Council of Canadian Academies
Conseil des académies canadiennes

# REPORT IN FOCUS

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# Small is Different: A Science Perspective on the Regulatory Challenges of the Nanoscale


## Abstract

Nanomaterials and nanoproducts present exciting new opportunities for improving the quality of life of Canadians. At the same time, the scientific knowledge on which one can quantitatively assess the risks associated with these materials is limited, especially given the diversity of nanomaterials and their potential applications. Many of the uncertainties associated with risk assessment and risk management are not unique to nanomaterials, but have been present in the introduction of other new technologies, such as biotechnology and nuclear technology. These uncertainties have been managed in Canadian regulatory frameworks by taking a precautionary approach – giving priority to ensuring the safety of health and the environment.

This Report in Focus summarizes the work of the Expert Panel on Nanotechnology (the panel) established by the Council of Canadian Academies (the Council) to assess "...the state of knowledge with respect to existing nanomaterial properties and their health and environmental risks, which could underpin regulatory perspectives on needs for research, risk assessment and surveillance."

Given the current limited state of scientific knowledge regarding many nanomaterials, the panel identifies the need to give priority to the development and resourcing of a strategic research agenda to improve our understanding of the risks associated with each specific class of nanomaterials. Research into metrology, into properties of nanomaterials that are linked to biological responses, and into effective monitoring and surveillance strategies should be given high priority.

Although the panel believes that it is not necessary to create new regulatory mechanisms to address the unique challenges presented by nanomaterials, existing regulatory mechanisms could and should be strengthened. First, an interim classification of nanomaterials should be developed. Second, the current regulatory "triggers" – i.e., the criteria used to identify when a new material or product should be reviewed for health and environmental effects – should be reviewed, as existing mechanisms will not identify all nanomaterials and nanoproducts. Third, standardized approaches to the proper handling of nanomaterials should be developed to ensure proper worker safety. Finally, the current metrological capacity for nanomaterials should be strengthened to ensure effective surveillance of their effects on consumers, workers and the environment.

The panel also focused on specific management-centred regulatory challenges. It identified an adaptive, life-cycle approach to the risk assessment and risk management of nanomaterials as most appropriate. The large number of classes of nanomaterials and the need to make case-by-case assessments of health and environmental risk mandate a coordinated approach across agencies within government, among levels of government and with international partners in order to avoid duplication of effort and the creation of inconsistent or conflicting regulatory regimes. A critical aspect of the management of risks in a regulatory context is the involvement of the public, which includes not only self-identified stakeholders but the broader public who act as citizens and consumers. Providing meaningful avenues for public participation in the formulation of regulatory policies governing nanomaterials is essential to the establishment and maintenance of public confidence in this technology.

The existing Canadian regulatory approaches and risk management strategies are appropriate for the challenges presented by nanomaterials, provided that a greater investment is made in strategic research associated with the risk assessment of these materials, that attention is paid to addressing issues of classification, regulatory triggers and regulatory capacity, and that regulatory agencies coordinate their activities with each other, between federal and provincial levels of government and with the regulatory agencies of other countries.



A Sample of Existing Nanoproducts
David Hawxhurst for the Project on Emerging Nanotechnologies
Available at: http://penmedia.org/stock/products/
Accessed July 9, 2008.

As our fundamental understanding of the physical world has evolved over the course of the last several centuries, so too has our ability to manipulate matter. We can create an extraordinary variety of materials and finished products, many of which have improved our quality of life. The ability to manipulate matter at the most minute scale – the nanoscale roughly defined as between one and one hundred billionths of a metre – has brought with it the ability to create new classes of materials. These materials, known generically as nanomaterials, have unusual, unexpected properties that at the same time are potentially very useful, with applications ranging from new pharmaceuticals to environmental remediation to sports equipment. At the same time, they present concerns arising from potential hazards to human health and the environment that are not well understood.

