nanotechnology, a point which has been frequently pointed out in recent media reports, notably a series of articles by the Canadian Press in January 2009.

The Canadian Nanotechnology Debate: Leadership by the Provinces

As indicated earlier in this paper, Canadian players became involved in the international nanotechnology debate at an early stage, particularly with respect to discussions around the Ethical, Legal, and Social Implications of the emerging technology. Two Canadian groups, as we have already noted herein, were highly influential in the early ELSI debate – the Ottawa-based Action Group on Erosion, Technology and Concentration (better known as the ETC Group), an NGO, and the Joint Centre for Bioethics at the University of Toronto.

The Canadian Institute for Environmental Law and Policy (CIELAP), an independent, not-for-profit research and education organization and registered charity, has held two workshops to date on the topic of nanotechnology policy in Canada – in March 2007 and February 2008. The first workshop led to the production of a *Discussion Paper on a Policy Framework for Nanotechnology*; this paper was subsequently updated in March 2008 following the second workshop. The 2007 Discussion Paper outlined twelve major areas requiring policy direction in Canada, including the identified need for a regulatory approach that would include science-based risk assessments and stakeholder involvement.

Environmental NGOs in Canada such as Friends of the Earth Canada have remained relatively quiet on issues related to nanotechnology, especially as compared with their counterparts in the US, Europe, and Australia.

An interesting aspect of the nanotechnology debate in Canada has been the leadership demonstrated to date by the provinces, and particularly Quebec, both in terms of developing strategies to foster innovation and commercialization of nanotechnologies but also in terms of responsible development and regulation of nanotechnology. In Quebec, NanoQuebec is a not-for-profit organization funded through a

combination of federal and provincial government monies, with a mission to strengthen innovation in nanotechnology with the goal of ensuring solid and sustained economic growth for Quebec and Canada.

In April 2007, the Commission de l'éthique de la science et de la technologie in Quebec issued a 158 page position statement with the title *Ethics and Nanotechnology: A Basis for Action*. Notably, this position statement contains a comprehensive analysis of laws and regulations currently in place, both in Canada and in Quebec, to manage the potential risks of nanomaterials throughout the product life cycle. In its deliberations, this S&T ethics Commission considered two possible regulatory approaches for nanomaterials: application of the precautionary principle, or adopting a life cycle approach to regulation. With respect to the regulation of nanotechnology, the Commission finally recommended:

> "that the Quebec Government, guided by the principle of precaution and from the perspective of sustainable development, be concerned with all phases of the life cycle of a product derived from nanotechnology or containing nanometric components, and that in this respect it should integrate the concept of "life cycle" into all policies where such an approach is appropriate, in order to avoid any damaging impact of technological innovation on health and the environment" (Commission de l'éthique de la science et de la technologie, 2007).

This position statement by the Commission de l'éthique also contains a substantive description of the ethical concerns associated with the products of nanotechnology. This document implies that the Government of Quebec, though committed to the continued development of nanotechnology in order to realize potential economic gains and the creation of jobs, takes seriously its responsibilities with respect to responsible development of the technology. In many ways, this document signals a European approach to the development of nanotechnology in Quebec.

Regulatory Developments on Nanotechnology

A large portion of Canadian activity on nanotechnology regulation to date has focused on cooperative efforts ongoing at the international level, particularly within the OECD (work by the OECD on nanotechnology will be described later in this report). Canada has also been actively participating in work by the International Organization for Standardization (ISO) aiming to develop standards for nanotechnology relating to terminology and nomenclature, metrology and instrumentation, and the development of reference materials and standard test methodologies. Canada currently serves as Convenor for the ISO Nanotechnology Technical Committee (TC229) Joint Working Group on Terminology and Nomenclature.

At the federal level in Canada, the two most active regulatory departments on the nanotechnology policy file to date have been Health Canada and Environment Canada. These two agencies are also part of an Interdepartmental Network on nanotechnology established in 2003; other participants include Industry Canada, the Canadian Standards Association and the National Research Council.

Responsibility for developing a plan to ensure the responsible and timely regulation of nanotechnology, a commitment that was outlined in the Government's 2007 S&T Strategy, has been assumed by Health Canada. In this regard, Health Canada is coordinating its efforts with those of other federal regulatory departments and agencies: Environment Canada, the Canadian Food Inspection Agency, and the Department of Fisheries and Oceans Canada.

Health Canada's position on nanotechnology regulation, as outlined in a two-page factsheet dated January 2007[31], is that existing legislative and regulatory frameworks (namely, the *Food and Drugs Act* and all associated regulations) can be (and are currently being) applied to regulate the health and safety aspects associated with applications of nanotechnology, with the caveat that new approaches may become required in the future in order to keep pace with technological advancements. In this regard, Health Canada is in general agreement with its international counterparts, including the US FDA. Health Canada has previously developed a Framework for Products of Nanotechnology; this framework called for action to fill knowledge gaps, identification of products already being marketed, work towards developing an internationally accepted and standardized nomenclature, an evaluation of currently regulatory frameworks and their ability to regulate the products of nanotechnology, development of communications products, and building of a nanotechnology products database[32]. As compared with its international counterparts such as the US FDA, Health Canada's position and activities in this area are arguably less transparent than in other jurisdictions, due to the lack of a website dedicated to discussions of nanotechnology[33].

In Canada, as in the US, the majority of the regulatory activity to date specific to the unique properties of products of nanotechnology has been in the context of chemicals management and environmental protection. In Canada, responsibility for the regulation of potentially toxic or dangerous substances which could be released into the environment is the shared domain of Environment Canada and Health Canada, who regulate under the *Canadian Environmental Protection Act 1999* (CEPA). Regulatory action by the Government of Canada under CEPA to date will be described in further detail below.

Regulation of Nanotechnology under the Canadian Environmental Protection Act, 1999

In Canada, provisions outlined under the *Canadian Environmental Protection Act 1999* (CEPA 1999) require the Ministers of the Environment and of Health to conduct environmental and human health risk assessments and appropriately manage the potential risks arising from industrial chemical substances. The purpose of CEPA is to protect the environment and the health and well-being of Canadians.

Under CEPA, as with the chemicals management programs in other jurisdictions including the US, there is a distinction made between "new" and "existing" chemical substances. Since 1994, all "new" chemical substances manufactured in or imported into Canada must be scientifically assessed for their potential risks under the New Substances Notification Program. The level of regulatory oversight depends on the quantities released into the environment. Chemicals deemed to be "CEPA-toxic" through this process are added to the List of Toxic Substances and thereby become subject to additional regulation by the federal government. "Existing" substances are defined as those which already appear on the Domestic Substances List (DSL).

In June 2007, the New Substances Division at Environment Canada issued an advisory note[34] clarifying the requirements for nanomaterials under the New Substances Notification Regulations (NSNR).

[31] This factsheet can be accessed from the Health Canada website, at: http://www.Health Canada-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/brgtherap/nt_factsheet_fichedocumentaire-eng.pdf; accessed March 22, 2009.
[32] Details noted at: http://www.Health Canada-sc.gc.ca/sr-sr/pubs/about-apropos/forum/2007-proce/plen-scien-eng.php; accessed March 22, 2009.
[33] As a point of comparison, compare with: http://www.fda.gov/nanotechnology/.
[34] Advisory note available online from: http://www.ec.gc.ca/substances/nsb/pdf/a200706_e.pdf; accessed March 22, 2009.

According to this advisory note, a nanoscale form of a substance already listed on the DSL would be classified as a "new" substance under the NSNR if it possesses unique structures or molecular arrangements (such as carbon nanotubes), as would nanosubstances not already listed on the DSL. Nanoscale forms of substances already on the DSL without unique structures or molecular arrangements, however, are considered "existing" and are therefore not subject to the Regulations. The Canadian approach closely mirrors the approach taken by the US EPA to the definition of nanomaterials as "new" or "existing" under TSCA.

