CANADIAN INSTITUTE FOR ENVIRONMENTAL LAW AND POLICY
L'INSTITUT CANADIEN DU DROIT ET DE LA POLITIQUE DE L'ENVIRONNEMENT
Since/depuis 1970

130 Spadina Avenue Suite 305
Toronto, Ontario M5V 2L4

Tel: (416)923-3529
Fax: (416)923-5949
www.cielap.org
cielap@cielap.org

# Multi-Stakeholder Workshop to Discuss Elements of a Policy Framework for Nanotechnology in Canada - Final Proceedings

**Friday, February 22nd 2008, 8:30 am – 5:00 pm**
**MaRS centre, 101 College Street, Toronto**

Thank you to those who sponsored and supported this workshop:
Health Canada
Ontario Centres of Excellence
Ontario Genomics Institute

## Welcome by Anne Mitchell, CIELAP Executive Director

Anne welcomed participants on behalf of CIELAP. CIELAP was founded in 1970 with the objective of providing leadership in the research of law and policy that promotes the public interest and sustainability. CIELAP has a current focus on emerging and neglected issues; hence the organization's interest in nanotechnology. CIELAP would like to thank Health Canada for sponsoring this workshop. Thanks also go to the Ontario Centres of Excellence for sponsoring lunch and the workshop space; as well as to the Ontario Genomics Institute for their support.

Nanotechnologies are emerging quickly and offer many potential benefits but also present many unknowns and uncertainties. Anne referred back to her attendance at the 2002 World Summit on Sustainable Development where she attended a workshop on Nanotechnology. The hope was that we would be able to develop sustainable frameworks for the management of nanotechnology in a more timely manner than has been the case for biotechnology. In the Canadian government's *Mobilizing Science and Technology to Canada's Advantage* strategy the government commits to putting in place an effective, forward-looking and responsive regulatory environment that supports a competitive marketplace and protects the health and safety of Canadians and their environment. In this document the government states that it will develop a plan to ensure that biotechnologies and nanotechnologies are regulated responsibly. The Prime Minister also says that all Canadians, not just the scientific, technical, and business communities, have a stake in getting it right. CIELAP wants to help the government get it right. In 2007, CIELAP held its first nanotechnology workshop that was also sponsored by Health Canada and the Canadian Biotechnology Secretariat. We look forward to continuing that discussion today.

**Participants introduced themselves to one another.**

**Welcome by Nigel Skipper, Health Canada**

Nigel Skipper welcomed participants and thanked CIELAP for organizing the workshop. Nigel clarified that Health Canada has sponsored this meeting on behalf of the larger group of regulators (Health Canada, Environment Canada, Canadian Food Inspection Agency, Fisheries and Oceans). The federal government's Science and Technology strategy commits the government to develop a plan to ensure that Nanotechnology, Biotechnology, and Information and Communications Technology are regulated in a timely and responsive manner, drawing on best practices.

The role of Health Canada, in coordination with the other departments, is to develop this plan. Stakeholder engagement is essential. Experience has shown that moving technologies forward with regulation that is not firmly grounded in public engagement is not effective. Health Canada will aim to move the workshop outcomes forward on behalf of the group of government agencies with regulatory responsibilities for products which may be related to nanotechnologies.

**Presentation – CIELAP's Nanotechnology Policy Framework**
**Susan Holtz, CIELAP Senior Policy Analyst**

Susan asked participants to consider three points throughout the day as they took part in developing and elaborating on elements needed for a policy framework for nanotechnology.

**1) What is policy, what are policy frameworks, and what are these for?**

*Policy is about determining the overall direction to take on key issues or questions for society or government in a particular area.* The key questions ask not only about what decision to take a direction on, but whether to commit to any decision and action at all. A related question is about timing: sometimes no decision for a long time means that actual policy is determined by unregulated and undirected private sector decisions. In this case policy is not necessarily developed deliberately and consciously with clear policy statements but it rather comes about through not addressing the issue. We do not want this to happen with nanotechnologies. It doesn't appear to be happening, however, given the government's recent efforts.

A policy framework is intended to identify the *issues or topics* about which there are obvious *choices in direction.* It is also intended to signal the *general direction* to be taken about such choices. As well, it can signal *specific approaches* for the identified topics. (This was done at CIELAP's nanotechnology workshop last year, where topical actions were determined for direction and recommendations were given on what direction should be taken).

Only rarely do governments issue and discuss formal policy frameworks and policy decisions. Policy statements most often come about in party platforms during election campaigns. That doesn't mean that policy frameworks are purely theoretical. For instance a framework such as CIELAP's can be used as a checklist by commentators, the public, and other interest groups to assess effective government policy and whether progress is being made on all the important

aspects of a topic. It can then help these groups determine the adequacy and appropriateness of those actions.

**2) Consider Sustainable Development as a Context for Policy.**

It is common for governments to say that they are framing a policy within a context of sustainable development. CIELAP has given a lot of thought as to what a sustainable development context for policy might mean and participants were referred to an excerpt from CIELAP's *Sustainable Development in Canada: 2005 Update* by Mary MacDonald and Susan Holtz (see Appendix A) that examined this theme.

A clear, stated sustainable development context for policy requires the interaction of social, economic, and environmental considerations. A number of challenges exist. Environmental achievements can be well articulated in an evaluation. Economics also has a huge body of knowledge and analysis. It is not usually clear, however, what the social aspect of sustainability means and this aspect is frequently ignored.

CIELAP has proposed that for practical purposes the social dimension can come from asking a number of questions. Is the proposed initiative socially responsible? Does it improve the position of the most vulnerable group affected? Does the activity equitably distribute costs, benefits, and risks (and attend to the most vulnerable people affected)? A lifecycle analysis is important to consider in this.

**3) CIELAP's 2007 Proposed Nanotechnology Policy Framework**

Susan then asked participants to consider CIELAP's 2007 Proposed Nanotechnology Policy Framework (see www.cielap.org), the policy framework that was developed from CIELAP's workshop last year.

She stated that the group was present to do three things today:

- Review what has happened with regard to the framework since it was first published. Susan has been surprised and impressed with how quickly the government has been developing activities and frameworks on this topic.
- Consider whether any topics should be added, or whether information or suggested approaches should be changed or made more specific;
- Assess progress on nanotechnology policy and what needs to be attended to in the immediate future (what could use a boost in terms of action and energy)?

Susan reviewed the checklist of CIELAP's recommendations from the year before. A brief summary of the items to be addressed are: goals; public education and engagement (this item was placed near the top of the list because it is an area that ought to be given priority but is too often ignored); developing an inventory of activities and information sources; the need to identify lead agencies; advancing metrology and other technical issues; taking on a regulatory approach; labeling; support for science and research; identifying social and economic benefits for commercialization and setting priorities; training; and security concerns.

Susan concluded that she was very impressed by the caliber of people in the room and that she looked forward to the day.

