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Stakeholder Meeting on Nanotechnology

Friday March 16 2007 at the MaRS Building, 101 College Street, Toronto, 9 am to 4 pm

Proceedings

Session 1	Welcome and Introductions
Session 2	Understanding the Issues
Session 3	Facilitated discussion about the important unknowns, advantages and potential problem areas
Session 4	Elements for an Appropriate Policy Framework for Nanotechnology
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Session 6	Immediate next steps.

OntarioGenomicsInstitute
The Future is in Our Genes.

Thank you to the **Ontario Genomics Institute** for Co-Sponsoring this event.

Thanks also to **Health Canada** for contracting this work and to the **Canadian Biotechnology Strategy** for helping to fund this workshop.

Summary:

On March 16 stakeholders from multiple sectors met to discuss an appropriate policy framework for nanotechnology. Some of the key points that came out of the day were that:

- Nanotechnology is a big issue, important to the economy that Canada should be dealing with in a comprehensive and coordinated fashion, with reference to the global context.
- Nanotechnology is likely to evolve in all sectors of the economy and a policy framework either has to build on a fragmented existing set of policy areas to include the nanotechnology dimension; or (more usefully) a broader policy framework can be created that will then be applied universally and at a high level across all sectors of the economy.
- An ethical framework will be essential for the development of an effective and consistent policy for Canada.

- Extended producer responsibility will be an important part of building in the economic discipline into the developmental processes – and Life Cycle Assessment will be an important part of that risk management process.
- Education will be an enormously important part of the process of creating an economy that promotes responsible nanotechnology applications. There are many publics who will need to be considered for a range of educational initiatives including industries, researchers, academia, politicians, general public, and the education system itself.
- Public engagement in the potential benefits and risks will be an important part of the eventual acceptance of a policy framework based upon accepted ethical principles.
- It will be important to create (or empower an existing) structure within Canada to address this important topic and create a focus for Canadian action as well as for Canada's interaction with the rest of the world on nanotechnology.
- There does exist a reasonable consensus between the stakeholders that gathered for this discussion, that despite the fact there could be difficulties to be resolved (e.g. Intellectual Property, Liability) there is an acknowledged need for multiparty discussions to continue to address the nanotechnology policy framework challenge

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1 Welcome and Introductions

Anne Mitchell, Executive Director of CIELAP welcomed the participants. She thanked Health Canada and the Canadian Biotechnology Secretariat, who are funding this initiative, and the Ontario Genomics Institute who are co-sponsoring the workshop and providing lunch. Anne pointed out that CIELAP, founded in 1970, has a mandate to provide leadership in the research and development of environmental law and policy that promotes the public interest and sustainability. She also discussed how CIELAP held its first workshop on biotechnologies in 1984 where participants called for a comprehensive policy framework for biotechnologies as they evolved. She reminded participants that considering a policy framework for nanotechnology is the purpose of this workshop. She pointed out that science has leaped ahead of consideration of ethical, environmental, social, legal or economic issues and that at the 2002 World Summit for Sustainable Development some groups were calling for a moratorium on nanotechnology until and appropriate policy framework had been developed.

She gave regrets for those who couldn't attend and introduced John Vincett, the facilitator for the day. There followed a round of introductions of all participants. John clarified that this is an initial discussion and that we looked forward to an interesting and invigorating day with so much expertise from different sectors in the room.

2 Understanding the Issues

There were three brief presentations on research; some applications in the motor vehicle industry; and some policy considerations:

i) Research: Dr. Shane Green, who oversees the Social Impact Programs at the Ontario Genomics Institute (OGI), talked about OGI's interest in and support of research at the convergence of nanotechnology and genomics and proteomics; e.g., Quantum dots (using nano with gene sequencing to detect single molecules that are indicators for infectious diseases); biodiversity (hand-held bar-coding devices); rapid gene sequencing; bioremediation. The rate of change is astonishing and the potential for the development of business and R&D opportunities is immense.

He provided a brief overview of OGI's three core activities: attracting and supporting investment in research through Research Programs; accelerating the realization of benefits from research through Business Development activities; and, increasing public awareness and understanding of genomics and proteomics research and their societal impacts through Outreach. He then talked about how research on GE^3LS (Genomics-related Ethical, Economic, Environmental, Legal and Social issues) is a priority within the genomics field and that the same should – and to some extent does – apply also to nanotechnology (i.e. NE^3LS)All projects funded by Genome Canada through OGI – and the other regional genome centres –need to have an integrated GE^3LS research component; it's not about auditing or policing, but rather it's about actively looking at the impacts of the genomics and proteomics, and to promote and enable the responsible use of these technologies.