In September 2007, Environment Canada and Health Canada jointly issued a *Proposed Regulatory Framework for Nanomaterials under the Canadian Environmental Protection Act, 1999*. This proposed framework seeks to "*to address nanomaterials in a manner which ensures the responsible introduction of nanomaterials to the Canadian market through a program which scientifically assesses and appropriately manages any potential risks*" (Environment Canada and Health Canada, 2007). The document proposes a two phased approach to the development of a regulatory framework for nanomaterials. The first phase consisted of: (a) continued engagement at the international level with the OECD and ISO, (b) informing manufacturers / importers of their regulatory responsibilities under CEPA, (c) developing information gathering initiatives to obtain more information from industry on the uses, properties and effects of nanomaterials, and finally, (d) a consideration of whether amendments to CEPA 1999 or to the NSNR might help to facilitate risk assessment and risk management of nanomaterials. Phase two, which was slated to begin in 2008, proposed to: (a) obtain resolution on a standard terminology and nomenclature for nanomaterials through the ISO technical committee on nanotechnology, (b) consider the establishment of nanomaterial-specific data requirements under the NSNR, and (c) consider using the Significant New Activity (SNAc) provision of CEPA to gather information on nanomaterials classified as "existing" under the current provisions of CEPA (Environment Canada and Health Canada, 2007).

Also in September 2007, Environment Canada and Health Canada hosted a one-day workshop, bringing together members of industry, NGOs, academia, and other stakeholders, to discuss and obtain feedback on the *Proposed Regulatory Framework for Nanomaterials under the Canadian Environmental Protection Act, 1999* and on possible options for information gathering initiatives. Based upon feedback obtained through this workshop, it was decided that Canada would adopt a mandatory reporting scheme for engineered nanomaterials.

In January 2009, it was widely reported in nanotechnology policy circles that Canada was planning to enact national regulation concerning a mandatory information gathering survey for nanomaterials under section 71 of CEPA. According to these reports, details of the new mandatory survey program would be published in the *Canada Gazette part I* at some point in February 2009. As of March 31, 2009, no details concerning this new mandatory survey had yet appeared in the Canada Gazette. The international nanotechnology policy community is watching this development closely, as this will be among the first mandatory schemes to be implemented that will extend to all nanomaterials in a given jurisdiction[35].

[35] But not likely the first - in January 2009, the French government tabled legislation that contains, under Article 73, the requirement that any person manufacturing, importing, or placing nanoparticle substances onto the market must periodically declare to the administrative authority the identity, quantities and uses of these substances. Full text of the proposed legislation is available online from: http://www.developpement-durable.gouv.fr/IMG/pdf/Texte_du_PJL_GE_2_cle21193f.pdf; accessed March 30, 2009.

Recently, EC and Health Canada have begun to take regulatory action on specific nanomaterials, by using the Significant New Activity (SNAc) provision of CEPA to gather information on nanomaterials classified as "existing" under the current provisions of CEPA. The SNAc provision under CEPA is essentially equivalent to the Significant New Use Rules (SNURs) already described in the current report for TSCA in the United States. In terms of procedure, a notice of intent to apply a SNAc to an existing substance must first be published in the Canada Gazette Part I, and is subject to a 60 day public comment period. All stakeholder comments are then reviewed and considered prior to the posting of a final SNAc notice in the Canada Gazette Part II.

In recent months, a number of notices of intent to apply the SNAc provisions under CEPA to nanomaterials classified as existing substances under CEPA have appeared. A comprehensive listing of all such nanoscale substances has not been published by the Government of Canada, nor has the precise rationale behind the choices of nanosubstances been communicated in an open, transparent manner. For the purposes of this regulatory action, the significant new activity for these "existing" nanomaterials is being defined as "*any activity involving the use of the substance in quantities greater than 10 kg per calendar year, where the substance has a particle size between 1 and 100 nanometres*"[36]. Note also the threshold amount of 10 kg per calendar year associated with this definition; this is ten-fold less than the normal requirements (100 kg per calendar year) currently under CEPA.

Regulation of Worker Health and Safety as it Relates to Nanotechnology

Responsibility for ensuring the health and safety of workers in Canada is a shared responsibility between federal and provincial regulatory agencies. At the federal level, Health Canada provides national leadership through its Workplace Health and Public Safety Programme. Health Canada also serves as the national coordinator for the Workplace Hazardous Materials Information System (better known as WHMIS). In addition, workplaces falling under federal jurisdiction are regulated by the Canada Labour Code, which is administered by Human Resources and Skills Development Canada (HRSDC).

Other aspects of ensuring worker health and safety are regulated by the provinces. For example, the Ontario *Occupational Health and Safety Act* administered by the Ontario Ministry of Labour, is intended to protect workers from health and safety hazards in the workplace; it sets out duties and workers rights, establishes procedures for dealing with workplace hazards and provides for enforcement under the Act.

A January 2009 study financed by the Quebec-based Institut de recherche Robert-Sauvé en santé et en sécurité du travail (IRSST) is notable in the context of nanotechnology regulation affecting worker safety. Entitled *Best Practices Guide to Synthetic Nanoparticle Risk Management*, the study report aims to provide information and best practices relating to the management of potential risks associated with nanotechnology in the workplace. The authors of the report recommend taking a preventative approach, "*even a precautionary approach*", to the avoidance of nanoparticle exposure. The authors' intent for this report is to support the development of good practices for nanoparticle handling in the workplace by Quebec industry and university laboratories. It will be interesting to see how the Quebec provincial government responds to this report.

[36] For an example of a recent SNAc notice of intent appearing in *Canada Gazette Part I*, see the issue of January 24, 2009, page 140, for Silane homopolymer, hydrolysis products with magnesium hydroxide (Significant New Activity Notice No. 15310, available from: http://canadagazette.gc.ca/rp-pr/p1/2009/2009-01-24/pdf/g1-14304.pdf; accessed March 31, 2009.

The Organisation for Economic Co-operation and Development (OECD)

At the international level, the bulk of the cooperative activity among jurisdictions relating to the risk assessment and regulation of nanotechnologies is occurring within the Organisation for Economic Co-operation and Development (OECD). Notably, all of the jurisdictions examined in this report – the US, UK, EU (through the Commission of the European Community), Australia and Canada – participate in the work of the OECD. A brief outline of the work currently being carried out by the OECD on nanotechnology follows.

There are two primary groups within the OECD working on activities related to nanotechnologies. Those are the Working Party on Manufactured Nanomaterials (WPMN), established in September 2006 by the OECD Chemicals Committee, and the Working Party on Nanotechnology (WPN), established by OECD's Committee for Science and Technology Policy in 2007. The WPMN coordinates international collaboration relating to the human health and environmental safety aspects of manufactured nanomaterials, in order to assist in the development of safety evaluation protocols for nanomaterials. In contrast, the objective of the WPN is to advise on emerging policy issues related to science, technology, and innovation, and to promote international co-operation to facilitate research, development, and the responsible development and use of nanotechnology. The work currently ongoing by the WPMN will very likely have a large impact on future regulatory amendment and regulatory development initiatives in individual jurisdictions in the coming years. We therefore provide an overview of the WPMN and its ongoing activities below.

The OECD Working Party on Manufactured Nanomaterials (WPMN)

The Working Party on Manufactured Nanomaterials focuses its efforts on determining the human health and environmental safety implications of manufactured nanomaterials, with a particular focus on the chemicals sector. This group is working towards ensuring a consistent international approach to hazard, exposure and risk assessment of nanomaterials, and its efforts are likely to be highly influential on the international stage. The work of the OECD WPMN is being implemented through a series of nine ongoing projects managed by separate steering groups. Each steering group has its own specific objectives and timelines. The nine projects are listed below:

Project 1: An OECD database on human health and environmental safety research

Project 2: Research strategies on human health and environmental safety impacts

Project 3: Safety testing of a representative set of manufactured nanomaterials

Project 4: Development of test guidelines for manufactured nanomaterials

Project 5: Co-operation on voluntary schemes and regulatory programmes

Project 6: Co-operation on Risk Assessment

Project 7: The role of alternative methods in nanotoxicology

Project 8: Exposure measurement and exposure mitigation

Project 9: Looking at the benefits / sustainability of nanotechnology (with the OECD WPN)

There are obviously close linkages between many of these projects, and the work of some steering committees is to some extent dependent upon the work of others. In addition, the WPMN is working closely with a committee of the International Standards Organisation (ISO) which is working to develop standards for nanotechnology, including terminology and nomenclature, metrology and instrumentation, specifications for reference materials, test methodologies, modelling and simulation methods, and science-based health, safety, and environmental practices.