**Presentation – International Comparison of Governmental Policy Frameworks**
**Delara Karkan, Senior Science Advisor, Nanotechnology Products, Office of Science and Risk Management, Health Products and Food Branch**

Health Canada has a wider range of activities and responsibilities than individual regulatory agencies. These include helping Canadians maintain their health and safety. Some of Health Canada's areas of responsibilities are; maintaining and improvement of air quality, water quality, environmental health, climate change and health, food and drug safety, and the safety of consumer products.

Health Canada has been looking into wider and more comprehensive governmental policy frameworks around the world, including large international initiatives such as the European Commission's initiatives on nanotechnology. Health Canada has looked for similarities and differences among these frameworks and has examined how much emphasis has been placed on different elements incorporated into them.

Some findings include:

- In the United States National Nanotechnology initiative involves numerous agencies including the FDA and EPA.
- Both the US and the European Commission have focused on research promotion but are also putting emphasis into public engagement and human health and safety.
- A recent (December 2007) plan from the US' National Nanotechnology Initiative (NNI) includes a jump in social and ethical research.
- Many of the frameworks have less concern about governance and more on environmental health & safety. Governance issues are important in the EU, however, because of the number of countries and organizations involved in this issue.
- Legal considerations include intellectual property (more important in the US). The US has also identified legal gaps in the area of regulation of cosmetics.
- A number of European communication portals include a nano forum / portal – an active website used to inform people about the health and safety issues relating to nanotechnology.
- Europe has seen a general trend toward interest in global cooperation.
- Nobody feels that completely new regulations are needed for nanotechnologies.
- Most agencies tend to be taking a case-by-case approach to regulating products with the perspective that one can't necessarily apply regulations to different classes of products that may have different properties.
- Comparison of international instruments of choice shows that where there is a pre-market evaluation process, tools may include new guidelines, information-based practices (asking

companies for more information), strong partnership development, strong public engagement, and the use of the precautionary principle. Where there is no pre-market evaluation process a number of other tools have been suggested including: voluntary / best practices, various risk-management frameworks (although these tend to present good theoretical frameworks but may not necessarily be applicable to real needs), economic-based tools, stakeholder engagement, research and science.

Health Canada is currently finalizing a summary of comparison of various regulatory/policy frameworks. This summary and the detailed analysis of how these frameworks can apply to Canada will soon be available. Assistant deputy ministers of Health Canada's Healthy Environments and Consumer Safety Branch, and its Health Products and Food Branch have asked that a framework for nanotechnology be developed. These two branches have taken the lead on this initiative and all other branches of Health Canada are being asked for their input into the framework.

Health Canada and Environment Canada have also been very active on this file on an international scale, including participating in OECD and ISO meetings, international research projects, and collaborating with research institutes and agencies (FDA, EU Commission).

**Table discussion.** Participants broke out into table discussions to discuss key similarities and divergences in frameworks and what should be applied to a Canadian context.

**Presentation – Health Canada's Draft *Framework for Products of Nanotechnology***
**David Clapin, Healthy Environments and Consumer Safety Branch, Health Products and Food Branch**

Health Canada's Healthy Environments and Consumer Safety Branch and its Health Products and Food Branch have been asked to lead and work with other departments to develop a Health Canada framework for products of nanotechnology. This framework is not a meant to be a policy but will be a beginning for an approach to address policy issues. The term *products* is intended to be broad and includes substance, commodities, manufactured products, impacts on ambient environments and workplace environments. Health Canada's regulatory focus will not be on technologies and but rather on specific products and consequences.

Health Canada is currently considering six components to its health portfolio and is interested in achieving a better synthesis of science and policy development, which need to come together in any understanding of how to regulate nanotechnology. David stated that, from the workshop, he is seeking a better understanding of stakeholder concerns and stakeholder perspectives as well as to gain the perspectives of colleagues in other Departments.

Nanotechnology presents a number of concerns for regulation and the development of a framework. Innovation and technology in this area are rapidly advancing. Rapid innovations in technology mean that technologies can get ahead of policy development, government programs, and guidance documents, which work at a much slower cycle.

Products of nanotechnology are both revolutionary and yet familiar. Some have said that nanotechnology may the 3rd wave of Industrial Revolution. Changes at that scale would present significant implications for regulation and policy.

Health Canada is currently looking for a framework to help guide the Department in its process of decision-making and to serve as basis for consultation, partnership, communication and engagement. Decision-makers are looking for a framework that addresses all of the Department's roles including science and research, education, communications and public engagement, policy development, the Department's roles in health-care and delivery of health services, and regulation.

The Framework will help the Department reach out to key stakeholders and partners, build relationships, and engage with other federal departments in the interest of coordinated action.

The draft framework that Health Canada presented for discussion at the workshop has been pulled together from various documents, including CIELAP's draft framework, and through consulting with a number of groups and individuals. The current draft framework has five components.

The first two components – Science and Research, and Legal and Social and Ethical Aspects – are geared toward seeking evidence and acquiring the knowledge to be able to make decisions and establishing appropriate triggers for action. Health Canada is a science and research enterprise and spends a large amount of money on research, although not much funding has been put toward nanotechnology.

The component Legal, Social, and Ethical Aspects seeks to answer a number of questions, including: What is evidence-based? What is the legal definition of nanotechnology? (The absence of this definition is currently a challenge for CEPA, cosmetics, and other products). It is important to engage consumers and understand stakeholder perspectives, as well as to equip these stakeholders with a better understanding of science and the important aspect of evidence.

A third key component of the framework is to provide the basis for Communication, Public Engagement and Partnerships. The fourth is to allow the Department to make Appropriate Choice of Instruments and to bring the full range of instruments into the picture, including education and awareness, research funding, voluntary codes of practice, and guidelines and policies. The fifth key component of the draft framework is to establish effective, efficient, integrated, and coordinated systems of Leadership and Governance.

Ultimately Health Canada needs to be aware of what a nanotechnology framework means for Canadians. The Department has developed four goals/objectives as a result of its framework:

- Canadians will have meaningful opportunities to provide input into decisions about how the Department manages its responsibilities in this field.
- Access to safe and innovative products will be facilitated, without compromise to safe food, existing standards of product safety, and a clean environment.

- Canadians will have the information they need to make informed choices that support healthy living.
- Public trust and confidence will be enhanced in an integrated, efficient and effective national approach to the impacts of technological innovation.

David also suggested that those who are developing the nanotechnology framework have a lot to learn from the development of biotechnology policy in Canada and should ask what has been learned from this process.

**Presentation - Update on Environment Canada work on Nanotechnology**
**Bernard Madé, New Substances Program, Environment Canada**

Different Departments and organizations have different roles with regard to nanomaterials. Environment Canada is responsible for assessing and managing risks. The subject of the talk today is to present the issues and how nanomaterials are being regulated under CEPA.

To give a bit of background on the issue, nanomaterials are currently being developed and introduced to the Canadian market. It is not necessarily understood, however, that many types of nanomaterials have been on the market for a long time and we have already been exposed to them. One example is paint pigments, which may have been introduced post-World-War-2 and contain particles at the nanoscale. Many such materials have been introduced to the market, have gone through assessments, and are regulated under CEPA.