Shane pointed out that the National Nanotechnology Initiative in the US mandates that nanotech research includes integrated research into the ethical and environmental issues relating to nanotechnology, but there is no comparable specific funding in Canada dedicated to NE^3LS. OGI actively promotes these considerations in a proactive manner. There are also implications of nanotechnology for the developing world. Equity, privacy, security, environment, human-technology interface and other implications of nanotechnology for the developing world are issues of concern currently being addressed through research funded through OGI, led by Drs. Peter Singer and Abdallah Daar. Shane hopes that out of this discussion today there will be greater encouragement to focus on some of these issues, as integral to the responsible development and use of nanotechnologies.

ii) Some Applications: Ron Challis of the Canadian Autoworkers Union began with a metaphor. When he began working in the automotive industry he learned that if you take part A in the assembly process (the function of which you understand) and attach it to part B (whose function you also understand), it worked. But later on you were given parts that you didn't know what they did. But they did improve emissions, they did make things work better. The industry has seen big improvements over the years. But now that nanotechnology is being introduced, we are seeing even bigger changes that are more difficult to fully understand - nanostructuring of alloys (making alloys and vehicles lighter and safer); painting; protection; batteries. All of these developments have brought benefits to performance, energy efficiency and the environmental footprint.

With these changes come potential hazards, some of which may well be presently unknown. Ron pointed out that although following and going beyond compliance with all health and safety standards re noise levels, he has two hearing aids. Therefore, even going above and beyond the

set standards, we could still be facing environmental, health and safety problems. He doesn't want to see that happen with nanotechnology, so it is important to create a good set of policies that can be as anticipatory as possible of potential risks so that they can be appropriately mitigated.

iii) Some Policy Issues: Delara Karkan provided us with a deck of slides (specific to drugs and biotherapeutics) which are attached at Appendix B. She provided us with a summary of a public meeting with the FDA - neither the FDA nor the EU had a clear idea of how they would develop a strategy for nanotechnology for drugs and biotherapeutics.

The F & D website used to say that "size doesn't matter" re: drugs. This has been changed because in reality size does matter, e.g. Gold can permeate cells (at 3nm) and could accumulate while this doesn't happen at above 100 nm

Health Canada is likely to be the first Canadian federal government department to hold public discussions about a possible strategy for nanotechnology. HC already has a draft issue identification paper. HC is involved with other initiatives as well, which are geared to raising awareness of nanotechnology, including a play that outlines the benefits and risks of nanotechnology. HC is aware that citizen perceptions of nanotechnology are important. HC is aware that it could get a call at any time asking how nanotechnology is being regulated. HC is hosting a workshop next week on worker safety issues. Toxicity research and other health issues are not currently being funded. Health Canada has done a lot of work, however, on developing a policy strategy. But other federal government departments need to be involved. Such as Fisheries, CFIA and Agencies - As an example; nanotechnology is being used in fish food in some other countries. HC is currently working on a life cycle approach to address issues all along product cycle. HC won't just have discussions with producer, but also with retailers and after a product has been released to the market.

Other issues: nano diagnostic kits - products made for people depending on their genes (ethical issue); science capacity inside and outside of the government; lack of information on exposure – how do we collect data about workers exposed to making these materials; we don't have the right tools to analyze the risk at this time. There is also the discussion about on-going modernization of regulation (smart regulation).

Questions & Answers:

- How will consumer products that fall under the Hazardous Products Act and contain nano particles be regulated?

  These products can't be regulated the same way as medical products which undergo product review. This act does not allow us to withdraw products from the market without a legitimate reason (such as morbidity and mortality due to these products). Even then, market withdrawal is a long and difficult process. The situation is more complicated due to lack of definition of nano. HC and FDA are trying to figure out how to deal with this issue. Health Canada is currently working on establishing a risk management frame work and a strategy for regulation of nanotechnology based products. We have produced a fact

sheet which includes 43 recommendations. Some of these recommendations may address the issue of consumer products.

- What about self-regulation?

  HC may be facing legal challenges. Will manufacturers accept to hand data over to HC when asked for - especially when it's not obligatory? HC cannot ask a health product manufacturer to hand over data unless there is a reason for them to ask. There is limited legal authority. If it's a self-regulated product, how do we get the data? FDA also wants to address this issue.

- Re science capacity – the scientists are there – there is just no funding – so it is not really a question of science capacity.

  It's not a question of science research capacity – but of scientific risk research capacity.

- Who is accountable once product is "out there"? What about disposal, etc…? Could an organization spring up to help facilitate this?

  Organizations like OGI - Ne3ls programs absolutely need to look at these considerations. "Here's how it's likely to be used; what comes next? What other issues are going to bubble up?" What they look at specifically will be up to them. Ne3ls programs need to be part of the team review processes. Ne3ls issues need to come up in the peer review process.

- If we don't have the money we don't have the capacity; from a standards perspective (1) the charge for environmental aspects is also a matter of environmental concern. (2) ISO – the basic problem that's being struggled with internationally is to summarize succinctly that we are starting to develop regulations for things that we don't have yet and can't even imagine yet. Do we need to do this?