In July 2008, the WPMN produced a *List of Manufactured Nanomaterials and List of Endpoints for Phase One of the OECD Testing Programme* in conjunction with Project 3, related to safety testing of nanomaterials. The WPMN has developed and agreed upon a priority list of fourteen representative manufactured nanomaterials that will be the focus of further investigation. The document also contains a list of approximately 60 endpoints dealing with the identification of nanomaterials, their physico-chemical properties and characterization, environmental fate and toxicology, mammalian toxicity, and material safety. The OECD Testing Programme will likely be very influential in individual jurisdictions as they seek to refine their own testing methodologies and risk assessment procedures.

Interjurisdictional Analysis

In this report, we set out to investigate the question: **"How have Canada and other jurisdictions reacted to the recent emergence of nanotechnology-based products in the marketplace?"**, focusing on the following questions, which are important from the perspective of regulatory governance.

- Which key event or events triggered **debate**, stakeholder consultations or policy development and how did jurisdictions involve the public and stakeholders?
- How have countries dealt with **policy options**? For example, have they swiftly moved to the development of regulations or did they carefully consider or use other policy instruments? How have jurisdictions addressed the issue of regulatory impact?
- How have the various jurisdictions addressed the conundrum that evidence-based regulatory action should be based on safety **data** but that such safety data is hard to obtain in the absence of established regulations?

Below, we will attempt to provide answers to each of these five questions in sequence, highlighting both commonalities and discrepancies in the approaches taken by the US, UK, EU, Australia and Canada.

Key Events in the Nanotechnology Debate

In our increasingly globalized society, the impacts of seminal events are not limited to the jurisdictions in which those events take place. In the case of the nanotechnology debate, two important early events have had broad-reaching international impacts: the announcement in 2000 of the US National Nanotechnology Initiative and the release in 2004 of the UK Royal Society and Royal Academy of Engineering report on the opportunities and uncertainties surrounding this emerging technology.

The 2000 announcement by US President Bill Clinton signaled that the United States was committed to capitalizing on nanotechnology, and proclaimed the US commitment to investing heavily in the development of this technology. In reaction to this announcement, other countries were pressured to

follow suit and subsequently released their own policy statements avowing their commitment to funding innovation in this emerging technology area.

A perhaps unintended impact of the availability of new research grants specific to nanotechnology through the US National Nanotechnology Initiative was an immediate re-branding of existing research programs. The sudden availability of dedicated funds for nanotechnology development provided an incentive for researchers to add the "nano label" to projects at the nano scale that previously had been labelled as "materials research", "semi-conductor research", "inorganic chemistry", and so forth. This process contributed to a perception that nanomaterials entered the research domain (and the marketplace) all of a sudden. Constructing a label in this fashion for innovation poses a communication problem for regulators who cannot and probably should not re-brand regulations in a similar way just to give the public the impression that they are part of the current surge in technological development.

The second seminal event was the 2004 report by the UK national academies (UK RS-RAE, 2004). Although the need to assess the ability of our regulatory systems to protect us from the potentially harmful impacts of nanotechnology had previously been raised by many (including David Forrest in March 1989), it was arguably the 2004 Royal Society report that triggered a substantive international policy debate surrounding the regulation of nanotechnology.

Beyond the international implications of these two seminal events, notable occurrences and past history in individual jurisdictions have contributed to "flavouring" the debate in different countries and have, to some extent anyway, underscored differences in approach.

In the US, policy statements on nanotechnology, particularly during the early days of the debate, tended to focus on innovative aspects and commercial potential. Until recently, there has been arguably less emphasis placed on the health and environmental risks of nanomaterials in the US to date than in other jurisdictions. A December 2008 report by the US National Research Council was critical of the federal government's lack of attention to date on EHS issues associated with nanotechnology. All signs indicate that this will be an area of renewed focus in the US in the coming years. The *National Nanotechnology Initiative Amendments Act of 2009*, which was passed by the House of Representatives in February 2009, contains measures for additional funding and research into the environmental, health and safety risks of nanotechnology. In many respects, the debate on nanotechnology in the US is similar to that in other jurisdictions, although it could be argued that there are more powerful (and heavily invested) industrial key players headquartered in the US than in other countries.

In contrast to the US, there has been far more emphasis in the UK and EU policy debates on the responsible and safe development of nanotechnology, and on the need for regulations to manage both EHS and ELSI aspects of the technology. Though innovation is a priority as in the US, there has been greater emphasis on proceeding with precaution. Formal and transparent public engagement and stakeholder consultation processes have been key features of nanotechnology policy development throughout the European Union. The EU and its Member States are leading the way internationally both in terms of their approach to the regulation of nanotechnology[37], and the extent to which they prioritize public engagement, consultation and transparency. Notably, the EU maintains excellent online resources

[37] **Note Added in Proof**: Particularly given very recent regulatory developments occurring at the end of March 2009.

pertaining to nanotechnology[38] which summarize international activities, EU research funding and innovation, activities and projects on education and mobility, safety aspects, as well as communication and debate. The European Commission has committed to informing the general public about nanotechnology, and has produced films, a brochure, and a series of leaflets toward that goal. This emphasis on public engagement has been informed by recent experience with genetically modified organisms. Another consequence of the GMO debate is a particular emphasis within Europe on assessing the potential risks of nanotechnology applications in food and food products (the focus on food can also be traced back to the widespread debate on "Mad Cow Disease" since the late 1980s).

Where foods are a source of particular focus in Europe, the nanotechnology debate in Australia has centered more on issues of workplace safety and specific health risks. This emphasis stems in large part from the Australian experience with asbestos, and the high incidence of mesothelioma in the country which has been associated with workplace exposures. At the same time that the debate on nanotechnology development and regulation was kicking into high gear in Australia, an inquiry into workplace exposures to toxic dust became a point of emphasis by civil society organizations like Friends of the Earth Australia and labour unions. Campaigns and input by such groups has had a large impact on the course of the Australia nanotechnology debate. Skin cancer rates in Australia are high. Coupled with recent governmental campaigns to increase the use of sunscreens, these facts have put another point of emphasis on the inclusion of nanoparticles in sunscreens in this jurisdictional debate.

On the international stage, Canada is well known for its early contributions to the debate on ELSI issues surrounding nanotechnology. Of late, Canada is additionally leading the way in terms of implementing anticipated regulatory measures outlining a mandatory reporting survey of all nanomaterials. Canadian provinces, particularly Quebec and Alberta but including BC and Ontario, have clearly stated their commitment to nanotechnology innovation and capitalizing on its future benefits. To date, however, there has been no formal statement of policy by the federal government. The Council of Canadian Academies recently completed a regulatory gaps analysis at the behest of the Government of Canada, but the government's reaction to this report remains an unknown at this time.

The public debate surrounding nanotechnology has unfolded in the contexts of pre-existing jurisdictional attitudes and differing focal points of perceived risk. Jurisdictional differences in the unfolding of the public debate have not, however, translated directly into substantive differences in policy development, as we shall see below.

Jurisdictional Approaches to Policy Development

A first step in policy development taken in the majority of jurisdictions was the release of a strategy (or policy statement) on nanotechnology. A draft document produced by the OECD Working Party on Nanotechnology indicates that as of 2008, seventeen of twenty-four OECD countries surveyed (71%) had developed dedicated strategies for nanotechnology at either the national government and/or agency level. The US, EU, and Australia all have named nanotechnology strategies; the UK also has a dedicated, though unnamed strategy. Notably, Canada is unique among the five jurisdictions examined in the current

[38] The Nanotechnology Homepage of the European Commission can be found at: http://cordis.europa.eu/nanotechnology/; accessed March 31, 2009.

report in that it has not yet communicated a national overall strategy for nanotechnology development and/or regulation (although individual provinces have done so, but there remains no national strategy).

A majority of the jurisdictions examined have additionally issued policy statements on nanotechnology regulation, and such statements have been remarkably consistent across jurisdictions:

1. Such statements first note the potential benefits of nanotechnology, and state the government's intention to pursue nanotechnology research and development with a view to future economic benefits.
2. Next, it is generally noted in such statements that the benefits of nanotechnology are, however, accompanied by potential risks, the extent of which we do not yet fully appreciate.
3. Jurisdictions then stress that until such a time as there is more information available regarding the potential risks of nanotechnology, existing regulatory frameworks are sufficiently rigorous to ensure the continued health and safety of consumers and the viability of the environment.
4. Next, jurisdictions tend to note the current lack of information pertaining to the novel properties of nanomaterials, and a lack of metrics, methodologies, and standards to deal with hazard and exposure evaluation and overall risk assessment.
5. Finally, jurisdictions note that they will review the need for nano-specific regulatory frameworks in the future, and update existing regulatory frameworks as required.

