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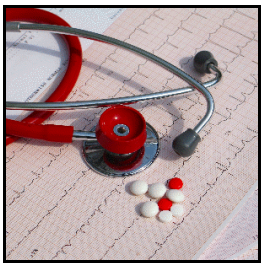
Discussion Paper on a Policy Framework for Nanotechnology



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Discussion Paper on a Policy Framework for Nanotechnology

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About the Canadian Institute for Environmental Law and Policy (CIELAP)

Founded in 1970, as the Canadian Environmental Law Research Foundation (CELRF), the Canadian Institute for Environmental Law and Policy (CIELAP) is an independent, not-for-profit professional research and educational institute committed to environmental law and policy analysis and reform. CIELAP is incorporated under the laws of the Province of Ontario and registered with Revenue Canada as a charitable organization. Our registration number is 11883 3417 RR0001.

CIELAP provides leadership in the research and development of environmental law and policy that promotes the public interest and sustainability.

About the Author

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Summary

On March 16, 2007, CIELAP held a one-day workshop in Toronto to explore policy considerations for nanotechnology. Along with additional research, this workshop provided the basis for CIELAP to develop a proposed Canadian Nanotechnology Policy framework, outlined in the body of this document.

CIELAP supports a goal statement and context for nanotechnology policy that is centred on an explicit recognition and endorsement of sustainable development. The policy challenges for nanotechnology are enormous, and currently are dominated by a lack both of scientific information and also of basic policy tools, including definitions and metrology; a legal and regulatory framework; and structures and resources for public engagement. Despite these huge gaps, however, many parallels with other issues and institutional arrangements exist, and could be adapted for nanotechnology. Due to nanotechnology's extraordinarily rapid commercialization and development, speed and a strong sense of urgency are needed by government for a responsible Canadian approach to the creation of policy for this area.

The following are twelve key elements that CIELAP believes must be addressed in any Canadian policy framework for nanotechnology: (1) Basic societal goals; (2) Public education and engagement; (3) An inventory of activities and information sources; (4) Lead agencies; (5) Technical issues such as terminology and metrology; (6) Regulatory approach, including science, risk assessment, and stakeholder involvement; (7) Labeling and consumer protection; (8) Liability and intellectual property regimes; (9) Science and research support; (10) Commercialization and social and economic benefits; (11) Training; and (12) Security concerns. CIELAP's perspective on each of these twelve topics is presented in the discussion.

1. Introduction

CIELAP has had a long history of interest in emerging environmental and sustainable development issues, frequently related to new technologies. In May of 2006, the organization published a series of five short *Fact Sheets on Innovative Technologies*, including four *Fact Sheets* on applications of biotechnology and one on nanotechnology (these are available on CIELAP's web site at www.cielap.org).

Nanotechnology, as discussed at greater length in that *Fact Sheet* and in many other sources elsewhere, is based on the rapidly advancing ability of humans to manipulate and utilize materials at the nanoscale, essentially at the molecular scale. (One nanometer is a billionth of a meter, which is about a hundred thousand times smaller than the cross section width of a human hair, and a thousand times smaller than a red blood cell. The nanoscale level is generally considered to range from one to one hundred nanometers.)

Since its beginnings in the 1980s and 90s, nanotechnology has developed swiftly, with more than 300 applications already in commercial use now and many more poised for development in a large number of different fields, from medical applications to cosmetics to industrial coatings to environmental sensors and remediation, to name only a few. What makes the technology so valuable is that materials at this scale can exhibit novel properties that are different from the same substance's properties at the macro or even micro scales. Colour, conductivity, reactivity, and a host of other properties alter in surprising and potentially useful ways.

At the same time, the environmental and health effects of nanomaterials are largely unknown, although in a number of studies nanoscale particles have been found to be substantially more toxic and reactive biologically than larger particles of the same material. It is generally believed that nanotechnology is a "platform" technology that will profoundly affect virtually every sector of society, and that its development will be very important to the economic success of Canada in the future. It should be noted that developing countries, though, are quite concerned about being left out of the benefits of these economic changes, and also about the displacement of their workers in traditional sectors. Such economic impacts could occur in regions or industries elsewhere, as well. However, despite nanotechnology's immense potential and significance, in Canada at present there is no formal regulatory or explicit public policy framework for managing the risks and benefits of this technology, nor for informing and consulting the public about the issues related to it.