  Yes. The unknown we are facing are un-fathomly large. The biggest challenge is to convince people that standards need to go along with research and help determine the research that needs to be done.

- How long did it take for lead to be recognized as a problem?

- Extended Producer Responsibility (EPR) has an important role to play. When the producer is responsible they will design things so that they are disposed of better at the end of their lives.

- Costs of all the modelling required for self regulation is going to be huge as well. How do we weigh up which one is better – self regulation or regulation?

- What about Liability?

This is being discussed. We also need to understand the legal picture. HC has no specific nano funding right now. We are planning to apply for funding for nano projects.

3 Facilitated Discussion about advantages, potential problem areas and important unknowns

Overview:

The timeframe for the technological development of nanotechnologies is VERY fast and what the group is talking about doing – developing a policy framework - is very slow. The 'barn doors' – the challenge of making the slow policy - needs to be addressed. We can, however, develop a very generic risk framework (use risk cells).

The facilitator drew a graph to illustrate how issues develop. An issue progresses with little political importance until a point of concern is reached – legislation is developed and enacted – regulations are developed – then it is argued in the courts. How long does this take? The process after the 'barn door' is opened often takes 5 – 10 years. There was consensus that the point of action is now, not when the concern hits the political process.

Some countries that are advancing nanotechnology work closely with industry. Canada doesn't necessarily have that capacity and does not interact with industry as closely. There is a knowledge gap. Nanotechnology is freely used in Asia in food products, for example food coloring and preservation. We are "getting a tsunami of products coming into Canada". This provides regulators with many challenges.

What about the new buzz words - regulatory cooperation (Canada-USA-Mexico)?; or framework development between Canada and the European Union? Nanotechnology is becoming a major focus. We need to develop a policy framework early before a crisis happens. We're nearing the 'elbow' of the graph but we haven't yet reached it – there is still time to develop a framework and responsible measures before we reach a crisis and public backlash.

Throughout much of the rest of the day groups explored the advantages, current and potential concerns, and important unknowns related to this issue and reported back to the group:

***Accountability; Governance; Responsibility*:**	
Advantages	
Concerns (Current or Potential)	• Canada Lagging behind in setting the policies • Vacuum of policy • Lack of coordination between nations; need for international policy / cooperation • Ability and desire to develop a framework appropriate to each

	application • Lead in commercial and policy decisions; do not follow what occurs on the international scene • Disclosure – if it's not food it won't need to be disclosed • Difficulty of getting industry involved in process noted – fear of IP loss / liability potential; Size of company an issue • Conflict over stem cells – US policy is driving the process
Important Unknowns	• Accountability – where will / should it be regulated? • How do we ensure effective implementation? Who leads this? • Who has responsibility to sort it out? • Need to define between competitive advantage and responsible behaviour • The line between commercial IP and disclosure • Value of tools that exist – need new tools predicated on incomplete knowledge • How (and who) should fund the enabling process to put framework in place – must be safe, responsible, productive, effective (pre-competitive stage) • What would be an appropriate interim management system? • Who currently regulates the products? • Canada / internationally – go along / find niche – needs provincial/federal strategy • Research is going faster than regulation – how do we deal with that? • In the chemical industry disasters drove voluntary regulation. There are ethical systems for industry and processes that we can build on. • Scale: Nanotechnology has no respect for boundaries; we're trying to regulate it at a human level because of a human response, not at the nano level (eg. Abortion debate brought about by biotech research) • "Smart regulation: - Health Canada (regulation should not impede research and development) • Accountability for risks – internal self-governance • "Inventory of capacity"; what is being done to build this capacity - research, education? • Transformational technology → Incremental adaptation of existing frameworks likely • Responsible Care® provides an existing ethical system that could address nanotechnology issues (those outside the self-regulation

	process are not using this process) • Nano could be an organizing principle for examining potential of developments – some capability to consider risk questions

Coordination and working together:	
Advantages	
Concerns (Current or Potential)	• Fragmentation within the government, little communication between them and other actors. • Multiple potential solitudes • No common definition of nanotechnology so that everyone is of the same understanding
Important Unknowns	• What is nanotechnology? Companies are staying away from calling it "nano" because of the potential negative implications. (whereas "bio" may be seen as positive). • What is happening in the way of collaboration and communication between groups working on this issue? • What can we do to build transparency between sectors? • How will it be coordinated (public & private)

Technology & Science:	
Advantages	• Enhanced research capabilities in Canadian universities and industries • Bridging the technology gap (with cheaper products) • Miniaturization in general, with all advantages involved • Better batteries • Better, faster computers and ICT stuff • Integrated sensors for physical, chemical, biological data • Better materials (stronger, lighter, cheaper) • Stronger consumer products • Food processing & storage • Water treatment and remediation • Vector & pest control • Nanocapsules for controlled herbicide release