There are admittedly nuances and slight variations of the above statement in different jurisdictions, but the fact that individual jurisdictions take the time and care to issue such statements is, in and of itself, noteworthy. Such statements are designed to serve a dual purpose. On one hand, they signal to industry that the jurisdiction in question is committed to the continued development of nanotechnology, and that it is therefore safe for companies to invest in that jurisdiction. On the other hand, they signal to consumers that jurisdictional governments are committed to ensuring the continued health and safety of its citizens and of the environment.

In Canada, the July 2008 report by the Council of Canadian Academies Expert Panel on Nanotechnology contains a number of recommendations of a similar vein. However, the Government of Canada has yet to respond to the CCA report and as such, there remains some uncertainty about the direction the federal government will take on the regulation of nanotechnology.

The importance of such policy statements should not be trivialized. They are a key aspect of ensuring the transparency of the policy development process, and help to signal to all interested parties – the general public, industry, and civil society organizations alike – that jurisdictional governments are aware of the issues and committed to working with stakeholders toward the development of solutions.

With respect to policy options, we observe again a number of commonalities that are only nuanced by subtle differences. These options have been undertaken in a roughly stepwise manner, as follows:

1. Formal statement of policy on nanotechnology, or preparation of a jurisdictional strategy;
2. Attempt to gain more knowledge of the potential risks associated with nanotechnology;
3. Perform or commission a regulatory gaps analysis; and
4. Make use of current regulations to "indirectly" regulate nanotechnology.

Twenty years later, in 2009, there are currently as yet no nanotechnology-specific regulatory frameworks in place in any national or international jurisdiction[39]. However, this does not mean that nanomaterials are not regulated. Very recently, one jurisdiction – the EU – has begun to incorporate definitions of nanotechnology and nanotechnology-specific regulatory requirements into legislation. However, the EU approach to the regulation of nanotechnology remains piecemeal at this time, in that it addresses the regulation of nanotechnology only in the context of other legislative initiatives, specifically the Cosmetics Directive recast and revision of the Novel Foods Regulation. By taking this arguably indirect approach to the regulation of nanotechnology, the potential impacts of regulating nanotechnology in cosmetics and foods are notably not addressed in regulatory impact assessments. In contrast, legislative proposals or regulatory measures directly aimed at evaluating the health, safety, and environmental impacts of nanotechnology across the full spectrum of products and industries would in theory precipitate regulatory impact requirements.

However, expert panels convened by governments to date have all unilaterally agreed that there is no immediate for the development of nanotechnology-specific regulatory frameworks. Such panels have generally concluded that the early products of nanotechnology entering the marketplace can be effectively regulated using existing regulatory streams, with the caveat that risk assessment methodologies will need to be reviewed and likely adapted in order to reflect the small size and unique properties of nanomaterials. Despite the level of general agreement by expert panels to date, certain stakeholder groups – most notably consumer groups and environmental NGOs – continue to call for the immediate development of nano-specific regulations or for a moratorium on continued development. Such calls have been previously considered by expert panels – for example, the UK national academies (UK RS-RAE, 2004) – but summarily ruled out and described as an inappropriate policy option for nanotechnology.

Expert panels have also commented on the uncertainty which remains as to whether the development of further nanotechnology-specific regulations will be required as more complex nanotechnology-derived products begin to enter the marketplace. In their 2007 policy brief *Nanotechnology Risk Governance*, the IRGC referred to four generations of nanotechnology products and production processes. These are as follows:

- First Generation: “Passive” (steady function) nanostructures (year 2000 onwards);
- Second Generation: “Active” (evolving function) nanostructures and nanodevices (from 2005);
- Third Generation: Integrated nanosystems (systems of nanosystems) (after 2010);
- Fourth Generation: Heterogeneous molecular nanosystems (after 2015).

The IRGC’s approach to discussions of nanotechnology risk governance was to divide these generations into two distinct frames of reference: Frame One, which refers only to “passive” (first generation) nanoproducts, and Frame Two, which refers to Generations 2-4, i.e. the more complex nanoproducts. In our assessment, expert panel opinions to date have really only assessed the need for nano-specific regulations to manage the risks associated with “passive” nanostructures. We note this here if only to point out that regulatory systems are realistically only now beginning to deal with products that have been on the market for the better part of a decade. If regulators are to have systems in place to deal with future generations of nanoproducts, including “convergent products” that combine biotechnology and

[39] However, the same cannot be said for municipalities – note the example of Berkeley, California as described on page 16 of the current report.

nanotechnology, then a good deal of research and work will need to be done prior to their entry onto the commercial marketplace – otherwise regulators will be left scrambling to keep up with the pace of innovation.

Regulating the Unknown: International Information Gathering Initiatives

A key aspect of our research is the question: how have Canada and other jurisdictions addressed the conundrum that evidence-based regulatory action should be based on safety data but that such safety data is hard to obtain in the absence of established regulations?

In answer, we find that jurisdictions continue to struggle with this issue. Despite experiences and lessons learned from previous cases of emerging technologies (for example, biotechnology) the challenge of regulating in the face of the unknown is considerable and complex; understandably, regulators continue to struggle with this issue.

When faced with a challenging scenario, i.e. how to regulate nanotechnology, it's worth acknowledging that as human beings our natural tendency – and this applies equally to regulators and policy makers – is to seek further clarification and additional information.

It is therefore not entirely surprising that one of the first regulatory steps taken in various jurisdictions seeking to manage the potential environmental, health and safety impacts of nanotechnology has been the implementation of product stewardship initiatives.

The first such initiatives – implemented by the EPA in the US, Defra in the UK, and NICNAS in Australia – were all voluntary in nature. The success of such voluntary initiatives is the subject of great debate. The regulatory agencies administering such programs have proclaimed them as successes, but they have generally been viewed as ineffective by the broader nanotechnology policy community. One of the criticisms associated with these voluntary programs has been a lack of incentives to encourage industry participation, which has resulted in responses from only a minor fraction of those companies actively engaged in developing nanoproducts in each jurisdiction.

Lately, regulatory bodies seem to be moving increasingly toward mandatory measures for the collection of information. There are two categories of such mandatory measures: (1) mandatory reporting measures applicable to priority nanomaterials, and (2) mandatory information reporting initiatives or surveys applicable to all nanomaterials.

The first category of such mandatory measures are currently being implemented in the US and Canada. In the US, the EPA and the California Department of Toxic Substances Control (DTSC) are taking regulatory measures to gather information relating to priority substances containing nanomaterials, such as carbon nanotubes. By issuing the October 2008 Notice that the EPA considers carbon nanotubes to be new substances under the *Toxic Substances Control Act*, the EPA clearly intends to gather health and safety data on carbon nanotubes through the Premanufacture Notices that companies will now need to submit. The DTSC's motives in launching their ongoing Chemical Information Call-in on carbon nanotubes are also clear. In addition, both the US and Canada have taken regulatory action to collect information on nanomaterials classified as "existing substances" under their respective chemical management programs, through the issuance of regulatory notices by the EPA regarding significant new

use rules (SNURs) under TSCA and by Environment Canada and Health Canada regarding significant new activity notices (SNAc's) for specific nanomaterials under CEPA.

Mandatory information reporting initiatives or surveys applicable to all nanomaterials are currently being considered or developed in France and Canada. In Canada, Environment Canada and Health Canada have recently signalled their intention to proceed regulatory action implementing a mandatory information gathering survey concerning the reporting and tracking of all nanomaterials manufactured or imported into Canada in 2008 (under section 71 of the *Canadian Environmental Protection Act 1999*). As of the time of writing, the specific details of this mandatory survey had yet to be announced in part I of the *Canada Gazette*.

It is likely that additional jurisdictions will move toward mandatory models for gathering information on nanomaterials in the coming years. However, it will be a few years before the success of such mandatory reporting models is known. While few would argue with the need to collect as much useful information as possible regarding the potential benefits and risks of nanotechnology, best practices in the collection of such information remain uncertain.