It is in this context that the Council of Canadian Academies (the Council) was charged by Health Canada as a lead agency, along with several other departments and agencies of the Government of Canada, to undertake a study focusing on the following question:

> *What is the state of knowledge with respect to existing nanomaterial properties and their health and environmental risks, which could underpin regulatory perspectives on needs for research, risk assessment and surveillance?*

To perform this task, the Council assembled the Expert Panel on Nanotechnology (the panel) comprised of leading scientists involved in research into the fundamental properties of nanomaterials, scientists who are engaged in the study of the hazards and routes of exposure of nanomaterials to humans and the environment, social scientists who are experts on the roles of government and society in the introduction of new technologies, and experts in the public and private sector with a broad range of experience in the development and regulation of new products. This Report in Focus summarizes the findings of the panel.

As anyone familiar with the history of innovation is aware, new technologies have the potential to harm human health and the environment. For that reason, governments have established clear mechanisms, usually implemented through regulatory procedures based on scientific knowledge, to ensure that any risks are appropriately managed. Mechanisms for regulating beneficial new technology have been quite successful, if measured by the very significant overall improvement over the last century in the health of Canadians during a time of enormous technological innovation. At the same time, some substances originally characterized as safe have been subsequently found to present serious risks to health and the environment. Examples include polychlorinated biphenyls (PCBs), used as an insulator and later found to be a toxic organic pollutant that bioaccumulates; the herbicide Agent Orange, shown subsequently to release dioxins that are now known to have serious health effects; and the most recent example of bisphenol A found in some plastics used in food and beverage containers and now suspected of having significant biological effects. These examples illustrate that regulatory mechanisms cannot guarantee that all risks can be eliminated.

The panel study is the first, comprehensive, Canadian effort to address the current state of scientific knowledge regarding the risks presented by engineered nanomaterials, and how that knowledge should guide the approach taken to steward the process through which nanomaterials are responsibly introduced into Canadian trade and commerce.

In the view of the panel, an assessment of what is known and not known about the health and environmental risks of engineered nanomaterials is urgently needed in both the Canadian and international context, given that hundreds of nanoproducts – consumer products employing nanomaterials – are already being marketed internationally. Countries such as the United States and the United Kingdom are actively pursuing assessments that would assist regulatory capacity. In Canada, there are numerous channels through which domestic nanotechnology capacity is being created. This creates, consequently, a need for attention to risk and public trust issues to complement and balance those activities. Indeed, there is a nanotechnology "buzz," both internationally and in Canada, among governments and within academia, industry and non-governmental organizations. This is animated in part by a concern about the risks of nanotechnology and the regulatory implications of those risks.

This Report in Focus distills into a few pages the findings arising from eight months of work by the panel. Besides the scientific knowledge of the panel members, these findings were informed by a web-based public consultation on the question of

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nanomaterial regulations and by informal dialogue with numerous stakeholders. In the end, the panel's findings and conclusions create a picture that hopefully will provide guidance to all the stakeholders involved in the development of this exciting new technology.

There have been many studies and reviews of nanotechnology performed over the last decade, with some of the most influential being the studies by the Royal Society and Royal Academy of Engineering of the United Kingdom (UK-RS/RAE, 2004); by the world's largest reinsurer Swiss Re (Swiss Re, 2004); the International Risk Governance Council (IRGC, 2007); and by the Woodrow Wilson International Center for Scholars (PEN 2007, PEN 2008). The unique contribution of this report is its clear focus on assessing the state of scientific knowledge concerning engineered nanomaterials from the perspective of risk assessment and regulation. In this regard, it is designed to assist the Government of Canada in developing a robust regulatory approach to these materials, a task that is urgent and time-sensitive. This report therefore provides an overview of what we know generally about nanomaterials, their properties, and how they differ from more conventional materials. It then discusses the current state of the science with regard to the risks associated with exposure to these materials, and identifies specific findings with regard to the nature of the regulatory approach that would most effectively address the issues presented by nanomaterials and products that make use of them.