	• Better catalysts (in general) • Improvement in agricultural techniques, land uses • Agri productivity & enhancement • Construction – nano cement • Identification tags • Molecular printing
Concerns (Current or Potential)	• Controlled roll-out • Dispersal is easy (so small) • Sustainability: both of research and impact of technolog • Unintentional unanticipated reactivity
Important Unknowns	• Independence of academics? • We also need to look at the impact of the molecule and what other impacts a "functionalized goal" might have? • Temporal scales and timelines (could have different impacts); how do the nano particles break down or bind to other particles? • What are the physical, chemical, other properties – for example the fact that size does matter when you get to the nano scale. This defies what has always been assumed. • Multiple science unknowns (tests, measuring, priority setting) • Technology sectors – took approximately 30 years to create the needed infrastructure (hydro – grid; computer – internet). What social innovations will be needed to provide the infrastructure to make it effective? • What work is being undertaken in labs and development centres? • Bio/nano/cogno → making things smarter; disruptive technology impacts

Public education /engagement:	
Advantages	• Increased interest in science and technology from public/ politicians
Concerns (Current or Potential)	• Lack of opportunity for stakeholders to engage • Informed public discourse • Lack of informed policy discourse – opportunities for regulatory development and standards • Public-research disconnect; no communication

	• Misinformation, public perception and lack of understanding • Channels of public communication; how will we reach the mass market? • insufficient public discourse
Important Unknowns	• What does the public know? - Level of trust - Level of information - Expectations/management • What adjustments do we need to make to the existing education system to take advantage of this opportunity? • How do we inform / engage the public on nano and who is responsible for that? ENGOs / NGOs / Industry / Government • How to open up the vision for society • What critical groups will form; what concerns will they have – "nano-peace"

Environmental:	
Advantages	• Energy efficient appliances, devices, etc... • Improved environmental monitoring devices (groundwater quality) • New technology to enhance environmental clean ups • Environmental remediation • Potential to shrink environmental footprint (increased efficient use of resources) • Fuel cell progress • More efficient lighting • Nano to energy storage production & conversion • CO2-nano-sequestration • Air pollution & remediation • Intelligent windows
Concerns (Current or Potential)	• Bioaccumulation • Toxicity • Biostability • Unexpected biochemical reactions • Environmental impact and assessment of impacts

	• Effects on biodiversity • Pervasion nature • Accumulation in food chain and impact
Important Unknowns	• What are the long-term environmental effects? • What about toxicology issues?

Economic:	
Advantages	• Commercial opportunity in many different fields • Investment opportunity • Supporting the transition to a knowledge economy • Health care cost savings for society
Concerns (Current or Potential)	• Destabilization of economies due to self replication • Developing countries – how will they be disadvantaged • Canada unable to keep up with other countries (economics, R&D) • What suffers to get funding? • Lack of funding • Negative patenting applications • Gap between 'haves' and 'have nots' • Marginal financial benefits compared to societal costs
Important Unknowns	• What is the economic impact (level of current activity) • No accurate profile of products out there. • Total life cycle obligation for producer essential to put economic discipline in place • Finding funding – what would go unfunded to enable funding of nanotechnology?

Social, Health & Ethical:	
Advantages	**Health:** • New and better medical diagnostics and treatments (cheaper?) • Improved diagnosis of diseases • Identification of food that is contaminated • Cheaper medical interventions

	• More efficient genetic engineering • Improved point of care diagnostics • Remediation of medical problems • Faster pharmaceutical development • Doc-in-a-box / Lab-in-a-box (bedside) • Drug delivery system • Disease diagnosis & screening **Other:** • Quality jobs for Canadians in all sectors • Educational opportunities for Canadian students • Tackle millennium development goals via nano/biotech convergence
Concerns (Current or Potential)	**Health:** • Adverse health effects; Health care costs to society • No special environments to ensure safety – ie. Biological safety cabinets • How will this affect clinical trials in developing countries? **Other Social:** • No interdisciplinary education programs • Balkanization: silo behaviour separating those interested and working in nano • Winners vs. losers: Risk takers vs. beneficiaries • Generation of a dependency (economically or environmentally) **Ethical:** • Winners will make the decisions at the expense of the losers • Nanoscience; nanotechnology – drug development ethical questions – sector specific • Privacy concerns such as public "bar coding" – covert intelligence (HIV testing – principles level ok, applications are new) **Security:** • Dual-use potential – nano-terrorism? (nano can be used by anyone if technologies fall into the wrong hands) • New types of weapons • Need for restrictive trade for security • Development of military hardware – it's hard to control