Toward Best Practices in the Regulation of Nanotechnology

It may be premature to evaluate what works and what does not in the regulation of nanotechnology, especially given that regulations in the strictest sense of the word are only just beginning to emerge. The perspective of regulatory governance, however, allows us to adopt a very wide perspective and to include all activities that have a regulatory aim (including public debate, policy announcements, data management approaches, voluntary schemes, industry self-regulation, etc.).

Based on the descriptive evidence collected above, we observe six key regulatory governance principles that we propose for consideration by regulators. For each of these principles, we will provide a short description of how we think they should be handled and will comment on any "best practices" that may have emerged to date. In developing this set of principles, the following sources on good governance principles provided inspiration for our selection: UK Better Regulation Commission (2000), Graham *et al*. (2003), Stern & Cubbin (2005), Government of Canada (2007b), United States Government Accountability Office (2009), and Slater (2009).

The six guiding regulatory governance principles are as follows:

1. The regulatory response should be **coordinated**. This should include coordination at the international level, between states, provinces or member states, as well as coordination at the inter-departmental and inter-agency level in individual jurisdictions.

2. Regulatory approaches to nanotechnology should be **flexible and adaptive.**

3. Information gathering initiatives, a key first step in an adaptive regulatory system, should be designed with the **endpoints** in mind, should offer **incentives** for participation, and should involve both industry and academic researchers.

4. Risk management approaches should strive to be comprehensive, by incorporating a **lifecycle approach** to govern the potential risks of nanotechnology, and should be designed with the importance of scope and timing horizons in mind.

5. Risk management approaches should strive for balance and **proportionality** between the costs and benefits of regulating. The **regulatory impact** of mandatory *versus* 'indirect' approaches *versus* an absence of regulation should be considered.

6. An understanding of the profile of the beneficiaries of nanotechnology and the risk bearers in concert with who is **accountable** would go a long way toward ensuring the appropriate deployment of both technology and regulatory oversight. Stakeholders should be engaged appropriately and regulatory systems should be **transparent**.

The Need for Coordination in Regulatory Governance of Nanotechnology

There have been repeated calls for a coordinated and international approach to addressing the regulatory governance deficits arising from the applications of nanotechnology (IRGC, 2007; Abbott *et al*., 2006). Currently, "*regulatory structures and processes are fragmented with respect to jurisdiction, type of regulation, and the lack of harmonization of risk assessment and management procedures, both nationally and internationally*" (IRGC, 2007).

The many potential applications of nanotechnology are extremely varied—encompassing food, chemical, and electronics products, medicines and medical devices, environmental technologies, and multiple other applications. This poses a unique regulatory governance challenge on a scale never before witnessed in the regulation of emerging technologies. At present, no single regulatory structure spanning such a wide range of consumer products exists in any jurisdiction in the world. Coordinating the regulation of nanotechnology between departments and agencies at the jurisdictional level, not to mention between regulatory streams within individual departments (e.g. pharmaceuticals, medical devices, or food products are all regulated by Health Canada), will be key to ensuring that we identify and fill any potential regulatory gaps which might exist. This coordination will also be essential to create a consistent and common language among regulators from different industrial sectors. Finally, the coordination will improve the consistency of decision-making and be less confusing to the regulated, who may have to deal with multiple regulatory agencies.

Beyond the challenge of coordinating regulation of nanotechnology at a jurisdictional level, there exists the additional complexity of coordinating policies at the international level. In the absence of a harmonized approach to risk management on the international stage, there is the risk of competitive arbitrage, whereby both companies and governments may seek to secure a competitive advantage by lowering regulatory barriers to research and manufacturing without regard to the potential health, safety, and environmental implications of such an approach. Global trade is now at a scale where regulatory decisions and oversight in other jurisdictions can quickly translate into a risk to consumers or the environment at home. Finally, safety data on nanotechnology products, including those already on the market, are scarce; the joining of forces and efficient exchange of knowledge are imperative. This exchange is going to be particularly valuable if international cooperation results in a measure of similarity in language, definitions, and regulatory requirements.

As for an existing "best practice", it is too soon to judge which jurisdiction has addressed coordination most effectively. The important role of the OECD comes to mind, however. It is fortunate that Canada is so well engaged at the OECD level, as this should results in excellent access to the development of the important work done by this international body.

Flexible and Adaptive Approaches to Regulatory Development

In the academic literature, flexible, responsive, and gradually evolving approaches to risk regulation of nanotechnology are generally favoured over a singular reliance on traditional "command and control" approaches. At an abstract level, it is difficult to disagree with the view that flexibility and adaptability go hand-in-hand with building and sustaining an emerging regulatory system in a rapidly changing environment (context does matter).

In the real world, discussions are ongoing. Certain stakeholder groups have called for mandatory ("command and control") regulatory approaches up front, but others such as the American Chemical Association, DuPont, and even Environmental Defense in the US have instead called for initiatives to increase the body of knowledge about risks.

We should note that flexibility and adaptability are also very helpful tools when building upon existing standards, structures and processes. Several expert panels in multiple jurisdictions have all reached the same basic conclusion – that there is no need at the present time to develop nanotechnology-specific regulations. However, this is not to say that there is no need for new testing protocols, new data, or an adaptation of existing regulatory systems[40]. Furthermore, a need for nanotechnology-specific regulatory frameworks or systems may emerge in the future based upon new knowledge or when next generation nanotechnologies or convergent technologies come to market (so-called active nanostructures and nanodevices, or integrated and heterogeneous nanosystems).

With respect to a best practice, we do not find a great diversity of approaches among the five jurisdictions surveyed. The EU is arguably at the forefront of nanotechnology regulation at present, although all jurisdictions are currently holding on to existing regulatory approaches (i.e. addressing nanotechnology in the context of existing statutes and regulations or on a case-by-case basis as statutes specific to cosmetics and novel foods are being revised and updated, as in the EU) and promise to review such approaches in the future when appropriate. It is interesting to note that these rather uniform policy responses follow comparatively diverse public debates that are flavored by diverging cultures and regulatory histories.

Sophisticated Information Gathering

No matter what the regulatory structure, decision-making will always depend on evidence. Experts agree that the existing evidence on the transportation, transformation and biological effects of nanomaterials is insufficient and that, thus, risk assessments are not feasible or grossly incomplete. Another issue lies in the lack of compatibility between the available data and the needs of regulators (who often have very specific data needs which allow them to render consistent and comparable regulatory decisions). This lack of required evidence is a serious issue considering the number of products already on the market.

[40] As currently seems to be occurring in the European Union, where nanotechnology-specific requirements are being introduced into regulatory systems for cosmetics and novel foods as they are being updated and revised.

A well designed information gathering initiative should therefore be the first step in adaptive risk management and regulation. It is critical to ensure that such programs are well designed, with regulatory endpoints in mind, and that incentives are provided to ensure compliance. In our opinion, the ongoing work of the OECD Working Party on Manufactured Nanomaterials is the gold standard in this regard. The WPMN document listing endpoints that will be assessed in the first phase of the OECD testing programme is a tremendous resource, and the results of the initiative can be predicted to have a broad impact on the international stage. International initiatives such as the work by the WPMN are likely to be far more effective than one-off initiatives undertaken in individual jurisdictions which do not offer appropriate incentives for participation by industry.

We believe that the full potential of *voluntary* reporting measures has not yet been explored because of insufficient attention to the incentives that would promote a response from industry (be they positive, as in compensation for compliance, or negative, in that they could result in a public outcry based on non-compliance). As such initiatives would continue to be classified as voluntary, they would not contribute to the perception that a given jurisdiction is unfriendly to industry, but the provision of incentives would help to ensure the collection of appropriate and thorough information.

Doug Sylvester and colleagues at Arizona State University have posited that "*in the immediate future, the greatest need for 'regulation' is to increase the accumulation and dissemination of knowledge about the current state of nanotechnology research, development, and application, and about the risks and benefits of specific products and processes*" (Sylvester *et al.*, 2008). We agree with this statement, but caution that jurisdictions must additionally take care to ensure that the information gathered through reporting initiatives, be they voluntary or mandatory, is of the highest possible quality. If the quality of the data obtained is poor, then it will be of only limited utility to jurisdictions looking to base future regulatory programs on the information gathered through these initiatives.