Concerns exist that some nanomaterials might have impacts on the environment. These concerns are primarily associated with new properties that these materials have. Part of the responsibility of CEPA, Environment Canada and Health Canada is to look at these concerns and to figure out whether these materials present risks and to ensure that these risks are properly managed.

Under CEPA 1999, part 5: Controlling Toxic Substances, the world is divided into two parts: new substances and existing substances. Existing substances are listed on the Domestic Substances List (DSL). Substances that are not on the DSL must go through an assessment process to determine whether they can be introduced to the Canadian market. CEPA was not designed with nanomaterials in mind. Some nanomaterials are considered new under CEPA because they are not on the DSL. Some of the materials are considered existing substances, however, because they have the same structure as a substance on the DSL.

Environment Canada began working on the issue of nanomaterials in 2006. In 2007 the Department published a paper entitled *A Proposed Regulatory Framework for CEPA*. A number of regulatory challenges exist. Ideally all materials that exhibit new properties should be treated as new under CEPA. This is not currently the case. A number of knowledge gaps exist on properties, fate, toxicity, and effects that make it difficult to properly assess and manage the risks. The New Substances Notification Regulations (NSNR) are also not designed for nanomaterials. Issues exist with the notification triggers (based on quantities) and information requirements. It is also the case that information about nanomaterials that are currently on the market is incomplete.

Environment Canada has developed a two-phase approach (short-term and long-term) to address the regulation of nanomaterials. In Phase 1 Environment Canada intends to inform companies of their obligations under CEPA; gather information on materials already in commerce through a CEPA, section 71 survey and a voluntary challenge; Consider whether changes to CEPA (and NSNR) are needed; and use Significant New Activity (SNAc) provisions for new nanomaterials, where applicable. Environment Canada plans to issue a survey to begin to gather information in September 2008. Phase 2 will involve considering more elaborate changes to NSNR to ensure information requirements are sufficient to assess and manage nanomaterials, and considering using SNAc provisions for existing nanomaterials.

Environmental Canada has also recognized the importance of aligning with other countries since no country can address all the existing questions on their own. ISO has initiated the development of standards for nanomaterials, including terminology and nomenclature. Environment Canada is chairing the Technical Committee sub-group on nomenclature. Canada is also active in the OECD Working Party on Manufactured Nanomaterials. The Department and Health Canada have been actively cooperating with the US EPA on these issues.

Environment Canada will continue to support the Canadian Standards Association in the development of standard nomenclature and terminology through the ISO. It will support the OECD's proposed testing program on nanomaterials identified as priorities. It will also cooperate with US EPA and others to test fourteen representative materials, which will be a huge amount of work.

Environment Canada is proposing to improve its research capacity. There is also a need to involve research funding agencies to develop the capacity for research in Canada to obtain information about the environmental health and safety aspect of these materials. Environment Canada will need to develop a research strategy to guide it in its involvement in the OECD testing program.

In conclusion, concerns with regard to nanomaterials must be addressed. This will not be done overnight as a lot of work needs to be done. Environment Canada is taking steps to address the aspects that fall under CEPA.

Question from participant: What kind of budget will the OECD four-year testing of fourteen substances get?
Answer: This is a sponsorship program that the working party has launched. Countries are being asked to volunteer to take part in some testing for the nanomaterials. This may involve many countries volunteering to test different materials. There is a list of basic testing requirements that has been put forward by the working party. Sponsors are being sought to make sure all the ground is covered. The OECD is not going to be testing any materials themselves.

Question from participant: It looks as though the focus is on passive nanomaterials but what about those that are more active / sophisticated?

Answer: Under CEPA Environment Canada is addressing "substances" or materials. We are not looking at devices, products, and things of those natures. Other government Departments are looking at other aspects, for instance Health Canada is looking at medical devices.

Question from participant: Can you comment on how the significant new activity criteria as a trigger might be implemented?
Answer: We need to establish: What is a significant new activity to receive notifications on?; What quantities trigger a notifications?; and What kind of information do we need to receive from companies? This will evolve over time and will be done on a case-by-case basis.

**Table discussion.** Participants broke out into table discussions to think through all the elements that have come through the presentations, to assess whether the process has been sufficiently developed, and to consider whether anything else needs to be added. Consider social, economic, research, and other components in addition to health and environment.

**Presentation - Scientific Developments and Implications for Health Policy**
**Walter Derzko, Smart Economy, Toronto and University of Toronto**
**Smart Technology Blog http://smarteconomy.typepad.com**

Walter gave an overview of scientific developments in nanotechnology. A selection of his comments has been summarized below

To put nanotechnology in perspective, the difference between two objects- a meter wide and a nanometer wide is like comparing your thumb (about 4cm long) to the circumference or equator of the earth (~44,000 km). Sitting in this room, we are about the size of quantum dots, compared to the globe.

Nano-materials come in many shapes or forms such as single layer carbon sheets, carbon tubes or carbon balls called Fullerenes or Buckyballs. Fullerenes (C60) are made synthetically but are also a natural by-product of sugar refining, and found in molasses. Fullerenes are also found in candle soot and as a byproduct of extreme heating, such as carbon arcs. These basic football-shaped nanoparticles have been around us for a long time.

Water soluble or Hydrated Fullerenes, are relatively non-toxic, (in fact biologically and medically beneficial), while nano-onions however, (fullerenes stacked inside one another) are quite toxic to human cells. The very shape of these materials determines their toxicity.

Some key timelines include: In 1980 the term 'nanotechnology' first began to be used. Fullerenes were (re-)discovered in 1985. Nano intermediates & consumer products began to appear on the market in early part of this decade. The European Commission began to fund research projects to address the potential risks of nanoparticles in 2003. A large number of nanotechnology milestones have been achieved over the past two years, and the pace is accelerating.

The Woodrow Wilson Center in the United States has developed a Consumer Products Inventory. It currently lists 580 products, produced by 305 companies, located in 20 countries. Industry Canada has identified about Canadian 80 companies that produce products with nano-materials.

If you are using L'Oreal cosmetics, you are already using cosmetics with nanoparticles. Many products don't currently report the presence of nanomaterials.

Polls show that most Americans know little or nothing about nanotechnology despite the fact that, in 2005 world-wide, nanotechnology was incorporated into more than $30 billion in manufactured goods.

There are major gaps with regard to our diagnostics and testing abilities.

The World Economic Forum has developed assessment criteria to determine what issues are of key concern. Nanotechnology has not been ranked as a high risk (a high likelihood or high severity) but the forum has stated that it is still something worth paying attention to.

The prevailing notion in toxicology is that 'the dose makes the poison'. With nanotechnology however, this is no longer the case. It is increasingly apparent that a whole host of other properties such as crystal structure, chemical composition, size distribution and surface area, surface chemistry, surface charge, shape, porosity and agglomeration state determine toxicity. Scientists recommend that the toxicity of new fullerene and nanotubes derivatives will need to be determined on case-by-case basis. Consumer end-products, environmental issues, worker safety, and other issues will also need to be addressed in any framework that is developed.