The sponsors of this assessment requested that the focus of the report be on the scientific knowledge that would inform regulatory perspectives on those engineered nanomaterials that are already in the marketplace in one form or another, or whose entry into trade and commerce could occur over the next several years. In order to maintain that focus, the panel has not discussed several other important issues that might have been included in its mandate, such as the current state of knowledge of the health and environmental effects of incidentally introduced nanomaterials (e.g., ultrafine particle exposure in the workplace), the implications of next-generation nanomaterials that are currently still in very early research and development, or specific proposals for regulation of nanomaterials *per se*. Rather, the panel hopes that its findings and recommendations will provide a science-based assessment that will assist the sponsors in taking appropriate next steps as quickly as possible in meeting what is an international challenge: the effective regulation of engineered nanomaterials entering trade and commerce.

## A Primer on "Nano"

Nanomaterials are defined broadly as those classes of materials that have one or more physical dimensions in the nanoscale – ranging from 1 to 100 nanometres (nm) – or materials with larger dimensions that have structures embedded on their surface that have nanoscale features. A nanometre is one billionth of a metre ($10^{-9}$ m), an incredibly small size that can only be understood by comparison to objects that we already consider quite small – the diameter of a human hair is approximately 100,000 nm, that of a red blood cell is approximately 8,000 nm, and a typical virus measures between 80 and 120 nm in diameter.

Nanomaterials can come in a variety of shapes, with nanoparticles being objects that are less than approximately 100 nm in every dimension. Scientists have been able to create objects from sheets of material formed into tubes with diameters in the nanoscale and lengths of several hundreds or thousands of nanometres. They have also been able to fabricate objects consisting of larger macroscopic devices with nanoscale features. The term nanotechnology has been introduced to encompass the technologies used to manipulate and characterize nanomaterials and nanostructures, as well as the resulting materials and products.

**A nanometre is one billionth of a metre ($10^{-9}$ m), an incredibly small size — the diameter of a human hair is approximately 100,000 nm.**

Although we define nanomaterials based simply on their size, what makes them of interest are the very novel properties exhibited by some of these classes of materials. In some cases, the manufacture of a commonly occurring substance in nanoparticle form – where particles of the substance are created with sizes less than 100 nm – results in a material whose physical and/or biological properties differ substantially from those of the substance in its bulk form. A good example of this is the element gold. Within the macroscopic realm, the factors that govern gold's physical properties are independent of size. However, in 5 nm nanoparticle form, the optical and catalytic properties of gold are vastly different from those of gold in 50 nm nanoparticle form. A second example, also in commercial use, is titanium dioxide ($TiO_2$), which in nanoparticle form is used as an active ingredient in sunscreen formulae. Its properties in nanoparticle and bulk form are quite different.

Nanomaterials include classes of objects having quite complex physical structure on the nanoscale, exemplified by those materials known collectively as carbon nanotubes (CNTs). Made primarily of carbon rolled up into tubes with diameters of a few or tens of nanometres and lengths of up to several thousand nanometres, CNTs have been shown to conduct electricity and heat exceptionally well and to exhibit extraordinary structural strength. These are all properties not seen in the various forms of bulk carbon.

The novel physical and chemical properties of nanomaterials arise from their extraordinarily small size scales, and are difficult to predict from the known properties of the same materials in bulk form, or even from theoretical extrapolations based on atomic or molecular properties. At the same time, the knowledge of their properties, while currently limited, is increasing very rapidly given active international efforts and the ability to more reliably extrapolate and predict the physical properties of nanomaterials is increasing at a comparable rate. However, the understanding of the biological effects arising from human or environmental exposure to these nanomaterials remains quite limited. Current literature suggests that the unique biological properties of nanomaterials stem from the relationship of their physical and chemical properties with (1) biological transport and environmental fate, (2) portals of entry into organisms, organs and cells, and (3) cellular response.

Public awareness of nanomaterials, and nanotechnology more broadly, appears to be quite modest, as determined by various surveys and studies assessing the public's knowledge of these materials. This has not deterred advocates and critics of nanotechnology from advancing various highly speculative or non-scientific views that from the panel's perspective tend to polarize public discourse. The low level of public awareness creates both the need and the opportunity for various stakeholders and the public to engage in informed discussion on the safe and beneficial introduction of nanomaterials into Canadian trade and commerce.

