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Innovative Technologies and Sustainability

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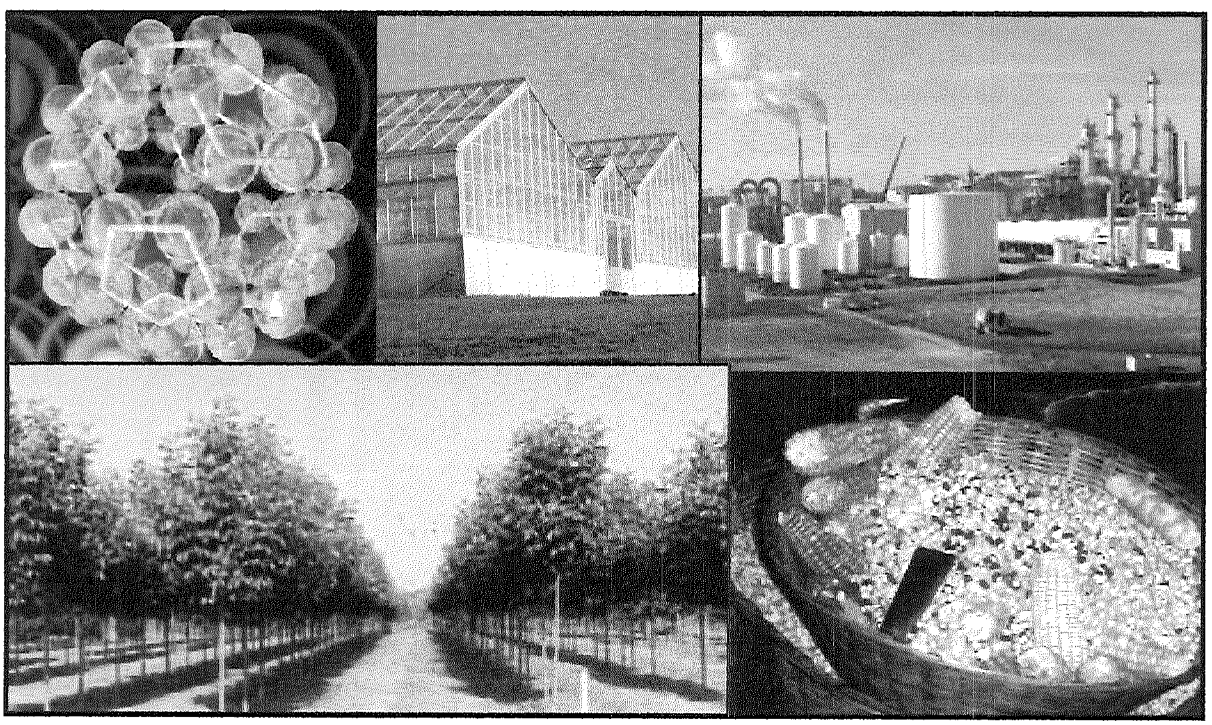

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About the Canadian Institute for Environmental Law and Policy (CIELAP)

Founded in 1970, the Canadian Institute for Environmental Law and Policy (CIELAP) is an independent, not-for-profit research and education organization, whose mission is to provide leadership in the research and development of environmental law and policy that promotes the public interest and sustainability. CIELAP is incorporated under the laws of the Province of Ontario and registered with Revenue Canada as a charitable organization. Our registration number is 11883 3417 RR0001.

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Susan Holtz is a policy consultant to CIELAP. She also works on related issues as a mediator, facilitator, and editor. Ms. Holtz was the founding Vice Chair of both the Canadian and Nova Scotia Round Tables on the Environment and the Economy. Ms. Holtz was also instrumental in setting up the Canadian Environmental Network (CEN). She has served on many advisory bodies and boards, including the Auditor General of Canada's Panel of Senior Advisors and the Commissioner of Environment and Sustainable Development's External Advisory Panel.

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Introduction to CIELAP's Innovative Technologies Project

The State of the Debate

Over the past decade we have seen an enormous expansion in research and development of innovative technologies such as various applications of biotechnology and nanotechnology. Although much of this momentum comes from developed countries, involvement and even leadership in aspects of these technologies are rapidly increasing in countries with fast-growing economies, like China and India. This explosive growth offers many opportunities but also brings many conflicts and questions, including concerns over environmental implications, access, proprietary rights, trade issues, and questions about the role of international institutions such as the World Trade Organization (WTO) and the UN Convention on Biodiversity (CBD).