It has been pointed out that numerous nanotechnologies can address each of the Millennium Development Goals.

We need traditional regulations, that control usage, as well as regulations to control against misuse.

A study sought public input around the question 'is nanotechnology morally acceptable?' The results diverged according to the country with 72% of French respondents saying yes, 62% of Germans saying yes, but only 29% of respondents in the United States said yes. In other words 71% of respondents in the United States find nanotechnology to be morally unacceptable.

Scientists are currently saying that we should be vigilant about nano-materials but we don't know the all the risks yet and what to be worried about. This is the opposite of the position that scientists took with the issue of nuclear power or biotechnology, where the public was more concerned then scientists.

There is an inability for regulating bodies to react rapidly to address emerging nanotechnology issues: there is no expert research and development database in Canada and internationally; there is no public Canadian nanotechnology product database, although a nanotechnology portal is in the development stage to provide the public with information; and there are few methods (such as McLuhan's Tetrad model) to anticipate or track social and cultural impacts of nanotechnology.

**Presentation – Legal and Liability Dimensions of Policy**
**Maureen Carter-Whitney, CIELAP Research Director**

Maureen specified that she would focus her presentation on liability.

One of the recommendations in CIELAP's March 2007 Discussion Paper on a Policy Framework for Nanotechnology urged that producer responsibility and legislated strict liability be considered essential principles in developing a policy framework for commercial applications of nanotechnology.

Given the potential for harm to human and environmental health from nanomaterials, there is a risk of eventual litigation. To some degree, potential litigation related to nanotechnology would be similar to other product liability lawsuits, involving claims such as a failure to warn, misrepresentation and design defects. On the other hand, product liability lawsuits based on harm from nanomaterials could be complicated by substantial unknowns in the science, a huge number of potential claimants, and long latency periods between exposure and the onset of harmful effects. There will certainly be challenges as to whether, or to what extent, it will even be possible to determine liability, or attribute liability to any given actor or action.

The insurance industry has taken notice of the potential litigation implications of nanotechnology. For example, the Swiss Reinsurance Company is trying to understand the inherent risks of nanotechnology to try to mitigate the financial consequences of possible losses, and notes that it is difficult to anticipate the future loss potential associated with nano-engineered materials.

A US lawyer has proposed a Nanotechnology Insurance Fund that would: provide an exclusive source of compensation for people such as consumers or workers who claim and can prove injury from nanoparticles; and pay for any required environmental clean-up and restoration costs. He suggests that such a fund could also be used to fund environmental, health and safety research related to nanotechnology.

Because of the uncertainty and obvious potential for litigation, CIELAP has recommended that a legislated strict liability regime be considered. It is important to be clear that legislated strict liability is only one of twelve recommendations in CIELAP's proposed framework for nanotechnology. Establishing a scheme to govern litigation of claims over harm caused by nanotechnology must not be regarded as a substitute for thoughtful and comprehensive regulation. Courts are not an ideal venue for resolving these issues because of the time and expense involved in litigation. A strict liability regime needs to be part of a broader, comprehensive approach to a policy framework for nanotechnology.

Under the common law, the traditional common law rules of civil liability prevail in the courts unless they are modified by legislation. There is no legislated liability regime for nanotechnology in Canada. In Canada, nanotechnology issues are subject to the traditional common law rules of civil liability. If the use of nanotechnology causes damage to a person, their property or their economic interests, the producer or user of nanotechnology might or might not be held liable for that damage by a court. The common law, as it has developed in Canada,

may not be flexible enough to meet the novel challenges raised by the potential for harm that nanotechnology applications may cause.

As noted in the International Risk Governance Council paper that was distributed for background reading prior to today's meeting, "nanotechnology raises issues that are more complex and far-reaching than many other innovations, [and] the current approach to managing the introduction of new technologies is not up to the challenges posed by nanotechnology." These technologies bring up general policy issues that should be resolved by legislators rather than judges. A strict liability regime, entrenched in legislation, would guide the courts in holding producers of nanomaterials responsible for any damage caused to human or environmental health.

Damages from nanomaterials may be uncertain and far-reaching, and the traditional rules of civil liability may not be effective to address liability related to nanotechnology and ensure that victims have access to compensation. It may be preferable for the government to create a legislated strict liability scheme that takes into account the unique properties and uncertainties inherent to nanotechnology.

A strict liability regime is appropriate when the need to protect the public and make available adequate compensation overrides the need to establish moral culpability on the part of a defendant. In the context of nanotechnology, a legislated strict liability regime would set out the rules that would govern civil actions over harm that may be caused by nanomaterials. These rules would govern:

- What damage will be covered?
- Who will be liable?
- Should there be a fault requirement?
- How will the burden of proof of causation be dealt with?

A strict liability regime might not require that the victim prove that the defendant is at fault in order to be awarded compensation. Due to the potential for a long delay in time before damage from nanomaterials is discovered, or the potential for difficulty in obtaining scientific evidence to establish a causal link, it may be very difficult for a plaintiff to establish causation in order to be eligible for compensation. A legislated strict liability scheme might ease the burden to prove causation placed on plaintiffs.

It is important to emphasize that the policy objective of protecting harmed plaintiffs does need to be balanced against the concern that defendants may be found liable for damage for which they are not responsible.

If the government proceeds with a legislated strict liability regime, it will need to decide whether it will govern liability for damage to public environmental resources, liability for damage to individual or privately-owned resources, or both public and private liability.

**Table Discussion.**

**Report back – Yellow Dot Group:**

- The group liked CIELAP's draft framework and its 12 key elements from the previous year. The group had some concerns about tone and/or wording, particularly re: implementation.
- Any framework should stay away from silos
- There is a major NEED to identify and enlist a *champion* and give them a message that they can convey and raise support for. We need to stop saying "its time to get started". It has started and we need to get a sense that we're going somewhere. The group doesn't see any other option than a champion from within government. Industry isn't in a position to do this. Appropriate questions and ethical notes have to come from civil society.
- The group suggested bringing the list of 12 elements down to a list of 3, 4 or 7. The main difference between one that listed 7 vs. 3 elements would be whether social issues (ie. ethics, public engagement, health issues) would be broken down or not.

Could be broken down into 9 Elements (references to CIELAP's elements in brackets):

1. Goals, Principles, Objectives, a Champion (1,4)
2. Scope of knowledge base; knowledge transfer (3,5,9 metrology, terminology, classification)
3. Communication, Public Education and Engagement, Partnerships (2,7)
4. Legal and Regulatory Issues including risk assessment (6,8,12)
5. Health, Ethical and Environmental Equity & Social Issues (10,12)
6. Commercialization and Innovation Issues (8,10)
7. Governance, Co-ordination, Roles and Responsibilities (4)
8. Global Equity
9. Democratic decision-making

Could be broken down into 4 Main Issues: Governance, Knowledge, Leadership, Social, Commerce/Economy:

1. Governance and Leadership
    - Including national and International
    - Coordination and Integration
    - Stakeholders roles and responsibilities
    - Legal/Regulatory
2. Knowledge
    - Including science and research (including IP)
    - Expertise (including training)
    - Methods, standards, nomenclature
    - Catalogue and analysis of capability
3. Social
    - Including ethics (and morality?)