The following discussion paper was developed out of a one-day workshop sponsored by CIELAP, with support from Health Canada, the Canadian Biotechnology Secretariat and the Ontario Genomics Institute, that was held in Toronto, Ontario, on March 16, 2007. The workshop was intended to explore the current status of policy concerns related to nanotechnology, and to tentatively identify the elements that need to be addressed in a comprehensive Canadian Nanotechnology Policy. This discussion paper draws on that colloquy, as well as on a number of recent reports about aspects of nanotechnology policy from various jurisdictions. (Because this is CIELAP's own analysis of key topics and positions, not a research report, we have provided related reference material on our web site, rather than in end notes or an appendix.) CIELAP hopes that this discussion document will contribute to the launch of a much broader public dialogue about the goals and priorities, the elements, and, ultimately, the details and implementation of a well-thought-out Canadian Nanotechnology Policy.

2. Goals and Perspectives

Policy Goals

Public policy is about deciding among the various options that can shape the direction of present and future choices and decisions in a particular policy area.

At its most fundamental level, policy is about the perspectives, goals, objectives, and priorities that inform the specific options that are considered and the decisions that are made. Thoughtful, values-laden discussions are quite rare in the world of political debate, where society-altering decisions are described in sound bites; but nevertheless, it would be wise to try to start with the

most basic questions when an entire new area of public policy will need to be constructed, as is the case with nanotechnology. Such questions include:

- What are the most important values and considerations?
- What outcomes would we like to achieve?
- What outcomes would we like to avoid?
- For various options, which groups in society would benefit and which would bear costs – and is that equitable?
- If not, what could be done to address that issue?
- Is public knowledge of and engagement with the issues broad enough to ensure that all significant perspectives have been brought forward? What are the best ways to encourage appropriate civil society representation and involvement?
- What action is urgently needed, and what are the consequences of delay?
- What resources are urgently needed, and what are the consequences if unavailable?
- What are the action priorities, or the order in which different things must occur?

Sustainable Development as the Context for Nanotechnology

CIELAP as an organization does have a perspective on some of these questions. For purposes of discussion about a Canadian Nanotechnology Policy we would put forward the following:

- The context for a Canadian Nanotechnology Policy should explicitly be sustainable development, with its equal valuing of the environment and human well-being, and its emphasis *equally* on simultaneously addressing environmental, social, and economic goals and considerations;
- The protection of the environment and human health, including occupational and public health, must be a priority consideration in, and from the beginning built into, all research and development proposals and funding support, as well as into manufacturing processes and products, and should be evaluated for the entire life cycle of products and research initiatives;
- There are great potential benefits for the environment, human health, and the economy from nanotechnology. Canadian policy should emphasize a foresightful, precautionary approach to potential nanotechnology risks not only for reasons of responsibility to protect human health and the environment, but also to prevent the curtailment of valuable projects because of public reaction to a serious failure in this responsibility.
- Public knowledge about and involvement in nanotechnology and the issues it raises is extremely limited at present, and there are no clear mandates or avenues for public input. This area also needs resources and attention to add breadth and depth to policy alternatives, and to forestall reactions based on lack of knowledge.
- Despite the fact that the unknowns in nanotechnology seem almost overwhelming, the rapidity of its development continues unchecked. It is imperative to start immediately to

prepare a comprehensive regulatory regime, even though much data for well-studied, science-based regulation is simply not yet there. Developing a complete data base of all the desired information before beginning to regulate may seem the logical way to proceed, but is not feasible in light of the pace of research, development, and commercial utilization. A greater sense of urgency about priorities and a more creative, flexible and adaptable process than has probably ever been used before in Canada in designing regulations must be developed.

- International developments and considerations are vital. The newly emerging global context for technological change, including equity considerations in the developing world as well as legal, regulatory, and other initiatives toward creating international agreements and standards have become a dominant reality in nanotechnology developments. Canada should strive both to utilize them and to shape them in ways that promote sustainability values. Commercial and economic success should not be the main touchstone in considering the adoption of approaches used in other jurisdictions such as Japan, the United States, and the EU.

Policy Challenges

Finally, a few words are in order on an overall perspective about the challenges of creating a Canadian Nanotechnology Policy. The two most important features that dominate the policy landscape now are the immense number of scientific unknowns, and the absence of some of the most basic tools to deal responsibly with these materials. Such tools that do not yet exist include widely recognized definitions, protocols, labels and universal descriptors similar to chemical CAS numbers and material data sheets; a legal and regulatory framework; scientific and technical capacity; and structures and resources for public education and engagement. Creating a policy regime under these circumstances is unquestionably an enormously large and urgent undertaking, a truly daunting effort.