This global expansion of new technology has received support and excited acclaim by governments, researchers and industry groups for the possibilities it offers. It has also been criticized for a lack of deliberation and caution by some governments, scientists and civil society organizations who are concerned about the pace at which these technologies are progressing and the potentially detrimental changes they could bring. Innovative technologies are now a topic of some public debate around the world, with promoters and opposition groups at times strongly divided over their potential risks and benefits. This debate is very much at play in Canada, but only within a small segment of the general population. The public remains largely outside the discussion, uncertain about the merits of different claims and even what the fuss is all about.

Platform Technologies

Biotechnology is defined in Canadian legislation as *the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms.* In its many applications, biotechnology, like certain key technological developments such as electricity or information technology, has the power to change the further direction of many technologies that shape the way we live. It can change the way that we think of, acquire and use food, medicines, health care, and natural resources. It has the potential profoundly to improve the lives of people, with applications such as foods that carry vaccines, can grow in salt water, or have important nutritional value. It also has the potential to profoundly damage the quality of life of many people and different species on the earth, as other technologies have as well.

Nanotechnology includes a variety of techniques that are used to manipulate materials at the nanoscale, the scale of atoms and molecules. Nanotechnology can bring together many different disciplines and applications, including biotechnology and robotic hybrids of biological and synthetic origins. The increasing use of nanotechnology promises to create shifts even more dramatic than those of biotechnology alone.

Both of these technologies can be seen as *platform technologies;* that is, they are significant breakthroughs that are central to the further direction of technological change in society in crucially important ways.

Canadian Policy: Are We Speeding Through a Blinking Yellow Light?

Innovative technologies have raised many issues among a diversity of stakeholder groups. From an environmental perspective there are several very broad concerns. Biotechnology often involves crossing the species barrier with recombined DNA. In nature, hybrid crossings such as mules sometimes happen between related species, but they are usually sterile. In animals, genetic mixing of unrelated species just doesn't occur. But recombinant DNA allows a virus or a plant gene to be inserted into a pig. What are the implications? It's not yet completely clear.

Nanotechnology presents even more unknowns; what the chemical, biological, and ecological behaviour of virtually any substance at this scale is going to be cannot be predicted, and the science to answer such questions just hasn't yet been done – or required by regulatory authorities. It is a significant worry that not only are products being developed without much obvious concern for possible problems, but also that they are being sent out into the external environment where they can disperse freely.

Despite the debate and uncertainty that exists, Canada is moving ahead to promote these technologies. A stated policy goal of the Canadian biotechnology strategy is to position this country as a *responsible world leader in biotechnology.* This position raises some red flags regarding Canada's commitment to the precautionary principle. Canada and the international community have in the past had to pick up the pieces after disastrous mistakes involving technological innovation, including the ecological effects of persistent organic pesticides and compounds and the human health problems related to the prescribed drugs thalidomide and DES. What should have been learned from these experiences is that we need to find practical ways to implement a precautionary approach, even while exploring exciting new advances in knowledge.

Canada's policies on these new technologies are also troubling because they have been informed primarily by possible economic benefits, while social and environmental concerns and uncertainties have not been very well examined. Canada's technology strategies need to consider the international implications of our positioning, looking beyond economic benefits to Canadians and Canadian companies to analyze social and equity dimensions in a global context as well as domestically.

Public Involvement

Another issue is that the Canadian public has not been well informed about or engaged in developing Canada's strategy or approach to either biotechnology or nanotechnology. In fact, there seems to have been considerable government resistance to citizen concerns that have been expressed about the need to examine risks more closely and to have required labeling of genetically engineered food. Similarly, consumer products that use nanotechnology applications are currently being developed and sold to the public, though there is no requirement for companies to identify what products these are. Unfortunately, this lack of attention to information needs for informed decisions by citizens, as well as few opportunities for meaningful public input, are not unique to Canada but are the case in many countries.

A barrier to citizen involvement in policies about new technologies is their technical and scientific complexity. With very limited knowledge of the science, members of the public often feel intimidated and don't know how to begin navigating through the many questions about potential benefits and risks. The patchwork of responsibilities for different biotechnology applications in the regulatory framework is also confusing, making it a challenge for members of the public to understand or have any access to regulatory decisions or policy making at the political level.