Another source of potential information regarding the potential environmental, health and safety impacts of nanotechnology (as well as other aspects) which should not be ignored is the realm of academic research. Currently, there remains a gap between research results reported in the academic literature and research which is of utility from the regulatory perspective. Regulators could address this gap by forming strategic partnerships with academia. By helping to improve the selection of research endpoints, experimental designs and approaches to data collection by academic researchers, this would help to improve the utility of such studies in the regulatory context. Input from regulators could additionally improve communication and cooperation between materials development experts and toxicologists, who do not always see eye-to-eye on the design of research studies. Industry stewardship initiatives are an important aspect of information gathering, but they are only part of the equation.

Strategic research programs initiated by jurisdictional research funding agencies in partnership with regulators can also yield results of importance to regulators when appropriately targeted. Notable initiatives are already underway which are expected to yield information on safety research, nanotoxicology, and environmental impacts of nanomaterials. For example, in September 2008 the US-based National Science Foundation in partnership with the US EPA announced awards to two Centers for the Environmental Implications of Nanotechnology. These centers will look at the interactions between nanomaterials, the environment, plant and animal life, and will as part of their mandate translate any knowledge thus obtained into evidence-based risk assessment strategies.

At this point in time, the OECD approach to information gathering appears to be is the most effective. Time will tell if direct partnerships between regulators and academic researchers or indirect funding arrangements though granting organizations will succeed. As for voluntary approaches to the disclosure of industry information, it would be worthwhile to consider systems with appropriate incentive systems.

A Comprehensive, Lifecycle Approach to Risk Management

In our survey, we found remarkably little explicit emphasis on the use of a "lifecycle approach" in risk assessment, that is to say, an approach which takes into account the full lifecycle of the products of nanotechnology from starting materials through to product disposal. A notable exception was the Cardiff report prepared for the UK Government. It will, however, be critical to managing the risks of nanotechnology that we consider both the biological and environmental fate of nanomaterials. On this point, the reader is directed to the work of others on this subject (for example: Shatkin, 2008), who have previously described the lifecycle approach in great detail and argued convincingly for the need for such an approach.

While it is likely that lifecycle assessments are actually already being used in most if not all of the five jurisdictions reviewed, we believe that it represents a best practice to *explicitly* state that nanomaterials will be evaluated in this fashion. Past experience with traditional chemicals has shown that leaving out an important lifecycle step (for example, disposal or transportation) can lead to serious environmental or human health impacts.

A Delicate Balance in Regulation: Weighting Potential Risks vs. Benefits

Regulation should be based on a balance between risks and benefits and rooted in an understanding of regulatory impacts. In the words of the International Risk Governance Council (IRGC):

> "A particular concern...is that the opportunities flowing from new technologies and innovations are not forgone due to inadequate or inappropriate risk governance, including poor communication. When these technologies have the capacity to alleviate major global concerns, a failure to adopt them has potentially catastrophic consequences"[41].

This comment from the IRGC underlines the importance of "getting it right" and achieving the proper balance when it comes to the regulation of nanotechnology. In Canada, as in other jurisdictions, there is the potential to eventually derive multiple benefits from the products of nanotechnology. Coordinated, transparent, and adaptive approaches to regulatory governance, with particular attention paid to cooperative activity at the international level, will help to ensure that Canada is well positioned to eventually derive maximal benefits from this significant emerging platform technology.

Nothing specific can be said about regulatory impact at this point in time. As we have already noted, no jurisdiction has yet implemented a set of nanotechnology-specific regulations. Instead, debate on nanotechnology risk assessment and risk management has primarily occurred in the context of existing regulations, or (as in Europe) as a side-effect of attempts to update outdated regulations. For example, in the US and Canada regulatory measures around nanomaterials have recently been implemented through

[41] http://www.irgc.org/-Nanotechnology-.html

jurisdictional chemicals management programs (TSCA in the US and CEPA in Canada). Because such measures have been taken using existing regulations, however, there has been no formal attempt (that we are aware of, anyway) to assess the impact such measures might have on the nanotechnology industry in particular.

Similarly, in Europe much of the debate surrounding nanotechnology regulation has taken place in the context of initiatives to update existing Directives or Regulations – in this report, we have focused our narrative on the new chemicals regulation (REACH), the Novel Foods Regulation, and updates to the Cosmetics Directive. As an example, consider the impact assessment of the European Commission proposal respecting the Cosmetics Directive Recast. The full *Impact assessment report on simplification of the "Cosmetics Directive" – Directive 76/768/EEC* notes the challenge posed by innovations in the cosmetics sector, including the "use of known ingredients in nanosizes" and the need to assess the safety impacts of such innovation and others, but it does not directly address the potential impact of regulating nanomaterials in cosmetics through the proposed Cosmetics Regulation (EC, 2008e).

Notwithstanding the high degree of consensus among panels of experts that current regulatory frameworks will be sufficient in the short term future to manage the potential risks of nanotechnology, it is unclear what impact, if any, this approach may have upon the burgeoning nanotechnology industry, particularly with respect to small and medium-sized enterprises. Small companies are more likely to struggle under an extensive regulatory burden than larger, well-established companies.

We believe that it would represent a best practice if the various jurisdictions would attempt to formally assess the impact of mandatory versus "indirect" versus no regulation at all.

Ensuring an Accountable and Transparent Approach

Stating that a regulatory system ought to be accountable may sound obvious. It is, however, worth spending some time thinking about what accountability should mean in the context of nanotechnology regulatory governance. The experience in the biotechnology context has shown that it is very important to understand the profile of risk bearers and beneficiaries of a new technology. People are willing to carry a risk as long as they derive a benefit. If there is no substantive benefit, then they are likely to be very skeptical. It is also important to pay attention to who has the burden of proof and who takes the fall if and when things go wrong. The power to make decisions has to be coupled with a willingness to endure the consequences (it cannot be a case of decision-makers assuming both risks and benefits provided things go well but laying blame on others when things go badly).

The appropriate engagement of stakeholders is another element of accountability. Stakeholder needs must be heard, fairly evaluated and acted upon. It is not easy to engage stakeholders well but a large body of knowledge has accumulated over the last twenty years and, arguably, the EU has found a way to implement a sophisticated system. It will be very interesting to compare jurisdictions in a few years time and to correlate stakeholder satisfaction and public trust with past public engagement activities. It is likely, however, that jurisdictions are so different culturally that no "best practice" can be formulated at an international level.

An accountable regulatory system also needs to be a transparent system. Transparency is often demanded as an essential component of democratic governance. In terms of the risk governance of nanotechnology, one can also make the argument that it will ultimately be the public's *perception of risk* which will have a greater impact on politically-sensitive risk management decisions than any actual measurement of risk. Regulators have an opportunity to narrow the gap between real and perceived risks through a transparent approach to assessment and decision-making. This outcome would benefit regulators, the regulated and consumers alike.

Transparency may require special attention in the nanotechnology context for several reasons. The rapid growth of information makes it challenging to achieve full access to information and transparency. Equally, the rapid growth of the nanotechnology industry and associated changes in the technology make it difficult to acquire knowledge and then to disclose it appropriately. One approach that may represent a "best practice" is the one-window internet access to nanotechnology information in the EU. We hope that the issues of transparency and accountability will be given full consideration by regulators seeking to manage the huge challenge of adapting existing systems to appropriately managing the risks and benefits of the massive wave of new nanotechnology products that is expected to enter the commercial marketplace in the very near future.

References

Abbott, Kenneth W., Gary E. Marchant, and Douglas J. Sylvester. (2006). *A Framework Convention for Nanotechnology?* Paper available online: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=925981; accessed March 31, 2009.

Australian Office of Nanotechnology. (2008). *National Nanotechnology Strategy Implementation Plan*. Available online: http://www.innovation.gov.au/Industry/Nanotechnology/Documents/NNSFeb08.pdf; accessed March 31, 2009.

Australian Senate Community Affairs References Committee. (2006). *Workplace exposure to toxic dust*. Report available online: http://www.aph.gov.au/senate/committee/clac_ctte/completed_inquiries/2004-07/toxic_dust/report/report.pdf; accessed March 31, 2009.

Commission de l'éthique de la science et de la technologie. (2007). *Ethics and Nanotechnology: A Basis for Action*. Position statement available online from: http://www.ethique.gouv.qc.ca/IMG/pdf/Avis-anglaisfinal.pdf; accessed March 31, 2009.