Parallels: Not Everything Is New

However, a closer examination of the situation is not quite so discouraging. We don't know the details of toxicity for nanomaterials, but Canada does have precedents and models for assessing toxic effects and an existing regulatory regime for environmental contaminants and toxic substances; there are frameworks for assessing and regulating new medicines and medical devices, cosmetics, and hazardous consumer products; and there is experience and regulatory guidance available in laboratory and industrial hygiene as well as worker health and safety. Canada has developed processes and venues for informing and engaging the public on many environmental and other policy issues. And international collaboration on similar issues, such as the more recently recognized class of environmental contaminants that are reproductive toxicants and endocrine disruptors, is becoming common. So too is a readiness to consider sustainability as the appropriate context for society's actions. Many of these existing legal, institutional and regulatory approaches can be adapted to the new requirements and challenges that the responsible advancement of nanotechnology will need.

As well, many of the ethical and social issues that have been raised about nanotechnology are by no means unique. Questions about how to address matters like privacy implications; security; and equity are part of ordinary public discourse in many areas.

Even the futuristic applications of nanotechnology, such as, in combination with biotechnology, the production of engineered microbes that can assemble materials and products, do not usually bring up issues that have never before been considered. Perhaps the one idea that is both unusual and frightening is the potential for nanotechnology to be used to build self-replicating systems that can get out of control. There has even been speculation about the escape of some such system possibly turning the world into "grey goo," though few researchers believe this latter science-fiction-sounding scenario is ever likely to be realized. Nevertheless, molecular manufacturing (MM) with self-assembling components has been accomplished in the laboratory and is certainly on the horizon commercially, bringing both potentially significant environmental and other benefits and questions about management and containment.

However, difficult-to-control technologies do already exist, including bioengineered crops, nuclear reactors and weapons, and the commercial production of vaccines for dangerous infectious diseases. And although such technologies have brought up similar questions before in other fields does not mean that there exist clear-cut, ready-made answers. It simply means that nanotechnology is another area where there must be the means to bring many ethical and social perspectives together for productive dialogue that can help determine appropriate application-specific restrictions – in time to make a difference to outcomes.

This latter observation about timing brings up the one area where there is little experience that is useful to build on. What Canada conspicuously lacks are precedents for rapid, coordinated government action in the absence of a major crisis like war or the SARS outbreak. If we can find ways to spur such action, it will be possible to make a reasonable start on a Canadian Nanotechnology Policy.

3. Elements of a Canadian Nanotechnology Policy Framework

Policies, Policy Processes, and a Policy Framework

In the CIELAP workshop described in the Introduction, one participant queried whether what was really wanted was a policy on nanotechnology – or a policy process.

In reality, of course, policy in the sense used here – decisions that shape future directions in a policy area – is always part of governance, though sometimes policy is simply the *status quo* results of taking no deliberate action to address an issue. However, for an intentionally created policy there is always some sort of policy development process, often with both internal and external consultation.

For a field as far-reaching as nanotechnology, and which at present is unregulated and with policy guidance best described as *laissez faire,* a responsible, comprehensive policy will include both instituting ongoing policy processes that lead to specific, but at the beginning undetermined,

action outcomes, and also certain substantive decisions themselves. In some cases, decisions will be part substance and part process, such as assigning responsibility for initiating action or identifying certain questions for substantive future policy decisions. Beyond pointing out the essential need for priority-setting and speed, we do not address questions of timing or sorting out longer- and shorter-term objectives. At this preliminary stage, our proposed policy framework focuses on ***goals;*** on ***what needs to be attended to;*** and to a lesser extent on ***how it should be done***: the ***elements*** of a policy framework.

However, filling out the framework into workable policy means determining which actors are responsible for what; how they are to be held accountable; who the stakeholders are and how they should be involved; what the time line for action is; and what resources are needed and how they will be supplied. Although various stakeholders may well have opinions about these matters, the generation of such detailed public policy is the responsibility of governments. Right now, government agencies and departments in Canada should be considering what the best options are to address these questions, and the implications of different approaches (thinking in the context of sustainability, it is to be hoped).

Elements of a Canadian Nanotechnology Policy Framework

The following are major areas that CIELAP believes need to be addressed, with comments on how it should be done:

1. ***Goals.*** As discussed in Section 2, the policy framework should include an introductory statement discussing its purpose, which should explicitly be linked to sustainable development and its values.

2. ***Public education and engagement.*** Bringing civil society stakeholders into policy discussions very early in the process is both the right thing and the prudent thing to do for the development of robust, publicly acceptable policy. It should be noted that there are organizations, including the ETC Group and the National Farmers Union, which, alarmed by the lack of government oversight and the speed of commercialization, have already called for a moratorium on the technology. Others will probably follow if tangible progress on policy and regulatory action is patently unable to keep up with commercial activity.