CIELAP's Innovative Technologies Project

This paper has been prepared as one initiative to help provide a better public understanding of issues in the ongoing development of these important new technologies. We hope that this will allow members of the public to become more confident and interested in becoming engaged in debate and decisions about these topics. Rather than providing a detailed scientific and technical overview of new technologies, we have opted for a brief but informative fact sheet description of important aspects of five specific technologies. Four of these are applications of biotechnology, and one treats the whole subject of nanotechnology. Each of these topics forms its own chapter in this consolidated report. CIELAP is also publishing each of these chapters as separate fact sheets. Both the separate fact sheets and this whole document can be accessed on CIELAP's website at www.cielap.org .

The new technology applications we have considered here are:
- Genetically Engineered (GE) Trees
- Genetic Use Restriction Technologies (GURTs) or Terminator Technology
- Biofuels and Biotechnology
- Nanotechnology
- Plant Molecular Farming (PMF).

We have provided basic information on the technology; some of the major players; potential benefits and concerns; the regulatory framework and agencies involved; and international implications. These are intended to give very condensed descriptions of these various aspects of the technologies. Our thinking was to try to provide an introduction that could help orient people in discussing what is, for many, completely new and often dauntingly complicated material. CIELAP hopes to develop additional and more detailed discussion documents and events for this project.

CIELAP's Involvement in Innovative Technology Issues

CIELAP has been concerned with the issue of biotechnology since the 1980s. The organization held its first workshop on the subject in 1985 and prepared a report on the need for the development of a comprehensive policy framework for the technology as it evolved. Since then, CIELAP has been active in policy research and public engagement relating to biotechnology, including the production of a *Citizens' Guide to Biotechnology* in 2002, which is also available on the organization's website, www.cielap.org .

Some Conclusions

CIELAP is not opposed to all biotechnology, but we believe that some of these applications have very inadequately understood risks. The regulatory system for them needs to be re-assessed, particularly with regards to making the road map for decision-making routes much clearer. Government policy and support for these technologies needs to be more open to perspectives from a broader section of the public. The government urgently needs to begin to consider how to regulate nanotechnology, perhaps starting with notification and labeling requirements and moving forward to such matters as health, safety, and ecotoxicity testing and protocols. And developing practical ways to apply the precautionary principle effectively to policy-making and specific decisions concerning these new technologies should be a high priority.

Genetically Engineered (GE) Trees

What are GE trees?

GE trees are trees which have had genetic material inserted into their genetic code through the techniques of bioengineering. This is done to produce trees with a particular attribute, like resistance to a specific disease, or sometimes to block the expression of a certain trait in the trees. Such inserted genetic sequences are not necessarily from a tree species, but can be from a species of any kind, including insects or even viruses. Some examples of genetically engineered characteristics include herbicide tolerance; cold adaptation; low or altered lignin production to make pulp production easier; delayed ripening of fruit to allow mechanical harvesting or to permit longer shipping times; and prevention of flowering or seed production in order to speed growth rates for faster biomass production. Most of these GE trees are intended for use in commercial tree plantations.

What potential benefits are claimed for GE trees?

Socioeconomic

Specific possibilities depend on the particular qualities that are linked to the added genes, but claimed benefits involve economically valuable qualities like disease resistance, faster rates of growth, and decreased lignin (the material that gives stiffness to wood) in trees for pulp production. For example, papaya trees in Hawaii (a non-native, commercially grown species) sustained heavy damage by the ringspot virus in the late 1990s, but the introduction of a genetically engineered strain of papaya that contained genes from the virus offered resistance to the disease and helped save the export industry for the immediate future (though not necessarily for the long-term, as noted below).

Environmental

Some researchers are trying to design GE trees for certain environmental benefits. One area of research involves utilizing the capacity of various plants and micro-organisms to absorb and thus "mop up" particular pollutants. For instance, a York University scientist is trying to produce a tree that incorporates genes from soil bacteria that could take up carcinogenic chemicals from soils contaminated by explosives in war zones and weapons test ranges. Other investigators are interested in engineering trees to have a faster uptake of carbon dioxide, a major "greenhouse" gas, in order to help slow climate change.

What sustainability concerns about the technology have been raised?