Important Unknowns	**General:** • Define opportunities at the societal level. Then apply to opportunity. • Re: ensuring that there's no technology gap – we're exploring the questions earlier in the game than any other technology. Will we be able to act fast enough? **Ethical:** • Will ethicists provide the necessary moral and ethical leadership? • How do you identify the key ethical issues? New ethical questions; research ethics boards; challenges managing risks • Consumer access (Canada vs. USA) - Requires policy discussion; Differences in privacy regulations • Information gathered through nano (and other technologies) – privacy issues • We need to redevelop how we look at cost-benefit analysis; (it really only looks as current applications – the tools don't exist to look at future 'creations') • How can we be creative with scenarios and anticipate new possibilities used for great things with unforeseen results? • Cost-benefit analysis, etc. can be used as an excuse; requires discourse and public engagement; false fears • The principles for an ethical framework already exist; how do we apply them to new applications?

Measurement and Standards:	
Advantages	
Concerns (Current or Potential)	• Lack of metrology and standards • Assessment is difficult (eg. In combo products) • Difficulty to measure their presence in the environment, and their quantity • Do we have the tools to evaluate short term & long term safety • Tracking and controlling nanotechnology
Important Unknowns	• What is the baseline (Environmental, human, species)? We haven't yet determined it. • When we develop technologies we need to understand that different countries and groups have different ethical standards. How do we deal with that?

In summary, participants foresaw great benefits being achieved in the areas of medical and health, the environment, material science, and other applications in addition to many economic benefits, all of which offer great potential for sustainable development. Concerns were centred on the lack of political framework to guide these applications; the lack of coordination and communication between stakeholders; a lack of public engagement in the issue at present; the potential for unintended negative health and environmental implications; the divide between the 'haves' and the 'have nots'; serious ethical and security-based issues; and concerns about the difficulty of measuring, tracking and controlling these technologies. There were many, many unknowns that emerged including: who will fund, regulate, monitor, and assess these technologies?; what are the short and long-term environmental and health implications? (there is a general lack of science at the moment); and how is this all coordinated?

A number of interesting mini-discussions were had throughout the day:

Moral and Ethical:

- We tend to slip into utilitarian arguments (cost-benefit analysis) rather than deontological arguments, which are based on principles
- There are four different ethical issues that we need to consider: Equity (rich/poor); Privacy (common good / privacy); Security; Humanity (where do you draw the line; how?)\
- Ethicists need to be able to consider applications on a sliding scale (medical breakthroughs should play out very differently than stain-resistant pants in a cost-benefit analysis)
- Nanotechnology is growing out of what we already have; we likely won't be creating new ethical dilemmas – only different permutations of what we already have. The applications are the issues; not the technology.
- Ethics tend to be "driven by disasters"; policy cannot wait for a happening – future focus is essential
- Beware of toolbox with potentially bad applications – be aware that others may take a different ethical basis
- Peter Singer's paper – 6 criteria: impact, burdens, appropriateness, feasibility, knowledge gap, indirect benefits

What do we need to do to design in safety?

- Establish measurement systems up front
- Fund excellent data collection and analysis systems
- Economic incentives built in
- General product safety directive
- Enforcement and penalties
- Life cycle commitment
- Producer responsibility

- Incentives to share data built-in
- Empower consumers to make informed decisions
- High level safeguards to avoid long term liability through regulation

ISO Committees Globally for nanotechnology (Chairs):

- Terminology & Nomenclature (Canada)
- Measurement & Characterization (Japan)
- Environment, Health & Safety (USA)

A Framework should:

- Be Adaptable
- Be developed sooner (we could start with one that is imperfect and then improve upon it)
- Be relevant across Canada

4 Moving Towards an Appropriate Policy Framework for Nanotechnology

Elements of a policy framework include:

- **Ethical & social impact component**
- **Public engagement**
- **Public education** *everyone needs to be informed including educating scientists about impacts, educating politicians about the field
- Transparency (both **disposition** and a result of it)
- **Regulatory regime**
- Legal and liability framework
- Accountability matrix
- Ability to deal with uncertainty (ways to cluster risks, etc…)
- Some degree of adaptability built into the framework
- Linkages to existing systems and policy frameworks (not reinventing the wheel)
- International engagement by Canada
- Inter-provincial collaboration
- Everyone working together, involved, and sharing information (industries, NGOs/ENGOs, government, academic/researchers, labour, civil society)
- **Distinction between social, environmental, health consequences** (including risk assessment – that consequences are factored in)
- **Lifecycle orientation**
- **Accountability** (partway bwn Lifecycle orientation and EPR)
- Extended Producer Responsibility
- Foresight (long-term thinking)
- Who is accountable for what / supposed to do what
- Indication of timing and priorities (what comes next; what is timeline)

Other points to consider re: a policy framework:

- The challenge is that we don't have a single sector and we're not talking about building a single sector here… A road map approach isn't necessarily the correct approach. One of the more appropriate ways to go may be evidence-based and building our policy on it.
- Any strategy will have to identify the players who should be involved.
- There was a general feeling that a policy framework should be developed sooner rather than later (even if it's something just to start out and needs to be adapted later as evidence is gained).
- The ability to detect nanomaterials has advanced and we now know about many substances that we didn't know about before. A policy framework can't just look at those that we design intentionally but needs to address all nanomaterials.
- One of the biggest gaps is the difference between dollars invested in research versus health and safety. There are not enough researchers to be working on the issues.
- A framework is supposed to be dynamic. Regulations are less so.
- We have tools but not enough experience to use them. We need a policy framework that is flexible enough but has some structure so that we can't say it's non-existent.