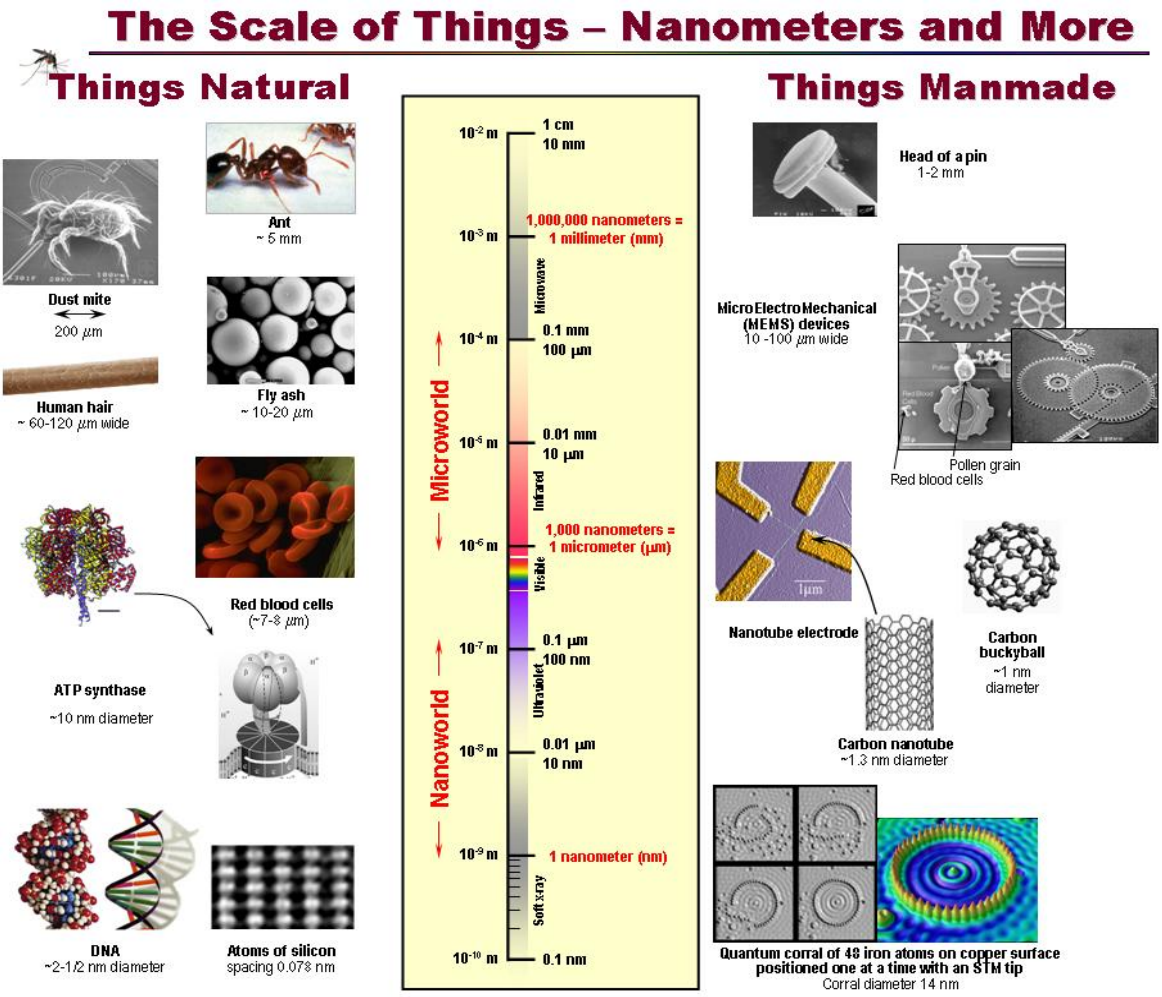
## A Science Perspective on Nanomaterial Risk

As with many new technologies, one of the challenges for regulators confronting nanotechnology arises from the need to ensure public safety when new products and materials are introduced. To achieve this, it has become best practice to perform a risk assessment of new products, to identify potential areas of concern for human health and environmental integrity, and to institute the appropriate risk management strategies. Frameworks of scientific risk assessment and risk management are well developed, in Canada and abroad. Though there are differences of detail in implementation in each jurisdiction, this risk analysis framework is based on the following steps:

- Identification of the hazards associated with a material;
- Assessment of human and environmental exposure; and
- Identification of the appropriate risk management strategies.