- Safety
- Public engagement and education
- Consumer choice and information

4. Commerce/Economy
    - Includes products
    - Risks and liability
    - Capacity building
    - Trade

- There is a need to transcend 'application-specific' policy, otherwise the goal of over-arching collaboration and cooperation will get passed over and the opportunity for passion may be lost.
- Communications shouldn't be its own category because it is involved in everything and manifests itself in different ways in different areas.
- A national nanotechnology strategy should be developed. The policy framework could help get us there.
- We are seeing a great sharing on application-specific policy (Health Canada is developing a health framework, Environment Canada is developing a framework under CEPA). It is difficult to extrapolate from specific to general, however, and so we should establish a larger over-arching quilt to cover all angles. Let's go from top then let everyone develop their own plan into the larger framework. Let's weave a tapestry as opposed to making a patchwork quilt.
- The government needs to provide a forum for public engagement, support, and education.

Participant Question: Do you have a nomination for a champion?
Answer: The current government – perhaps someone from the Prime Minister's Office, the Privy Council Office, or the Treasury Board. Or someone from one of these offices could set up a special office.

Question: Could NINT play a key role in pulling things together?
Answer: NINT has only recently become a major player at the National Research Council while NRC has been single biggest contributor to nano knowledge. NINT may also be too much of an advocacy group to achieve a balanced approach. Collaboration is absolutely needed, however.

Question: Did the group consider morality? We will be faced with a need for a code of conduct for research.
Answer: The group noted a lively literature of ethics but did not want to muddy it up with confusing terms such as morality. It is important to keep informed by nano codes.

Comment: Let's try to bring changes into academia. It's too late once you've reached the development stage in industry.

Comment: Can we develop a mental construct that comes from ethics and morality - that forces us to ask certain specific questions?

Comment: Public engagement around a strategy for a champion has to be done by Canada and Canadians. We can't just import another model because acceptance will only come by educating and engaging Canadians in the development of a strategy.

**Report back – Blue Star Group:**

The group began by asking whether there was a consistent understanding of what nanotechnology *is*. They concluded that papers such as that by the Internal Risk Governance Council and the NNI paper (what is nano?) have come up with a general concept of nanotechnology – the definition shouldn't be a roadblock because the descriptions are there.

**Discussion 1:** Is the group comfortable with the CIELAP Framework Elements? Is there anything to add or improve on?

- The group had concerns related to element # 2 re: informing consumers about nano. They felt that consumers are starting to understand that there are pros and cons to nano and that they are not necessarily all evil. The group cautioned that there is a potential for public opinion to change rapidly.
- A discussion needs to be held about how to generate and provide the information needed for public education.
- Nanotechnology is raising the bar, creating a greater need for us to understand the impacts of chemicals on health and the environment.
- CIELAP's element # 7(labeling): The group had a concern about informing consumers of nano via labeling of consumer products. What do we want to tell/convey to consumers through labeling? Just because something contains nano doesn't necessarily mean it's risky or hazardous. This element needs to be given more thought. Does anything need to change from current framework to asses and manage labeling?
- One issue is the complexity of the matter. Eg. a material may behave differently depending on how it is functionalized.
- What is the message to convey to the public? Is it a new material? There is a need to figure out how to assess these materials.

**Discussion 2:**

- We need to look at materials over their *entire* lifecycle (for instance, concern of bioaccumulation). It is not apparent that this has been factored in.
- Co-ordination needed at the international level.
- Environmental monitoring needs to be considered; there is a need for federal-provincial coordination.

- There is a need to find out what the research community is working on (Environment Canada code of conduct).
- Elements that support the use of international standards are being introduced internationally (eg. international code of conduct – in EU; DuPont / ED guidance on managing risks within manufacturing of these materials).

CIELAP's Policy Framework Elements:

- Policy framework elements should consider the use of a code of conduct – for use in both research and manufacturing (corporate social responsibility)?
- Frameworks need to be "put to the task" in current activities and to make connections to the international dialogue. How do we factor other countries into global efforts? It is missing the importance of international co-operation.
- CIELAP's Element #5: needs to add *classification* in the list. There is a lot of work on terminology; we also need classification so that we know consequences and what can be used. We need identifiers.

**Discussion 3:**

- The group asked whether a strict liability regime existed for any other chemical or product? They thought no – so why would it be important to have it for nano? No other countries are proposing something similar to a strict liability regime.
- International dialogue/coordination is an important aspect as well. Whatever we do in Canada needs to consider the international level – more information is being generated outside of Canada. This should be added to the policy framework.

**Report back – Green Dot Group:**

The group stated that they liked the 12 principles and focused on short-term and long-term goals that should be implemented in a path forward.

**Short Term Goals:**

- Strengthen *existing* chemical safety programs, including: Monitoring and surveillance reporting; Reporting by industry; Compliance and enforcement.
- Nanotechnology is already out there and the nano-specific framework won't be developed immediately. Existing programs for regulating technology and chemicals exist. They should be strengthened in the short term and made to apply to nano. Strengthening existing frameworks will also help protect against other hazards.
- We don't have nano-specific legislative solutions at present. We should develop interim guidelines (eg to identify and monitor as we go along).

- In the absence of concrete science-based knowledge what can we do in the meantime? We can set guidelines (not legislation) that can incorporate a review process based upon specific named timelines.

**Long Term Goals:**

- A funded, coordinated body to harmonize departments. We don't want just an individual champion, we want an entire body with resources to coordinate and centralize the discourse. This could involve maintaining a clearing house of information for nano issues including a coordinated database. NNI in the US is an example.
- A clear path needs to be created for new materials to go through government so that health and environment are protected, but innovation is not stifled. This would involve clear guidelines on what is considered safe; clear on-going guidelines after market review so that producer liability does not become unlimited, making the "risk" profile so big that R&D investment is not made.
- Industry groups don't want to commercialize until they know what's safe. No one knows what's safe so how do they demonstrate what's safe in the interim? How do we continue to assess and monitor safety as products go out to marketplace?
- Industry needs clear guidelines of what to follow, what not to. Liability needs to be made crystal clear. If a strict liability regime is developed, make sure that it doesn't backfire to industry. The framework also needs to be made very clear so that we understand how to follow it and abide by it clearly. Clear benchmarks in the regulatory framework are needed
- How can a company demonstrate the safety of a new product? Importance of public perception.

Comment from participant: If we are working towards international standards we need *rigidity* and international dialogue. Is the occupational world aware of the documents (ISO, others) that have already been developed – global perspectives on best practicing for handling and safety etc…? Health Canada and Environment Canada should help bring these to attention of appropriate Canadian stakeholders. Similar to the point made by the other group – there is a need for a champion to coordinate information and make sure stakeholders are educated.