Council for Science and Technology. (2007). *Nanosciences and Nanotechnologies: A Review of Government's Progress on its Policy Commitments*. Report available online from: http://www2.cst.gov.uk/cst/news/Files/nano_review.pdf; accessed March 31, 2009.

Davies, J. Clarence. (2009). Testimony before the Subcommittee on Commerce, Trade, and Consumer Protection of the Committee on Energy and Commerce, US House of Representatives. February 26, 2009. Available online: http://energycommerce.house.gov/Press_111/20090226/testimony_davies.pdf; accessed March 31, 2009.

Chaudry, Q., Blackburn, J., Flyod, P. George, C., Nwaogu, T., Boxall, A. and Aitken, R. (2006). *Final Report: A scoping study to identify gaps in environmental regulation for the products and applications of nanotechnologies*. This report (commissioned by Defra) is available from: http://randd.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&Completed=0&ProjectID=13855#RelatedDocuments; accessed March 31, 2009.

Department of Health and Human Services. (2009). *Interim Guidance for Medical Screening and Hazard Surveillance for Workers Potentially Exposed to Engineered Nanoparticles*. Document available online: http://www.cdc.gov/niosh/docs/2009-116/pdfs/2009-116.pdf; accessed March 31, 2009.

EFSA Scientific Committee. (2009). *Scientific Opinion of the Scientific Committee on a request from the European Commission on the Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety*. The EFSA Journal. **958**: 1-39. Opinion adopted February 10, 2009, available from: http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/sc_op_ej958_nano_en,0.pdf?ssbinary=true; accessed March 31, 2009.

ETC Group. (2003). *From Genomes to Atoms: The Big Down*. January 2003 report available online: http://www.etcgroup.org/upload/publication/171/01/thebigdown.pdf; accessed March 31, 2009.

European Commission. (2000). *Communication from the Commission on the precautionary principle*. Document available online: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2000:0001:FIN:EN:PDF; accessed March 31, 2009.

European Commission. (2004). *Towards a European Strategy for Nanotechnology*. Communication from the Commission adopted May 2004. Available online: http://ec.europa.eu/nanotechnology/pdf/nano_com_en.pdf; accessed March 31, 2009.

European Commission. (2005). *Nanosciences and nanotechnologies: An action plan for Europe 2005-2009*. Communication from the Commission to the Council, the European Parliament and the Economic and Social Committee. Available online from: http://ec.europa.eu/nanotechnology/pdf/action_plan_brochure_en.pdf; accessed March 31, 2009.

European Commission. (2007). *REACH in brief*. Document available online from the EC website: http://ec.europa.eu/environment/chemicals/reach/pdf/2007_02_reach_in_brief.pdf; accessed March 31, 2009.

European Commission. (2008a). *Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee: Regulatory Aspects of Nanomaterials*. Available online from: http://ec.europa.eu/nanotechnology/pdf/comm_2008_0366_en.pdf; accessed March 31, 2009.

European Commission. (2008b). *Commission Recommendation of 07/02/2008 on a code of conduct for responsible nanosciences and nanotechnologies research*. Available online from: http://ec.europa.eu/nanotechnology/pdf/nanocode-rec_pe0894c_en.pdf; accessed March 31, 2009.

European Commission. (2008c). *Commission Regulation (EC) No 987/2008 of 8 October 2008 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes IV and V*. Published in the Official Journal of the European Union on October 9, 2008, and available from: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:268:0014:0019:EN:PDF; accessed March 31, 2009.

European Commission. (2008d). *Proposal for a Regulation of the European Parliament and of the Council on cosmetic products (recast)*. Full text of the proposed simplification of the Cosmetics Directive available from: http://ec.europa.eu/enterprise/cosmetics/doc/com_2008_49/com_2008_49_en.pdf; accessed March 31, 2009.

European Commission. (2008e). *Commission Staff Working Paper: Impact assessment report on simplification of the "Cosmetics Directive" – Directive 76/768/EEC*. Full report available online from: http://ec.europa.eu/enterprise/cosmetics/doc/com_2008_49/sec_2008_117_com_2008_49.pdf; accessed March 31, 2009.

European Commission. (2008f). *Proposal for a Regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No XXX/XXXX*. Document available online from: http://ec.europa.eu/food/food/biotechnology/novelfood/COM872_novel_food_proposal_en.pdf; accessed March 31, 2009.

European Food Safety Authority. (2009). *The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety: Scientific Opinion of the Scientific Committee*. Document, adopted February 10, 2009, available online from: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902361968.htm; accessed March 31, 2009.

Food Standards Agency (FSA). (2008). *Report of FSA Regulatory Review*. An August 2008 review of the potential implications of nanotechnologies for regulations and risk assessment in relation to food prepared by the UK Food Standards Agency. Report available online at: http://www.food.gov.uk/multimedia/pdfs/nanoregreviewreport.pdf; accessed March 31, 2009.

Forrest, David. (1989). *Regulating Nanotechnology Development*. Paper available online: http://www.foresight.org/nano/Forrest1989.html; accessed March 31, 2009.

Frater, Lori, Elen Stokes, Robert Lee, and Taiwo Oriola. (2006). *An Overview of the Framework of Current Regulation affecting the Development and Marketing of Nanomaterials*. Commissioned report prepared for the UK Department of Trade and Industry (DTI) by Cardiff University. Available online from BERR: http://www.berr.gov.uk/files/file36167.pdf; accessed March 31, 2009.

Friends of the Earth Australia. (2005). *Submission from Friends of the Earth Australia to the Senate Community Affairs Committee: Inquiry into workplace exposure to toxic dust*. Available online from: http://nano.foe.org.au/filestore2/download/77/FoEA%20submission%20to%20senate%20inquiry%20into%20toxic%20dust.pdf; accessed March 31, 2009.

Friends of the Earth Australia. (2008). *Mounting evidence that carbon nanotubes may be the new asbestos*. Report available online from: http://nano.foe.org.au/filestore2/download/265/Mounting%20evidence%20that%20carbon%20nanotubes%20may%20be%20the%20new%20asbestos%20-%20August%202008.pdf; accessed March 31, 2009.

Gavelin, Karin and Richard Wilson, with Robert Doubleday. (2007). *Democratic Technologies? The final report of the Nanotechnology Engagement Group (NEG)*. Report available online from: http://www.involve.org.uk/assets/Publications/Democratic-Technologies.pdf; accessed March 31, 2009.

Government of Canada. (2007a). *Mobilizing Science and Technology to Canada's Advantage*. The Government of Canada's Science & Technology Strategy is available online from the Industry Canada website: http://www.ic.gc.ca/eic/site/ic1.nsf/vwapj/S&Tstrategy.pdf/$file/S&Tstrategy.pdf; accessed March 31, 2009.

Government of Canada. (2007b). *Cabinet Directive on Streamlining Regulation.* Available online from: http://www.regulation.gc.ca/directive/directive01-eng.asp; accessed March 31, 2009.

Graham, John, Bruce Amos and Tim Plumptre. (2003). Principles *for Good Governance in the 21st Century*. Institute on Governance Policy Brief available from: www.iog.ca/publications/policybrief15.pdf; accessed March 31, 2009.

Grobe, Antje, Ortwin Renn, and Alexander Jaeger. (2008). *A report for IRGC: Risk Governance of Nanotechnology Applications in Food and Cosmetics*. Report available from the IRGC website: http://www.irgc.org/IMG/pdf/IRGC_Report_FINAL_For_Web.pdf; accessed March 31, 2009.

International Risk Governance Council. (2007). *Nanotechnology Risk Governance: Recommendations for a global, coordinated approach to the governance of potential risks*. Policy brief available online: http://www.irgc.org/IMG/pdf/PB_nanoFINAL2_2_.pdf; accessed March 31, 2009.

Kulinowski, Kristen M. (2008). *Environmental Impacts of Nanosilver: An ICON Backgrounder*. Available online from the ICON website: http://cohesion.rice.edu/centersandinst/icon/emplibrary/ICON-Backgrounder_NanoSilver-in-the-Environment-v4.pdf; accessed March 31, 2009.

Ludlow, Karinne, Diana Bowman, and Graeme Hodge. (2007). *A Review of Possible Impacts of Nanotechnology on Australia's Regulatory Framework*. The "Monash Report" may be found online at: http://www.innovation.gov.au/Industry/Nanotechnology/Documents/MonashReport2008.pdf; accessed March 31, 2009.