These steps provide an approach that can be applied to the evaluation of the potential risks of nanomaterials to human health and the environment. Much greater scientific understanding of the complex behaviours of these materials is, however, required before science-based regulation of the technology can be fully implemented.

Consequently, there are significant challenges in the application of this framework to nanomaterials, arising largely from a lack of scientific knowledge in a number of key areas. The hazard identification process for nanomaterials is difficult because of the limited knowledge of how the diverse physical and chemical properties of nanomaterials affect the biological/toxicological properties of most nanomaterials under development. Although there is a significant body of data on the biological and environmental effects of nanomaterials – one recent review identified over 400 different peer-reviewed studies – there remains significant scientific uncertainty on the degree of exposure to nanomaterials and the resultant biological effects of such exposure.




Adapted from - Office of Basic Energy Sciences, U.S. Department of Energy
Available at: http://www.science.doe.gov/bes/scale_of_things.html Accessed on July 9, 2008

The principal challenges can be identified as (1) introduction or establishment of a systematic and standardized metrology (i.e., the science and technology of measurement) for physically characterizing nanomaterials, (2) uncertainty in the nature of the dose-response relationship between exposure of nanomaterials and biological effects (hazard characterization), and (3) the difficulties associated with measuring exposure to nanomaterials and surveillance once they are introduced into the environment. Most of these challenges arise from the sheer magnitude of the number of different nanomaterials, and the lack of a comprehensive predictive model that would allow researchers to effectively classify them into manageable hazards classes.

Metrology – The challenges associated with metrology are substantial, given that the current scientific literature is equivocal on fundamental issues such as what physical properties are of most relevance to the biological interactions of a nanomaterial. Perhaps the only clear consensus at the current time is that the traditional measures of dose – either in terms of mass or volume of a substance – are unlikely to be appropriate when working with nanomaterials. This arises directly from the one physical property shared by all nanomaterials: that they have unusually high ratios of active surface area to volume compared with materials in bulk form. Hence, studies are forced to look at multiple metrics in order to yield reproducible and systematic results. The panel identified at least 10 physical and chemical properties that should be considered in the characterization of a nanomaterial: size, mass, composition, surface area, shape/morphology, crystallinity, surface charge, surface chemistry, solubility, and aggregation and agglomeration. In most cases, standard classification and measurement tools are lacking and limit scientific progress.

Dose-Response – The enormous diversity of nanomaterials and their relevant properties makes it a daunting challenge to conduct *in vitro* and *in vivo*[i] evaluation of their biological effects. Preliminary results show that *in vitro* testing may not always accurately predict hazards. At the same time, reviews of the large number of *in vivo* studies have concluded that most have been limited and difficult to reproduce.

Exposure – The uncertainty regarding the appropriate metrology for nanomaterials has presented very significant difficulties in monitoring nanomaterial exposure in the workplace and the environment. Furthermore, the biological and environmental pathways unique to nanomaterials are still largely unexplored in detail. Issues such as the potential for bioaccumulation and possible long-term persistence in the environment have been studied only for a very small number of nanomaterials.

New ways of measuring exposure, dose and response in relation to nanomaterials require development. This strongly suggests that any regulatory approach adopt a life-cycle strategy for nanomaterials. Although not a new regulatory concept, past experience with chemical substances has shown that simply looking at manufactured nanoproducts and their immediate uses is not sufficient to predict long-term health and environmental outcomes.

Overall, the lack of a robust body of comprehensive scientific data on nanomaterial hazards and dose-response relationships, nanomaterial exposure in biological systems and the environment, and long-term consequences to health and the environment provide for only a qualitative risk assessment of a few nanomaterials. These "gaps" in our scientific knowledge should inform priorities for targeted and coordinated research into nanomaterial metrologies, toxicology, exposure routes and long-term health and environmental effects.