   There are many models for consultative involvement in Canada, and it should be noted that citizen groups require resources to participate effectively. Government-run forums in which information flows mainly from government experts to the public are an outmoded and ineffective approach. The Internet has made an enormous difference in the ability of a motivated public to become informed about a topic, and the best motivator is a real opportunity to be effectively involved in shaping aspects of policy decisions. A one-stop, comprehensive, well-designed, and easy-to-use website is a very useful approach, though not so easy to achieve. Consideration should be given to building on the single information window used for biotechnology, especially since future nanotechnology applications are likely to include components that are bioengineered.

3 ***Inventory of activities and information sources.*** It is surprisingly difficult to assemble a comprehensive overview of nanotechnology activities in Canada; an updatable web-based inventory would be useful in a variety of ways. Transparency about government planning and action is vital.

4 ***Lead agencies.*** A fast-tracked process to designate, clarify or affirm lead agencies for various areas of specific responsibility, to name lead contacts, and to identify the role of the main lead government agency should be quickly established. For this latter, Health Canada and Environment Canada jointly may be most appropriately positioned to lead progress overall. Information about these decisions should be part of the information inventory.

5 ***Terminology, metrology and related technical issues.*** These need to be resolved as soon as possible, preferably in collaboration with others internationally. Much that is essential for comprehensive legal and regulatory action depends on such activities.

6 ***Regulatory approach, including science, risk assessment, and stakeholder involvement.*** It is clearly unrealistic to expect comprehensive regulations in the immediate future, since far too much is not known about a long list of crucially important factors, including potential human health hazards, exposure routes, mechanisms of action, nanomaterial properties and behaviour, environmental fate, including bioaccumulation and transport, dispersion, and sensitive species and ecosystems – among other things. Every effort must be made to prioritize what needs to be known and to acquire that information quickly. Using a life cycle approach, efforts should be made to refine and use an appropriate risk assessment model, such as that developed jointly by Dupont and Environmental Defense in the United States, to assist in developing priorities for a defensible regulatory system, although it should be noted that risk assessment alone does not provide automatic answers to many regulatory questions. Much of Canada's regulatory system for different types of products and chemicals can probably be adapted to address nanotechnology. It should be understood that the assumption that regulation will be necessary does not imply any criticism of the ethics and mindfulness of researchers currently involved. It is, rather, a judgment that there are indeed risks that society will want to investigate and address, and many of these, such as privacy concerns, bring forth a range of legitimately differing ethical and social perspectives.

The United States Environmental Protection Agency (EPA), facing the same difficulties with the information base as Canada and everyone else, this year has taken steps to regulate washing machines that have included nanosilver, which has antibacterial properties, built into their design. For medical uses, consumer products, laboratory, medical and industrial wastes and other items in the waste stream with nanomaterials that come in direct contact with humans or can enter the environment, an interim approach to assessing priority risks and developing appropriate controls is needed.

7 ***Labeling of nanomaterials in consumer products and consumer protection.*** Especially in the absence of a regulatory regime, ways to legally require labeling of consumer products with nanomaterials that can come in contact with humans, other animals, or enter the environment directly should be found. Recent steps for nutritional and cosmetics labeling are part of a welcome move toward producer responsibility and stronger governmental support for consumer information and the consumer's "right to know."

8 ***Liability and intellectual property regimes.*** Producer responsibility and legislated strict liability should be considered as essential principles for commercial applications of nanotechnology and a process to address them should be put in place quickly. Intellectual property rules should, as much as possible, encourage open access to scientific information.

9 ***Science and research support.*** More science in support of regulatory action is obviously a great need. Granting councils should encourage safety and the environment as a design requirement of every project from its inception, along with supporting work on so-called NE³LS, nanotechnology and ethical, environmental, economic, legal and social concerns.

10 ***Commercialization and social and economic benefits.*** Most of the public discussion to date has been about nanotechnology's potential for generating economic benefits, about how best to position Canada's industry in that regard, and about how to encourage research that leads to commercial developments. Should Canada take a *laissez faire* approach and let research develop where it happens to go, or should there be more support for particular targeted niches? How should these decisions be determined? As well, there are questions about whether research should be deliberately supported for particular social or environmental ends. The EPA, for example, is especially interested in supporting work in nanotechnology on environmental sensors and environmental remediation applications. There must be a discussion and decision process about which of these paths to follow to maximize Canadian economic benefits, and about what social and environmental needs and opportunities exist in Canada that should be supported.

11 ***Training.*** Increased support for and expansion of training in this new field is easy to overlook but is essential for every other policy component.

12 ***Security concerns.*** There are many potential military applications of nanotechnology; for instance, a centre for such research was established at MIT in 2002. It is possible to imagine criminal and terrorist possibilities for nanotechnology as well. Understanding such uses and threats and determining ways to avoid them and to prepare for and minimize their consequences should be a part of the policy agenda. As with land mines, Canada should be prepared to lead international efforts to outlaw military uses that create environmental damage and civilian casualties.