Ecological

Unlike annual field crops in agriculture, trees are a long-lived feature of landscapes, and forests provide many ecological services, including habitat for an enormous range of species and the regulation of climate and rainfall regimes. Trees produce large quantities of pollen and seed that can travel for many kilometres, and it is widely considered inevitable that trees in unmanaged forests as well as in parks and on private property, including nurseries, woodlots, and residential areas, would be genetically contaminated by GE trees. The escape of genetic traits from GE tree plantations into native forests could potentially have severe consequences. Specific effects could include contamination from the Bt toxin gene, which kills butterflies and moths and could also affect their predators, including songbirds. The low lignin gene could lead to forest trees with lowered protection against herbivores, insect attacks, and storms, and the gene for faster growth could lead to transgenic trees that out-compete native vegetation for light, water, and nutrients. Because of the complexity of interactions in forest ecosystems and the long life span of trees, impacts are very difficult to predict and could take decades or even generations to become evident.

Even deliberately engineered changes in GE trees may not create simple or entirely desirable solutions to perceived problems. Ringspot-resistant papaya trees, for instance, are proving very susceptible to blackspot fungus. The ecological dictum that "You can never do only one thing" is especially relevant to genetic engineering, in part because gene expression remains highly complex and scientific understanding is far from complete. And as past experience shows, disease- and pest-resistance are not necessarily permanent. The rapid rate of reproduction by insects as well as other mechanisms in pathogens generally allows them eventually to adapt to new conditions.

To counter these various problems, some proponents of the technology have suggested that GE trees be genetically engineered to make them sterile in order to avoid interbreeding with other trees (using "Terminator technology" – see page 9), but environmentalists have responded that sterile forests without flowers or seeds are problematic in themselves. Many forestry professionals consider that natural regeneration of forests after harvesting is a better practice than replanting. Moreover, some scientists consider that genetically engineered sterility would not be reliable and could be overcome by the tree during its lifetime.

Ethics and equity

Some believe that access to the rich heritage represented by forest ecosystems is a right, and that it would be compromised by replacing natural forests with patented GE trees, especially if the technology is controlled by private interests. In agricultural crops, Monsanto, which holds patents to many GE crops, has initiated more than 100 civil suits. These involve alleged patent infringement by farmers, many of whom claim that their crops had been contaminated by nearby GE crops. There are fears that a similar situation could develop with trees.

Economic

There is increasing consumer interest in and pressure for environmental certification programs, such as that of the Forest Stewardship Council for "green" forestry products. Producers who could not obtain such certification because of contamination by GE trees would have to forego any associated economic benefits. This situation would also apply to fruit growers for organic crop certification. For the same reason, environmentally certified producers would face losses if their trees or crops were to lose their status through inadvertent contamination by nearby GE trees.

What is the status of GE trees in terms of commercialization?

Unlike medical and industrial applications in biotechnology, where there has been much interest by investors, it has mainly been forest products corporations and governments and universities in forested countries like Sweden which have funded GE tree research. In Canada, the Canadian Forest Service and some companies are investing in research projects, which include limited field trials, on a number of GE tree species, such as various fruit trees, spruce, tamarack, poplar, and willow. In the U.S., large scale commercialization could be on the horizon for forests in the Southeast and Northwest (this, however, is being actively opposed by many citizen groups). In China, it has been reported that more than 8000 square kilometres have already been planted with GE poplar in efforts to reverse the lack of forest cover.

What about government oversight and policy?

Research and development (R&D)
Canada, which has about 10% of the world's forests and is a major forest products producer, is spending only a modest portion of its biotechnology research dollars in the natural resource sector, which includes GE trees.

Regulatory framework
As with other biotechnology applications, the regulatory framework in Canada is a patchwork, with no single agency in charge overall of biotechnology regulation. Depending on the specifics of the application, the main departments responsible include Industry; Agriculture and Agri-Food; Health; Environment; Natural Resources; Fisheries and Oceans; and International Trade. Field trials are approved for genetically engineered plants –"Plants with Novel Traits" or PNTs – by the Plant Biosafety Office (PBO) of the Canadian Food Inspection Agency. However, much of the forested crown land in Canada is within provincial jurisdiction, and provincial decisions would be required for use of GE trees there. Elsewhere, there have been individual countries within the EU, such as Greece, which have outlawed GE trees. In the U.S., despite the salvage of Hawaii's papaya industry through the technology, that state's legislators have recently banned outdoor field trials for GE trees.

Liability regime
There is no legislated liability regime in Canada. In Canada, those who promote biotechnology are subject to the traditional common law rules of civil liability. If the use of biotechnology causes damage to a person, their property or their economic interests, the producer or user of that biotechnology may or may 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 unique and novel challenges raised by the potential for harm that biotechnology may cause. Biotechnology raises general policy issues that should be resolved by legislators rather than judges. A strict liability regime, entrenched in legislation, would hold producers of biotechnology responsible for damage to human or environmental health.