## Underpinning Regulatory Perspectives on Nanomaterials

The Canadian regulatory system is based upon the principle that where there are significant levels of uncertainty in the scientific assessment of risks, it is appropriate to exercise caution in favour of protecting human health and the environment. This presumption in favour of safety, usually denoted the "precautionary principle," would be appropriate in the context of any specific regulatory approach to nanomaterials and nanoproducts, given the uncertainties identified earlier. However, it is important to understand how the precautionary principle is applied as an overall "approach" in Canada. Quoting directly from the Privy Council Office report of 2003 (PCO, 2003): "Sound scientific information and its evaluation must be the basis for applying precaution; the scientific information base and responsibility for producing it may shift as knowledge evolves" and "mechanisms should exist for re-evaluating the basis for decisions and for providing a transparent process for further consideration". This suggests that an adaptive, life-cycle approach should be an element of any regulatory framework for nanomaterials and nanoproducts.

**Currently, there are no nanomaterial-specific regulations in effect in Canada.**

Given the current state of knowledge, the panel identifies the need to give priority to the development and resourcing of a strategic research agenda to improve our understanding of the risks associated with each specific class of nanomaterials. Research into metrology is of highest priority, specifically focused on the development of validated measurement methods and standards, along with nano-capable instrumentation, so that researchers are provided with consistent methodologies and criteria for evaluating nanomaterial properties and their behaviours. Research is needed to identify those properties of nanomaterials that induce biological responses. Research is also needed into the most effective means of monitoring and surveillance of nanomaterials and nanoproducts over their entire life-cycle.

Currently, there are no nanomaterial-specific regulations in effect in Canada, although Health Canada and Environment Canada have both taken first steps in recognizing the potentially unique aspects of nanomaterials. The regulatory agencies are relying on existing legislative authority delegated to them through such instruments as the Canadian Environmental Protection Act (EC, 2006). Although the panel is of the view that it is not necessary to create new regulatory mechanisms to address the unique challenges presented by nanomaterials, it does note that the existing regulatory mechanisms could and should be strengthened in a variety of ways.

First, an interim classification of nanomaterials should be developed. Although internationally-coordinated efforts in this area are underway under the auspices of the Organisation for Economic Cooperation and Development (OECD) and Canada is playing an appropriate role, adoption of an interim classification mechanism would facilitate the identification and regulation of nanomaterials entering Canadian trade and commerce. In particular, any reporting mechanisms – whether voluntary or mandatory – will be ineffective without standardized terminology.

Second, the current regulatory "triggers" – that is, the criteria used to identify when a new material or product should be reviewed by regulatory bodies for health and environmental effects before introduction into commerce – should be reviewed, as it is not clear that the current triggers would identify all nanomaterials and nanoproducts.

Third, the current lack of monitoring tools and standards specific to nanomaterials means that workers and employers cannot effectively monitor worker exposure. Standardized approaches to the proper handling of nanomaterials are required to ensure proper worker safety.

Finally, the current metrological capacity – having the standards and methods for measuring properties and effects of nanomaterials – is insufficient to allow the surveillance of their effects on consumers, workers and the environment.

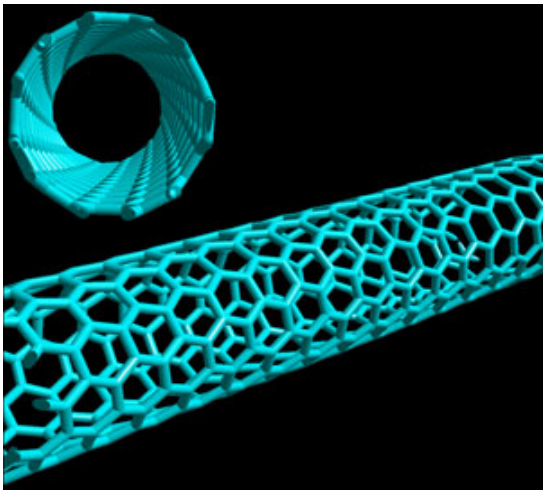
The panel focused on specific management-centred regulatory challenges. Given the expected evolution in the scientific knowledge surrounding nanomaterial risk assessment and management, a regulatory perspective that takes a life-cycle approach should also be adaptive as it accumulates experience and scientific knowledge evolves. The large number of nanomaterial classes, and the need to make case-by-case assessments of health and environmental risk mandate a coordinated approach to research into risk assessment and management across agencies within government, among levels of government and with international partners in order to avoid duplication of effort and the creation of inconsistent or conflicting regulatory regimes. A successful regulatory environment will depend on the production and distribution of a significant amount of knowledge.