**Report back – Gold Star Group:**

**Discussion 1:**

- There are differences in the frameworks: CIELAP framework looked at responsible development (including environment, social, and health factors) while other frameworks didn't – particularly the NNI framework coming out of the US.
- There is a need for *national leadership* on nanotechnology or a national strategy (particularly given the closure of Office of National Science Advisor) – agreed with other groups on this point.

- Need to distinguish between different types of nanotechnology. We are very familiar with some nanotechnologies but not others; it is important not to lump different types together and confuse the risks of different groups. Some nanomaterials are already on the market (e.g., aspirin) and it is important that we don't throw the baby out with the bathwater when trying to regulate nanomaterials that are much more questionable in their effects (see Frame 2 in IRGC paper). The IRGC framework paper is a useful tool to help identify these differences and its discrimination between passive nanomaterials and other types should be considered by the Canadian government. It is important to learn from different technologies; it's important to recognize that we can look at different models.
- Is it possible to regulate something that we have very little information on? What does a concentration level mean? How do we decide on concentration level, per se, that's safe? What exposure level is acceptable? We need standards of measurement but we also need to have standards of risk to determine what exposure levels are 'safe'.

**Discussion 2:**

- Labeling of nanoparticles in products:
    - Is it possible?; What would be on label?
    - It would be difficult to track the lifecycle of a nanomaterial without even knowing what products they are in. Labeling could help to evaluate the lifecycle of nanomaterial.
    - How difficult would it be to evaluate lifecycle of a nanoparticle? Could look at the lifecycle of a product.
    - A barrier/challenge to labeling is that nanomaterials do not fall into one single class of nanoparticles or materials.
- End of nanoparticle lifecycle is a concern. This is also true for other materials (similar to drugs). How do you store, analyze them, etc… More research needed.
- Is a new model of Risk Assessment needed? Traditional risk assessment models may apply. Current science suggests that current risk assessment models (for measuring toxicity and exposure) are still applicable. What are needed are the standards for measurement.
- Regulation of the process of production is necessary in addition to product.
- How do you collect a sample in the environment, then transport, store and analyze it? Is the nanoparticle product that is collected comparable to the original?

**Discussion 3:**

- Liability (regulatory regime)
    - Who is at most risk – environment or consumer? One of the largest concerns regarding strict liability will likely be occupational health of workers involved in the production of nanoproducts.
    - We need new models for all stakeholders to play a part and so that they all share benefits and risks. Perhaps we identify a new model in which stakeholders

collectively fund research and distribute risks and benefits. How would this model fit with other risk management models?

    - A common fund (such as the US EPA's Superfund) could be established to cover the risks. Stakeholders would contribute to the fund, which would finance research on the risks of nanotechnology. This would reduce the responsibility for each individual stakeholder to evaluate the risks. How would this model interact with other models of risk management (eg. the Canadian Chemical Producers' Association Responsible Care initiative)? Would a common superfund preclude other risk assessment models?

- Labels
    - What criteria would one use to identify whether a nano-label would be used on a certain product and what would go on the label?
    - Costs of analysis would be very high if every component of a product was labeled.
    - What would be the utility of labels? (Particularly without knowledge as to the acceptable levels of exposure or toxicity). Consumer choice?
- Proportionality of Risk
    - Nanoparticles could be identified in products to consumers, but we are exposed to nanoparticles all the time. We are more exposed to nanoparticles from the furnace emissions than from many products!

Question from participant: Could you expand on your last point (exposure to furnaces).
Answer: This is an attempt to keep everything in context (with reference to labeling – there are already nanoparticles in products…)
Comment: But we can't forget that vulnerable and non-vulnerable people are being exposed to these. We can't say "well, so what if we're already exposed".
Answer: The point was intended to make this comprehensive, not say it is ok.

Comment: The table seems to go beyond the concept of packaging labeling to consider the use of labeling to track a product through its lifecycle. This is a very interesting concept.

Comment: How can we just zero in on nanomaterials with that kind of lifecycle analysis without drawing in all other types of chemicals that should be treated in a similar manner? We do know, however, that nano-sized materials are an issue.

Comment: We don't have the tools to track / monitor these, even many chemicals.

Comment: Could consider different classes of labeling.

**Blue Dot Group:**

**Discussion 1:**

- Development of standards, terminology and nomenclature are needed internationally and nationally to define what nano is and what it is not. Nomenclature is important – should look at existing nomenclature systems to determine how a naming system could be developed, or how nano could fit into the current system for bulk materials.
- Classification – there are needs in this area; some work is taking place at international forums and ISO. We should look at international activities rather than growing them here in Canada.
- Labels must be based on science – otherwise they won't have a meaning and may be ignored by consumers.
- A proactive approach to regulation should be taken where it is needed.
- There is a need for a regulator to transmit information and initiate information sharing. Multiple stakeholders need to be involved to help develop the right messages.

**Discussion 2:**

- Overall, support for proposed elements in CIELAP's structure.
- CEPA structure needs to be re-worked for "new" vs. "existing" substances – should follow the precautionary approach.
- CEPA appears to be using an effective approach for nano; how could it be used to apply to products, not just materials and substances? How can it and does it need to cover manufactured products?
- Information-sharing is necessary and the public needs to be involved early and in all processes.
- Mandatory vs. voluntary regulations – general consensus was that mandatory may be best way to go to ensure fairness. Concern with mandatory regulation, however, is the need for more government resources for enforcement. What can industry do to move these regulatory frameworks forward?
- There was some concern for government taking on an "advocacy" role, but support for the government's role in disseminating information.

**Discussion 3:**

- When we talk about nano how much of our discussion is a reaction to a name/ label?
- How should we translate complex science topics to the public and give perspective? We need to give a balanced view. Communications should have multiple interests expressed. Information should be science-based and targeted at the public. E.g. Jay Ingram, Discovery Channel to put concepts in perspective.
- There may not be a need for new legislation and we can use existing legislation instead. It should be consistent with legal initiatives that are taking place in other countries. It is

important to be consistent with global legal initiatives. International standards should be involved form the beginning. De Facto legislation can be based on international standards and adopted for use here in Canada. There are mechanisms within regulations that will make standards de facto regulation.

**Red Star Group:**

- Research $$$ should not all be spent on promotion and commercialization. A percentage should be spent on public awareness and education and looking for the problems and downsides of the technology.
- From an industry perspective, the public needs to get a certain amount of education. Public education on things where the science isn't known can be problematic.
- There is a lack of political will from the politician standpoint. Are we "waiting for the dead Canadian"? The group agreed that a political champion is needed and urged that this champion be established before, not after, a disaster.
- Is there a simple solution? Can we have a simple structure? There could be simple solutions with some materials – we don't want to problematize and make a mountain out of an ant-hill. At the same time, don't want to downplay the concerns. We need to understand this more.
- Consumer choice and labeling: people do need information and should have a choice. What should people be told? If the substance is not toxic, how much information should be given?
- Different generations of nanomaterials (IRGC paper) and different frameworks to address each is worth taking a look at.
- Industry perceives government Departments as going off in different directions. Environment Canada and Health Canada need to work better together and bring in other government departments. Industry feels that it's up to them to pull the two groups together. From a perception standpoint both departments should be seen as going down train-tracks on same train.
- What happened to the document that went to the Minister of Industry Canada re: a national strategy on nano? (acst.gc.ca)
- Other regulatory agencies (transportation, security) need to have an input at some time.