Transparency and citizen engagement
The main avenue provided for formal citizen input about the technology is the Canadian Biotechnology Advisory Committee (CBAC), set up through the Canadian Biotechnology Strategy and assisted by the Canadian Biotechnology Secretariat (CBS).

What international implications are there?

There are many concerns in the South that forest-based livelihoods and cultures would be negatively affected by ecological change and access issues.
As well, the U.N. Convention on Biodiversity's Cartagena Protocol requires the parties to the treaty to obtain prior consent for the introduction into the environment of genetically modified organisms if this involves the intentional crossing of international boundaries.

Canada has ratified the Convention on Biodiversity but has only signed the Cartagena Protocol; the U.S. has not signed or ratified either.) However, although there is evidence that tree pollen can travel hundreds of kilometres, this Protocol does not apply to transboundary movement through insects, birds, or wind borne pollen and seeds. Nevertheless, a statement from the Eighth Conference of the Parties Regarding Genetically Engineered Trees held in March 2006 recognized potential social, environmental and transboundary impacts and recommended that the parties take a precautionary approach.

Additional sources of information specific to GE Trees

- The website of the organization Northwest Resistance Against Genetic Engineering (NW RAGE), at www.nwrage.org
- The Canadian Institute for Environmental Law and Policy's *The Regulation of Agricultural Biotechnology in Canada* (November 1999) and *A Citizens' Guide to Biotechnology* (March 2002)

Genetic Use Restriction Technology (GURT) or Terminator Technology

What is GURTs or Terminator Technology?

Usually simply called Terminator, GURTs is the term used at the United Nations and in the scientific community and is applied to plants that have been genetically engineered to restrict their ability to reproduce or to exhibit other specific traits.

V-GURTs (Varietal GURTs), which refers to restrictions on reproduction of a plant variety, also called the Technology Protection System (TPS) by the company holding its first patent, involves a several-step gene sequence that results in killing a plant's seeds at a specified time, usually very late in its development. Thus, these Terminator crop seeds are designed to be sterile, and can't be used to produce next season's crop.

T-GURTs (Trait GURTs) genetically modify plants so that particular commercially valuable traits, such as resistance to herbicides, are expressed only if the genes are "switched on" by spraying the young plants or soaking the seeds with a proprietary chemical. The viability of the seeds of these crops can (in theory) be designed to be unaffected. This kind of externally activated gene-switching molecular mechanism is called an inducible system, and can be used for both T-GURTs and V-GURTs.

What potential benefits are claimed for GURTs?

Socioeconomic

These technologies were developed primarily as a means of protecting companies holding patented crop varieties from the unauthorized use of seeds saved from earlier crops. Patent protection laws are the standard approach for this purpose, but are difficult to enforce; GURTs are intended to create built-in patent protection. Some promoters claim that, with better patent protection, more commercial effort can be expended to improve varieties of minor crops, with gains from added value and increased yields.

T-GURTs have the questionable benefit of allowing farmers not to use the chemical treatment and therefore to continue to use ordinary methods and to save and use seeds, though the advantages of the engineered traits must be foregone.

Ecological

Transgenic plants have genetically contaminated other species, and many groups and individuals are alarmed about the unpredictable effects of genetically altered crops on wild plant populations. Promoters believe Terminator technology would reduce (though it would not eliminate) this threat, since wild plants that are pollinated by Terminator crops will produce (largely) sterile seeds. However, it should be noted that genetic engineering, like all technologies, will have a certain failure rate, which has not at this time been precisely determined; its success as a biosafety tool cannot be guaranteed.

Along similar lines, the biotechnology company Maxygen has been developing a technique to get rid of foreign DNA from genetically modified (GM) plants. The idea is to incorporate a gene that, alongside the other inserted genes, will snip out DNA sequences between genetic markers placed around the foreign gene sequence. It is not certain, however, whether the technique will work as intended, or what its failure rate might be.

What sustainability concerns have been raised?

Socioeconomic

The major issue is the impact on Indigenous peoples and the 1.4 billion people who depend on farmer-saved seeds for their lives and livelihoods. Poor farmers, who make up about half the world's agricultural producers, mostly in the South, depend on saving seeds from previous crops and would not be able to afford commercial seeds each year or the chemicals required to switch on the value-added T-GURT characteristics.

Many Indigenous peoples view Terminator as an attack on cultural and spiritual traditions based on honouring fertility. Contamination through cross pollination could disrupt seed exchanges and other customary practices.