A critical aspect of the management of risks in a regulatory context is the involvement of the public, which includes not only self-identified stakeholders but the broader public who act as citizens and consumers. The level of acceptance of nanomaterials into Canadian trade and commerce will depend on how effectively communication surrounding the benefits and risks of this new technology is performed. While it may be important to producers to communicate the benefits of any new nanomaterials and nanoproducts, government regulatory bodies should focus their efforts on fostering an open and informed public debate. Several examples of how this can be done already exist, such as the "Nanodialogues" approach undertaken in Britain. The establishment of meaningful avenues for public participation in the formulation of regulatory policies governing nanomaterials is essential to the establishment and maintenance of public confidence in this technology. The widest spectrum of stakeholders should be involved in the determination of the approach to regulating the introduction of new nanomaterials and products to the market, especially with respect to the desired level of precaution appropriate to ensure safety to human health and the environment.

**Summary of Specific Findings**

Regarding the definition of nanomaterials and current public awareness of the issues surrounding them:

1. Nanotechnology encompasses the technologies used to manipulate and characterize nanostructures as well as the resulting materials and products. Nanomaterials and nanotechnology are not the same thing.
2. The physical, chemical and biological properties of many nanomaterials differ from those of their constituent atoms and molecules, and from those of the bulk material.
3. The properties of nanomaterials are very diverse due to the many possible permutations of structure, chemical composition and shape.
4. Nanomaterials have novel but potentially controllable properties. These allow them to be used as precursors in the development of new products and devices.
5. The physical and chemical properties of nanomaterials may lead to unanticipated behaviours in environmental and biological systems.
6. Public awareness of nanotechnology in Canada is relatively low and public attitudes are therefore vulnerable to exaggerated claims by both proponents and critics.



Carbon Nanotube (CNT)
R. Bruce Weisman, Rice University
Available at: http://www.nsti.org/img/nwn/mf0601_single-walled.jpg Accessed on July 9, 2008

### Summary of Specific Findings

Regarding the state of the science informing nanomaterial risk assessment and risk management:

1. Nanomaterials can pose particular challenges to risk assessment, and hence to regulation, because they exhibit properties based on their physical structure and their chemistry.
2. The diversity of possible nanomaterials is vast and the tolerances of a biological system to changes in the physicochemical properties of nanomaterials that determine their behaviour are poorly understood.
3. To date, there are no unique biological effects associated with exposure to nanomaterials, but there is still a poor understanding of how specific nanomaterials lead to specific endpoints.
4. Prevailing human and ecological risk assessment frameworks are robust, but their application to nanomaterials requires new ways of measuring exposure, dose and response.
5. Changes in the potential for nanomaterials to cause harm at different stages in their life-cycle imply a need for a life-cycle approach to risk assessment.
6. There are inadequate data to inform quantitative risk assessments on current and emerging nanomaterials. At most, only qualitative risk assessments are feasible given the current state of knowledge.
7. Systematically-targeted research is needed to fill the gaps and reduce uncertainty.