5 How to move forward? Where do we go from here?

- Let this not be the end – but let this be the beginning of a process to engage more stakeholders.
- CIELAP will develop proceedings; consult with those who couldn't come; develop a report on CIELAP's view of what next.
- Any next steps would need to have a very clear purpose of what they are seeking to achieve.
- NGOs and others need to be funded to attend future discussions.

Three building blocks to next steps:

- who are the right stakeholders?
- what capabilities exist?
- what is happening and projected to happen in the next 5 or 10 years?

Several workshops and processes on nanotechnology are happening. Can CIELAP partner with another group to develop a combined document? Eg Dupont and Env Defense in the US?

Health Canada is moving quickly towards a strategy. They are consulting and gaining feedback from different stakeholders and countries.

Departmental strategies need to be developed; provincial governments must be involved. Who is the responsible authority to commission a national strategy re nanotechnology in Canada? CIELAP's report will not be a national strategy but may include suggestions about how to get to a national strategy. You need buy-in to get the right people at the table. We need a mechanism to create consensus and then commission a strategy. HC is setting up an expert panel comprised of all different groups and has commissioned the Council of Canadian Academies (CCA) to prepare a report on the most important considerations for a risk approach to nanotechnology. Who would be the most effective motivator? Health Canada, Environment Canada and Industry

Canada are involved. The CCA process will include witnesses, peer review, public meetings and will last 12 – 18 months. It is important to figure out a clear model for involving the public. The question was put – is this going to be a transparent process? The response from CCA was that the final report will be from the committee – the expert panel. The CCA's board can state that the methodology was followed but it will be the committee's report.

Further exploration required in several areas:

- We need to build standards development into all of this and become a part of this process
- There is a strategy framework for innovation but the risk side seems to be left out.
- Any document that is put out should have both perspectives – risks and benefits - into account.
- We need to create partnerships among different 'silo' events and participants.
- Policy isn't something that we just spit out in a day. It's developed in a multitude of ways.
- Need to have clear accountability to the public.

It was suggested that we come up with a straw proposal out of this group; get that done very quickly and get feedback and then there's something to talk about. We also need contacts and other information of people who would be interested in considering such a straw proposal.

We need to effectively funnel this dialogue into the process, for example the CCA process: any information, contact info, etc… can be provided to the scientific and academic panel. CCA will try and ensure that all relevant groups (stakeholders and otherwise) will be represented in the process. Reports will be made publicly available and it is hoped that they will be relevant across all interested sectors of society.

Health Canada is also working on other initiatives (youth plays, public meeting, other ways…). We need to gather information about what government departments and other groups are working on all of this. Participants were asked to send any information they have of other processes and initiatives that are happening to cielap@cielap.org.

6 Immediate Next Steps:

1. Send any information of processes, workshops, reports, websites re nanotechnology to CIELAP at cielap@cielap.org
2. CIELAP will prepare proceedings and send them out to participants, along with a list of participants and coordinates, as soon as possible.
3. CIELAP will develop a website to distribute resources as well as documents that come out of the workshop.
4. CIELAP will distribute the proceedings to those who expressed interest in the workshop but were unable to attend.
5. CIELAP will develop a policy document for discussion purposes and distribute to participants and others.
6. CIELAP aims to help move policy forward. We want to build on the discussion held at this workshop and perhaps engage more stakeholders in a larger, national discussion. We will consider whether it would be useful for CIELAP to seek funding to hold a future workshop in the fall.

Thanks

CIELAP's Executive Director, Anne Mitchell, thanked the participants for attending, Health Canada and the Canadian Biotechnology Secretariat for funding; Ontario Genomics Institute for co-sponsoring; and John Vincett for facilitating the discussion. Anne concluded by saying that CIELAP wants to build on this day and hopes to keep in touch with those who were able to attend and also engage with those who had expressed interest but had not been able to attend.