**Green Star Group:**

- Environmental Health & Safety concerns / Research should be balanced to avoid hampering commercial opportunities and development.
- Need to understand what 'Nano' means and includes in order to know what to regulate and communicate and how to deal with it (it's now used as a buzzword).
- Communication needed between government levels and stakeholders and public.

- Comprehensive mapping of 2 types – *normal* (players, who and where) and *roadmaps* (timeline, when, who will do what actions) – is recommended to co-ordinate and engage.
- Commercialization requires clarity of liabilities and regulations.
- Fragmentation is a significant problem. We have heard different groups, departments having workshops etc… Where is all this information coming together? How is anyone here going to find out what happens at other workshops that people are going to?
- We need a champion but it shouldn't be only one person – it needs to be a group, institution.

**Red Dot Group:**

- The group reiterated the need for a national strategy. There needs to be a national body to do this and to link the departments together.
- We need a centre for knowledge transfer and sharing and this centre should help in the coordination of a strategy.

**Discussion 1:**

- Need for better early legal involvement and expertise
- Need strong international collaboration.
- Need foresight (common trends)

**Discussion 2:**

- Need better national co-operation.
- Should better support International activities (Canada is not a major player).
- Need an independent stakeholder panel to build common database for knowledge sharing.
- Canada should lead in policy making and R&D (disagreements at table).*
- Who will be responsible for a lifecycle approach to ensure that products are assessed in the long-term? This will be important for the public to understand.

**Discussion 3:**

- We need a national inventory of substances and applications to be shared by all departments and offices to coordinate substances, applications, products.
- We need a system to track imported products and share that knowledge.
- Consultations are important. These need to take place proactively with Multi-National Corporations ahead of time to get information on directions and proposals and to ask them about next steps (e.g. DuPont risk framework).

- Federal funding is needed to invest in adequate instrumentation (research, research labs, giving the government the research tools it needs).

**Facilitator's Summary on the Reports Back:**

John summarized key points that were consistent across group discussions:

- The notion of a champion was very strong and consistently came up in each presentation. Clearly this is a leadership effort, a national strategy, the opposite of fragmentation. It is funded, is likely an institution (not just person), and can actually get things done.
- International congruency is needed. If we're not plugged into the international processes we could get left behind or move in different directions from the international community.
- Nearly every group mentioned the need for a communications process. Whether this is through the championship centre or a different process, it involves engaging the public in a constructive process that allows people to understand what is a very complex area.
- A lot has also been heard about nomenclature, labeling, clarity, and collaboration between different governments and organizations.

**What Will Take Place After the Workshop:**

Anne Mitchell informed the group that draft proceedings from the workshop will be sent out to all participants once they have been completed. Participants should then let CIELAP know if anything is missing or if anything is not represented correctly. CIELAP's plan is to make the proceedings available on the CIELAP website, after participants have signed off on them. They should be available around the beginning of March. CIELAP is also working on a second document that will bring forward our recommendations on short and long term priorities, based on the discussions today. This document will be available some time in March as well.

**Developing a Path Forward:**

Anne Mitchell began the discussion by pointing out 3 areas where we could move forward immediately:

1) Mapping and sharing what we know and what is going on in Canada – what are federal departments, provincial governments, academics, civil society groups, industry doing re nanotechnology in Canada – so that we are not reinventing the wheel. For example, there already is a draft national strategy for nanotechnology document which is languishing somewhere in Industry Canada.

2) Helping to generate the political will to find the 'champions' in Canada – those who can encourage governments to ensure that we move forward in a responsible, transparent and honest way acknowledging the potential problems and unknowns as well as the potential benefits.

3) Making sure that a percentage of research dollars are allocated to public engagement and stakeholder involvement, as well as to actively seeking the potential problems and downside of nanotechnology.

Comments from participants:

- Any policy statement needs to be simple, snappy, and understandable. A sales pitch needs to be developed (it's hard to sell anything when no one has died or concretely been affected). We're a bit late in engaging in public education. We need to help people become familiar with the issue – the media can become extremist if there isn't enough literacy among public.
- A framework needs to transcend different levels of government.
- The champion should be bigger than one individual. It needs to be a process that is funded and has staffing. Being realistic we can't expect immediate movement on this. The NNI in the US has a very small budget. Can we start small?
- Public participation costs a lot of money. Agriculture and Agri-Food Canada has been looking at how other countries engage their publics. Germany has used online chat rooms, which are much less expensive than physically bringing people together. Japan held a discussion on internet among 10,000 scientists. People need to be exposed regularly. We need to develop materials and make them available to encourage literacy. Japan and Singapore have developed cartoons for kids on nano. Design exchange and the Ontario Science Centre are interested but the funding isn't there.
- We can learn a lot from the biotechnology era. Everyone was talking about biotechnology and safety. The messages about safety were also very corporately controlled. This produced a "yuck" factor in terms of public opinion. One participant suggested that we shouldn't even try to predict public perception will be because it may be completely different from what we expect. Perceived corporate control tends to bring out public concern. What we need is transparency and to be prepared for all types of public opinion.

Discussion about a strategy:

- A proposal has been put forward for a national nano strategy (as opposed to a policy framework or a champion). It's worth making a distinction between a strategy document (that a lot of energy goes into producing but may not necessarily see results) and a strategy (that details what is going to be done; who will do it; how will it be funded; when it will get done). We may be best with a national lead at a national level who has a say into who does what, when, and how. Policy can be limited (doesn't deal with who, what, where).
- A strategy should be used to suggest what we hope to achieve; an energetic, vigorous vision (rather than just policies). The US strategy has come out very late in the game it is a playbook of who's on the field. We don't need a champion if we limit ourselves to thinking that an assessment of our current capability is enough.
- There are countries that are doing fine without a national strategy such as Japan and Singapore. These nations operate in a much more top-down manner, however. Maybe

provincial strategies are enough with good coordination at the national level. A national strategy could be adopted by Canada based on one of the provincial models (could be driven from the bottom-up).