### Summary of Specific Findings

Regarding regulatory perspectives on nanomaterials:

1. Uncertainty in science and regulation can inhibit technology development and undermine public confidence in the ability to protect adequately human health and environmental quality. Uncertainty in science can be offset by clarity and certainty in the terms and conditions under which such materials may enter trade and commerce.
2. Evidence from other industries suggests that the private sector prefers to have regulatory certainty even if the level of precaution invoked is relatively high.
3. At present, it is not possible to implement a robust and reliable "science-based" regulatory approach to nanoproducts. In this situation, it is important to ensure that the appropriate precautionary measures guide the scientific assessment of risk and the selection of standards of safety.
4. A transparent and robust precautionary approach normally includes prior approval before allowing entry into commerce of any material over which there is the type of uncertainty displayed by nanomaterials and nano-enabled products.
5. The establishment of meaningful avenues for public participation in the formulation of regulatory policies governing nanotechnology is essential to the establishment of public confidence in the governance of the technology.
6. Until such time as a robust, science-based risk management regime is feasible, it is critical to involve the widest spectrum of stakeholders in the determination of the approach to regulating the introduction of new nanomaterials and products to the market, especially with respect to the desired level of precaution as it concerns potential human health and environmental risks.
7. Interim terminology and classification are needed to help regulators effectively oversee this emerging group of materials and products.
8. Current regulatory triggers are not sufficient to identify all nanomaterials entering the market that may require regulatory oversight.
9. In the absence of standardized terminology, information being acquired from monitoring systems is likely to be inconsistent and limited in its usefulness. In the context of occupational settings, standardized information regarding the proper handling of nanomaterials is required to ensure proper worker safety. New tools are needed to accurately monitor worker exposure.
10. The current metrological capacity for identifying and monitoring nanomaterials is insufficient to ensure the surveillance of their effects on consumers, workers and the environment. This is further limited by the inability to ensure adequate identification of existing and future nanomaterials and products containing them.
11. An adaptive, life-cycle approach explicitly allows for regulatory adaptation to scientific and technological uncertainties by revising earlier decisions as new information arises.
12. The diversity in both material type and usage of nanomaterials, the magnitude of scientific research that is needed and the increasing presence of nanomaterials in both Canadian and international products will require governments to work collaboratively. High levels of intra- and inter-governmental coordination will be needed.
13. The safe introduction of nanomaterials into trade and commerce will require a targeted research approach to both risk assessment and risk management. Additional human and monetary investments will be required to respond to the increasing knowledge and management demands posed by nanotechnology.
14. As scientific research fills in the knowledge gaps, the decisions respecting the precautionary measures applied to nanoproducts can be revised.
15. Validated measurement methods and standards, along with nano-capable instrumentation, are needed in order to provide researchers with consistent methodologies and criteria for evaluating nanomaterial properties and behaviours.
16. Research is needed to identify these properties of a nanomaterial that enable it to elicit an adverse biological response. Further research is needed to identify appropriate regulatory responses regarding nanomaterial exposure.
17. Research, monitoring and surveillance (over the entire life-cycle of the material) will all need to be carried out in order to assess where and how these exposures are most likely to occur.

## In Conclusion

Nanomaterials and nanoproducts present exciting new opportunities for improving the quality of life of Canadians. At the same time, the scientific knowledge on which one can quantitatively assess the risks associated with these materials is limited, especially given the diversity of nanomaterials and their potential applications. Many of the uncertainties associated with risk assessment and risk management are not unique to nanomaterials, but have been present in the introduction of other new technologies, such as biotechnology and nuclear technology. These uncertainties have been managed in Canadian regulatory frameworks by taking a precautionary approach, giving priority to ensuring the safety of health and the environment.

The panel believes this is an appropriate approach to the introduction of this new technology. The existing Canadian regulatory approaches and risk management strategies are appropriate to this new challenge, provided that a greater investment is made in strategic research associated with the risk assessment of these materials, that attention is paid to addressing issues of classification, regulatory triggers and regulatory capacity, and that regulatory agencies coordinate their activities with each other, between federal and provincial levels of government and with the regulatory efforts in other countries.

## Endnote

[1] In vivo studies involve tests performed on a living organism, such as a controlled clinical study involving human test subjects while in vitro are those carried out on cells or tissues that have been cultured in petri dishes and occur outside of the body.

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*Science Advice in the Public Interest*

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