Marburger, John H., III, and James L. Connaughton. (2007). *Principles for Nanotechnology Environmental, Health and Safety Oversight*. Memorandum for the Heads of Executive Departments and Agencies dated November 8, 2007. Available online: http://www.ostp.gov/galleries/default-file/Nano%20EHS%20Principles%20Memo_OSTP-CEQ_FINAL.pdf; accessed March 31, 2009.

Mnyusiwalla, Anisa, Abdallah S. Daar, Abdallah S., and Peter A. Singer. (2003). '*Mind the gap': science and ethics in nanotechnology*. Nanotechnology. **14**: R9-R13. Article available online from: http://www.iop.org/EJ/article/0957-4484/14/3/201/t303R1.pdf?request-id=38de99b4-e000-4728-ada2-20a865e24d4d; accessed March 31, 2009.

NICNAS. (2007). *Summary of call for information on the use of Nanomaterials – January 2007*. Information sheet available online from: http://www.nicnas.gov.au/Publications/Information_Sheets/General_Information_Sheets/NIS_Call_for_info_Nanomaterials.pdf; accessed March 31, 2009.

Organisation for Economic Co-operation and Development. (2008a). *List of Manufactured Nanomaterials and List of Endpoints for Phase One of the OECD Testing Programme*. Series on the Safety of Manufactured Nanomaterials. Number 6. Document available online: http://www.olis.oecd.org/olis/2008doc.nsf/LinkTo/NT00003282/$FILE/JT03246895.PDF; accessed March 31, 2009.

Organisation for Economic Co-operation and Development. (2008b). *Current Developments/Activities on the Safety of Manufactured Nanomaterials/Nanotechnologies*. Tour de Table at the 4th Meeting of the Working Party on Manufactured Nanomaterials held in Paris, France, June 2008. Document available online: http://www.olis.oecd.org/olis/2008doc.nsf/LinkTo/NT0000799E/$FILE/JT03257288.PDF; accessed March 31, 2009.

Prime Minister's Science, Engineering and Innovation Council (PMSEIC). (2005). *Nanotechnology: Enabling technologies for Australian innovative industries*. Australian PMSEIC report available online: http://www.dest.gov.au/NR/rdonlyres/1E1B501A-727A-4153-85EF-134B2DAF0925/4112/nanotechnology_pmseic110305.pdf; accessed March 31, 2009.

Roco, M.C. (2001). *From vision to the implementation of the U.S. National Nanotechnology Initiative*. Journal of Nanoparticle Research. **3**: 5-11.

Royal Commission on Environmental Pollution (RCEP). (2008). *Novel Materials in the Environment: The case of nanotechnology*. Twenty-seventh Report of the RCEP presented to the UK Parliament in November 2008. Available online from: http://www.rcep.org.uk/novelmaterials.htm; accessed March 31, 2009.

Schlyter, C. (2009). *Draft Report on regulatory aspects of nanomaterials (2008/2208(INI))*. Committee on the Environment, Public Health and Food Safety. Text of the draft report is available online from: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+COMPARL+PE-418.270+01+DOC+PDF+V0//EN&language=EN; accessed March 31, 2009.

Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). (2006). *The appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies*. Modified opinion adopted by SCENIHR in March 2006. Available from: http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_003b.pdf; accessed March 31, 2009.

Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). (2009). *Risk Assessment of Products of Nanotechnologies*. Report available from: http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_023.pdf; accessed March 31, 2009.

Shatkin, Jo Anne. (2008). *Nanotechnology: Health and Environmental Risks*. CRC Press.

Slater, Robert. (2009). *The Regulation of Known Unknowns: Toward Good Regulatory Governance Principles*. Regulatory Governance Brief will be available online as of April 2009 at the following link: www.regulatorygovernance.ca.

State Government of Victoria. (2008). *Victorian Nanotechnology Statement: Taking Leadership in Innovations in Technology – February 2008*. Statement available online from: http://www.business.vic.gov.au/busvicwr/_assets/main/lib60021/2008%20nanotechnology%20statement.pdf; accessed March 31, 2009.

Stern, John, and John Cubbin. (2005). *Regulatory effectiveness: the impact of regulation and regulatory governance arrangements on electricity industry outcomes*. World Bank Policy Research Working Paper available online: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=695386; accessed March 31, 2009.

Sylvester, Douglas J., Kenneth W. Abbott, and Gary E. Marchant. (2008). *Risk Management Principles for Nanotechnology*. Nanoethics. **2**: 43 – 60. Available online from the Social Sciences Research Network: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1020104; accessed March 31, 2009.

UK Better Regulation Commission. (2000). *Five Principles of Good Regulation*. This document, which is based on principles originally developed by the UK Better Regulation Task Force in 1997 is available online from: http://archive.cabinetoffice.gov.uk/brc/upload/assets/www.brc.gov.uk/principles.pdf; accessed March 31, 2009.

UK Government. (2008). *Statement by the UK Government about Nanotechnologies*. This statement, issued on February 28, 2008, no longer appears to be accessible online.

UNESCO. (2006). *The Ethics and Politics of Nanotechnology*. Report available online from: http://unesdoc.unesco.org/images/0014/001459/145951e.pdf; accessed March 31, 2009.

United Kingdom - Royal Society and Royal Academy of Engineering (RS-RAE). (2004). *Nanoscience and nanotechnologies: opportunities and uncertainties*. Report available for download from: http://www.nanotec.org.uk/finalReport.htm; accessed March 31, 2009.

United States Environmental Protection Agency (US EPA). (2007). *Nanotechnology White Paper*. Document available online: http://www.epa.gov/osa/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf; accessed March 31, 2009.

United States Environmental Protection Agency (US EPA). (2008). *TSCA Inventory Status of Nanoscale Substances – General Approach*. Document dated January 23, 2008 is available online from: http://www.epa.gov/oppt/nano/nmsp-inventorypaper2008.pdf; accessed March 31, 2009.

United States Environmental Protection Agency (US EPA). (2009). *Nanoscale Materials Stewardship Program Interim Report – January 2009*. Available online from: http://epa.gov/oppt/nano/nmsp-interim-report-final.pdf; accessed March 31, 2009.

United States Food and Drug Administration (US FDA). (2007). *Nanotechnology: A Report of the U.S. Food and Drug Administration Nanotechnology Task Force – July 25, 2007*. Report available online from: http://www.fda.gov/nanotechnology/taskforce/report2007.pdf; accessed March 31, 2009.

United States Government Accountability Office. (2009). *A Framework for Crafting and Assessing Proposals to Modernize the Outdated U.S. Financial Regulatory System.* Document available online from: http://www.gao.gov/new.items/d09310t.pdf; accessed March 31, 2009.

US National Research Council. (2008). *Review of Federal Strategy for Nanotechnology-Related Environmental, Health, and Safety Research*. Free executive summary available online, or book available to order, from: http://www.nap.edu/catalog.php?record_id=12559; accessed March 31, 2009.

van Calster, Geert. (2008). *Risk Regulation, EU Law and Emerging Technologies: Smother or Smooth?* NanoEthics. **2**: 61-71.

Which?. (2008). *Small Wonder? Nanotechnology and Cosmetics*. Briefing available online from: http://www.which.co.uk/documents/pdf/nanotechnology-and-cosmetics-161175.pdf; accessed March 31, 2009.

Carleton UNIVERSITY | School of Public Policy and Administration

The Regulatory Governance Initiative

The Regulatory Governance Initiative (RGI) at Carleton University builds on the proven track record of Carleton's School of Public Policy and Administration to develop regulatory capacity and competence through research, education, and dialogue. Its scope is regulatory policy, governance, and management. Its approach is holistic and problem-driven. The RGI assembles expertise from the humanities, social and natural sciences as needed. For most projects, practitioners in the private, public and nonprofit sectors collaborate with scholars from the RGI network.

School of Public Policy and Administration
Carleton University
1125 Colonel By Drive
Ottawa, Ontario, Canada, K1S 5B6
Tel +1 613 520 2600
www.carleton.ca/sppa

Address inquires and comments to:
info@regulatorygovernance.ca

The Director of Research can be reached at:
marc_saner@carleton.ca