Appendices:

A List of Participants
B Powerpoint presentation – Health Canada
C List of suggested resources from the workshop participants

Appendix A – List of Participants

Name	Affiliation
Maureen Carter-Whitney	CIELAP
Ron Challis	Canadian Auto Workers
David Creasey	Canadian Biotechnology Secretariat
Richard Crossman	Canadian Council of Churches
Walter Derzko	Consultant
Lesley Esford	National Research Council - Industrial Research Assistance Program
Trina Foster	Council of Canadian Academies
Shane Green	Ontario Genomics Institute
Jim Heller	University of Toronto
Susan Holtz	CIELAP
Delara Karkan	Health Canada - Office of Biotechnology and Science
Geneviève Lavertu	Medtronic of Canada
Anne Mitchell	CIELAP
Marc Nantel	Ontario Centres of Excellence
Elizabeth Nielsen	Canadian Standards Association
Linda Prang	Environment Canada
James Rusthoven	Biotechnology Reference Group
Geoffrey Sunahara	National Research Council - Applied Ecotoxicology Group Biotechnology Research Institute
Alan Steele	National Research Council - Institute for National Measurement Standards
Christine Toczeck	CIELAP
Anna Trikoupis	Ministry of the Environment - Research and Best Practices and Special Projects
John Vincett	Facilitator – PDAlternatives
Carolyn Webb	CIELAP
Bernard West	Consultant – Chemical Industry
Andrea Wood	Conference Board of Canada

Please let us know if any of this information should be corrected. We will be including it in our summary report unless you ask for it to be omitted.

Current State of nanotechnology initiatives at Health Canada

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Nanotechnology (NT)

There is no official definition but NT is generally described as the science and technology that creates and/or manipulates materials at the nanoscale.

There are two generally recognized special features of nanotechnology:

- **size:** the applications are at the nanometre scale (< 100 nm)
- **properties:** behaviour and structure manifest novel properties at this scale that differ from bulk matter

The Nanometre Scale

1 nanometre = 1 billionth of a metre

1/80,000 of the diameter of human hair 

~1/100 the size of viruses (20-450 nm) 

1/2 of the diameter of a DNA helix (2-5 nm) 

Are Ultrafine Particles Equivalent to Manufactured Nanomaterials?

Ultrafine Particles	Manufactured Nanomaterials
Released by-products without an application	**Engineered and manufactured for an application**
Broad size distribution	**Restricted size distribution**
Short life-span, agglomerate to larger particles	**Long life-span, many modified to prevent agglomeration**
Chemically complex, less reactive	**Chemically well-defined, highly reactive**

Extraordinary Diversity of Nanomaterials

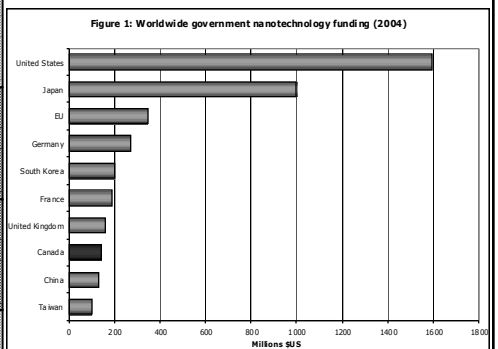
- Fullerenes 
- Carbon Nanotubes 
- Quantum Dots 
- Dendrimers 
- Nanomushrooms 
- Others

Why is NT special?

Nanomaterials can have significantly different properties from bulk matter

- Insulator vs. conductor (e.g., silicon)
- Insoluble vs. soluble (e.g., solvent-free drug delivery)
- Opaque vs. transparent (e.g., "clear" sunscreens)
- Solid vs liquid at room temperature (e.g., gold)
- Inert vs reactive (e.g., gold)

Gold
Bulk: yellow, inert
1 nm: blue, low reactivity
3 nm: reddish, catalytic



International Activities

NT is an international field which is attracting much attention by governments, industry, academics and NGOs. NT has emerged as a national strategic priority in virtually all OECD countries, and over 35 countries have already established or are initiating national NT programs. Some initiatives include:

- OECD Working Party on Manufactured Nanomaterials
- OECD Committee on Science and Technology Policy
- ISO TC229
- International Risk Governance Council (IRGC)
- International Council on Nanotechnology (ICON)
- Global Dialogue on NTs and the Poor (Meridian Institute)
- US National Science Foundation International Dialogues
- Global Nanotech Network (GNN)

Canadian Federal Activities (1)

- Public Service of Canada NanoNetwork (chaired by IC)
- Federal Action Plan
- NT working groups in major health related organizations
- NT events in 2003, 2004, 2005 and 2006
  - NRCan seminars
  - Regulatory workshop March 29-30, 2006
- The Presidents of the Granting Councils, Foundations and Agencies have identified NT as a key area for collaboration and cooperation.
- National Nanotech Strategy (broader policy)
  - Office of the National Science Advisor (ONSA)
  - Prime Minister's Advisory Council on Science and Technology (PMACST)

Canadian Federal Activities (2)