- When we deal with other countries Canada looks very good. We've been proactive – early in some cases, late in others. We have many elements in place. Our Science and Technology strategy gives direction to what we should be doing relating to various technologies. Do we have an ICT strategy? No. Then why do we need one for nano? Is there more public risk? Is more public engagement needed? Most workshops have concluded with the same thing – that we do we need framework. We're on course and we don't need major changes. We should ask "what's missing?" We need to include more NGOs with various specializations to consider what we haven't yet covered.
- Significant questions still need to be addressed from a regulation point of view. Hearing from SMEs brings forward significant concerns about how the current system prevents opportunities for innovation. There is not enough R&D at a fundamental level and there is no capacity for the regulatory system to address this. There is also concern that public is disconnected from what's going on. No one knows what nano has to offer. That may be why public isn't engaged. We should be cautious about saying that things are in good shape.
- A national strategy is critical particularly given the current absence of political will. The process of developing a strategy would involve setting a vision and making it easier to get there. The public and other stakeholders need to be a part of it and then they would be more willing to accept the conclusions.
- We need to ask some questions at a high policy level: What are we good at? Where do we want to be in 5-10 years? How do we get there? Comment: this exercise has been done; why do we need to do it again? Answer: because it hasn't been published. Until then it is not a strategy.
- Identifying gaps presupposes that we know what we want – what gaps do we choose to pay for? Canada needs to ask – what are we trying to accomplish? Do we want to do good research; shape our economy; educate kids about good science questions?
- A strategy is important because it can direct research to fill the most important gaps (e.g. in Health Canada, it's hard to find an expert on medical devices because the expertise isn't there. A strategy help determine where funding goes.
- There is a disconnect in this discussion. Everyone is talking about how we need a strategy on how to move forward on this technology but we still need to determine what we do about this technology.
- There is a big disconnect between the earlier conceptual framework and the jump to operationalization and commercialization – hopefully a much broader framework will be developed out of this workshop. This could then help us get to a national strategy. Can we work towards this? A lot has been done. In Edmonton participants identified and prioritized gaps; identified key priorities; and assigned funding ceilings to each of these items. Key agencies were identified to conduct research and to develop baseline data to inform a strategy. More coordination is needed.

- We need to speak to a broader array of stakeholders, than just the enthusiasts, to help set policy. The public won't support corporate-driven interests that are backed by government.
- Nanotechnology can't be boiled down to one issue – it is very, very broad. We should examine literature on diffusion theory (work of Rogers), how publics adopt new innovations. Have these principles been addressed in framework?
- A national strategy is important but we need to get to the immediate nuts-and-bolts. Discussions on both are needed.

**Wrap-up by John Vincett, Workshop Facilitator**

John pulled the discussion to a close and made some summary statements. When we look at what we do next we see a couple of approaches: 1) incremental - we modify what already exists, or 2) we develop entirely new systems. There is a sense that some prefer an incremental approach and think it can be sufficient, at least in the interim. Others take the view that there is a novel element in nano that requires a new approach to the regulatory process. It may be that the distinction between these two approaches approximates the short term and long-term strategies concept – but we should note that there are probably different definitions of the duration of the 'short term' involved in this kind of a consensus. A winning strategy for the majority of the participants involves pulling the best of the ideas for short and long term strategies together. There are a number of resonant points. A deliberate and involved leadership structure is needed that can bring information together and share it domestically and internationally. An important part of the process of "championing" will be the fostering of a meaningful and educational dialogue with Canadians that helps them: understand the issues; be aware that there are gaps in our knowledge; and that there is an ethical process in place to apply scientific method to deal with the information gaps. John thanked the sponsors and organizers for creating the opportunity for a useful and stimulating discussion, and the participants for applying their energy and intellect to make it a learning experience for all.

**Thank you from Anne Mitchell, CIELAP Executive Director**

Anne thanked the sponsor, Health Canada. She also thanked the Ontario Centres of Excellence for sponsoring lunch and the Ontario Genomics Institute for assisting with the room. She thanked the presenters: Susan Holtz, Delara Karkan, David Clapin, Bernard Madé, Walter Derzko, and Maureen Carter-Whitney; the facilitator – John Vincett; and Carolyn Webb and Laura Turley for helping organize the workshop. She also thanked all the attendees for their enthusiastic participation and contribution to the success of the workshop.

**Reference Materials recommended by participants:**

"Laypeople's and experts' Perception of Nanotechnology Hazards", *Risk Analysis* 27(1) 59, 2007.

"Nanotechnology Lifecycle Risk Management", *Human and Ecological Risk Assessment,* 12: 528, 2006.

**Appendix A: Excerpt from CIELAP's *Sustainable Development in Canada: 2005 Update***
**By Mary MacDonald and Susan Holtz**

# Appendix A

## Overview of Analyzing and Creating Sustainable Development Initiatives

| | | |
|---|---|---|
| **CORE VALUES, equally and simultaneously** | • Human well-being | • Ecological health and integrity |
| **DRIVING CONCERNS, equally and simultaneously** | • Meeting human needs that are mediated through<br>– social &<br>– economic development | • Avoiding new negative anthropogenic changes & reversing past damages to the environment, including<br>– chemical<br>– physical &<br>– biological changes |
| **CORE AREAS for FOCUS and ACTION** | • Social<br>• Economic | • Environmental |
| **POLICY FRAMEWORKS and GOALS** | • No widespread consensus on framework for social & economic topics & goals<br>• Topics used in many approaches include<br>– Population/demographics<br>– Human health and its determinants, such as food security & nutrition; shelter; sanitation<br>– Literacy/education<br>– Security, crime & corruption<br>– Basic human rights, equality & democratic rights<br>– Income, employment<br>– Competitiveness & innovation | • Widespread use of the World Conservation Strategy framework for environmental topics & goals<br>– Maintenance of essential ecological processes and life support systems (addresses pollution & waste)<br>– Preservation of genetic diversity (addresses habitat loss, invasive non-native species)<br>– Sustainable utilization of species & ecosystems (addresses rates of harvesting & extraction) |
| **CHECKLIST of CONSTRAINTS on ACTIONS & INITIATIVES in order to integrate goals** | • All actions & initiatives must<br>– Be effective<br>– Take into account environmental constraints (minimize waste & pollution; minimize habitat impacts of physical restructuring & avoid biological restructuring; restrain harvesting & extraction to sustainable levels)<br>– Be economically sustainable (allocate or generate sufficient resources for the anticipated lifetime of the project or initiative)<br>– Be socially responsible (improve or at least maintain the position of the most vulnerable group affected)<br>– Be equitable (distribute costs, benefits & risks equitably) | |

## Notes

- The decision flow described in this OVERVIEW chart is as follows: an actor (a policy analyst, a manager, etc.), accepting the **core values** of sustainable development, might want or be mandated to act on its **driving concerns**. Depending on circumstances, a proposal (a policy, program, or other action) within one of the core areas is developed to address **goals or objectives for one or, if possible, several topics** (pollution control or literacy, for example) within the overall **sustainability framework**. But however brilliantly that proposal addresses its main objective(s), all actions have a variety of unintended consequences, environmental, social, and economic. The proposal must therefore be reviewed and perhaps revised in light of how the **constraints** related to all dimensions of sustainable development affect its various implications.

- Social, economic, and environmental domains used as a sustainability framework are often referred to as the "Three Pillars" of sustainable development. Occasionally social and economic areas are considered together as the socio-economic domain. Political and governance dimensions are usually encompassed in the social (as here), but are sometimes broken out as a "Fourth Pillar."

- Some analysts might consider efficiency as an additional basic constraining criterion. We place it as part of the general design criteria for good programs, such as ease of administration; these considerations are instrumental and operational, not fundamental. In a sustainable development context, economic efficiency as a substantive objective can be trumped by the above social, environmental, or equity considerations.