- National Institute for Nanotechnology
  - research institute established in Edmonton, Alberta in 2001 (grand opening June 22, 2006)
  - tripartite operation (NRC, University of Alberta, province)
- Institute for National Measurement Standards (NRC)
  - 2002-07 Strategic Plan calls for $4.7 M in new funding to develop a nano-metrology lab
- Standards Council of Canada
  - established new ISO committee to work on terminology and nomenclature, metrology, and risk/environmental issues
- Public Opinion Research
  - July 2005 Cormex Emerging Technologies Report, 2005 Decima Report

About Health Canada:

Consumer Product Safety
Diseases & Conditions
Drugs, Food & Health Products
Emergencies & Disasters
Environmental & Workplace Health
- Air Quality
- Climate Change & Health
- Contaminated Sites
- Environmental Contaminants
- Environmental Health Assessment
- Noise
- Occupational Health & Safety
- Radiation
- Water Quality

Health Canada Activities

- Issue identification paper and Health Portfolio strategy
- Nanotechnology fact sheet
- Bi-weekly electronic NT updates
- Health Canada/Public Health Agency working group
- Research on assessing and characterizing toxicological effects of nanoparticles
- Health policy research (ethics)
- Federal lead in NT proposal to Council of Canadian Academies
- Federal lead in March 2006 workshop on health and environmental implications of nanoproducts

Regulatory Role

Regulatory responsibility:

- Regulating products to manage risks to the health of Canadians and their environment is a government priority.
  - Health Canada has approved nano products
  - There is a strong science-based regulatory role for Health Canada, Environment Canada, the Canadian Food Inspection Agency and Fisheries and Oceans Canada
  - Regulatory regimes primarily involve pre-market assessment but increasingly will address the life-cycle, including post-market surveillance activities for safety and/or effectiveness.
- Regulating to provide access to beneficial products (Smart Regulation/competitiveness).

Decision-making by Canadians

- Inform Canadians by providing information (in addition to that provided by the regulatory decision)

Federal Tools for Managing Health and Safety Risks

- Legislation (not an exhaustive list)
  - Food and Drugs Act
  - Canadian Environmental Protection Act, 1999
  - Pest Control Products Act
  - Hazardous Products Act
  - Fisheries Act
  - Consumer Packaging and Labelling Act
  - Canada Agricultural Products Act
  - Feeds Act
  - Seeds Act
  - Fertilizers Act
  - Assisted Human Reproduction Act
  - Hazardous Materials Information Review Act
  - Health of Animals Act
  - Plant Protection Act
  - Canada Labour Code (Part II, OHS)

Gaps in Science

- Lack of science capacity in and outside the government for research to support regulation needs
- Impact on human health and the environment is not well established
- Lack of information on exposure (e.g,. baseline, sources, routes, bioaccumulation, compartmentalization, persistence)
- Appropriateness of existing tools/lack of tools
- Modernization of regulatory system based on evidence
- Rapidly evolving nature of the technology

Summary

Nanotechnology has tremendous potential for improving the quality of life and the environment.

Scientific innovations can give rise to benefits but also to health and environment concerns. Responsible introduction of nanotechnology means providing for benefits by addressing risks.

Canada's current regulatory regime can provide a framework for the advancement of nanomaterials and nanoproducts, but there may be a need for modified regulatory and risk assessment approaches as better understanding of their properties is gained.

All stakeholders, nationally and internationally, are on a steep learning curve confounded by a very rapidly evolving technology. We are, however, positioned to develop an internationally harmonized approach from "the ground up". Canada must actively participate in international initiatives.

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Useful websites:

Industry Canada www.ic.gc.ca
National Institute for Nanotechnology - Institut national de nanotechnologie
http://pint-innt.nrc-cnrc.gc.ca/
National Research Council Canada:

From Discovery to Innovationhttp://www.nrc-cnrc.gc.ca/

University of Alberta , http://www.ualberta.ca/

http://www.nrcan-rncan.gc.ca/inter/index_e.html

The Natural Sciences and Engineering Research Council of Canada (NSERC)
http://www.nserc-crsng.gc.ca

Canadian Institutes of Health Research (CIHR),
http://www.cihr.ca

NanoQuébec,
http://nanoquebec.ca

The Canada Foundation for Innovation (CFI),
http://www.innovation.ca

Appendix D: List of suggested resources from the workshop participants

- Robert Sauvé – www.irsst.qc.ca
- Rice University (CBEN)
- Nano/Bio/IT/Cogno-Convergence http://smarteconomy.typepad.com
- NRC-INMS Tri-National Workshop on Standards for Nanotechnology http://inms.nrc.gc.ca (includes slideshows)
- Office of emerging technologies (Health Canada) delara_karkan@hc-sc.gc.ca
- ISO TC229 / IEC TC113: Nanotechnologies Canada Advisory Committee Secretariat brian.haydon@csa.ca
- Peter Singer's group's paper on how nano addresses the MDGs