The greatly increasing consolidation and vertical integration of the agro-chemical/seed industry raises concerns about fewer options and reduced leverage for farmers. This ongoing trend toward control over the seed market by a few multinational companies is encouraged by GURTs, an approach which is very expensive to develop but which promises major new market opportunities for companies able to fund the R&D.

Ecological

The pollen from Terminator plants could contaminate and kill seeds of other nearby plants. Thus, neighbouring crop seeds in the first generation could be rendered sterile, unbeknownst to the farmers harvesting them. Wild plant populations could be reduced or endangered.

Treatments used to activate Trait technology in seeds or plants could be ecologically damaging in various ways. The antibiotic tetracycline, for instance, has been suggested as one such gene-switching substance, but increasing its use in the environment could add to the growing problem of anti-microbial resistance in disease-causing bacteria.

With commercialization of these technologies the genetic diversity of the world's major food crops will be narrowed, thus increasing their vulnerability to disease and insects and reducing local crop adaptation to local conditions.

What is the status of these technologies in terms of commercialization?

In 1998 the first patent on Terminator was jointly awarded in the U.S. to a cotton and soybean seed company, Delta & Pine Land Company, and the U.S. Department of Agriculture. The "suicide seeds" gave rise to intense controversy, and in 1999, Monsanto, the world's largest GM seed company, declared that it would not commercialize the Terminator technology. Nevertheless, a number of multinational companies continued to do research in GURTs and to obtain patents. There have been greenhouse trials of the technology in the U.S., but no field trials to date there, in Canada, or elsewhere.

What about government oversight and policy?

In 2000, governments at the United Nations Convention on Biodiversity (CBD) created a *de facto* moratorium which recommends countries not approve Terminator technology for field testing or commercial use. Canada has ratified the CBD, but the United States has not. In March 2006, the Conference of the Parties (COP) to the CBD met in Curitiba, Brazil, and rejected language for a case-by-case risk assessment approach that would have undermined the moratorium, which is ongoing until ended by the parties. The next COP is in 2008. Some 500 civil society groups from around the world, including farmers' organizations, church groups, development agencies, and others supported the moratorium, and most are calling for a lasting ban as well as national bans.

Canadian Government policy

Canada states that it "neither promotes nor opposes" GURTs, but has taken actions in U.N. meetings to end the moratorium. Along with New Zealand and Australia, Canada is generally seen as allied with the U.S. and industry on Terminator; Agriculture and Agri-Food Canada is considered the main driver of government policy on GURTs.

Regulation

A number of different federal departments are involved in a patchwork of legislation originally created for controlling other products, substances, and processes. The main departments responsible for different aspects of biotechnology regulation include Health Canada, Environment Canada, the Department of Fisheries and Oceans (DFO), and the Canadian Food Inspection Agency (CFIA). The regulatory approach is explicitly science-based and in the main does not consider socio-economic concerns.

There is no Canadian legislation that puts in place a liability regime. In Canada, biotechnology issues are subject to the traditional common law rules of civil liability. If the use of biotechnology causes damage to a person, their property or their economic interests, the producer or user of that biotechnology 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 biotechnology applications may cause. These technologies bring up general policy issues that are better resolved by legislators rather than judges. A strict liability regime, entrenched in legislation, would hold producers of biotechnology responsible for damage to human or environmental health.

There is no legislatively mandated labeling for foods or other commodities produced by transgenic organisms, including GURT. However, products generally cannot be certified as organic if they are from GM organisms, a fact which could affect organic growers if Terminator crops (and potential contamination from them) became a reality.

What international implications are there?

As well as concerns about impacts on poor nations, farmers, and Indigenous peoples, there are unresolved questions about the rights involved in saving seeds. There are also potentially conflicting national approaches about intellectual property (patent protection) over genetically modified plant traits and about trade barriers related to biosafety and their justification. Such issues can produce strong political pressures both for and against harmonization internationally.

Additional sources of information specific to Terminator Technology

- Website of ETC Group, an Ottawa-based organization opposed to Terminator Technology www.etcgroup.org and the Ban Terminator Campaign website www.banterminator.org
- The Canadian government website on biotechnology, www.bioportal.gc.ca

Biofuels and Biotechnology

What do the terms biofuels and biotechnology refer to?

Biofuels are fuels produced from biological sources, such as corn, sugar cane, straw or wood chips. ("Fossil fuels" – oil, coal, and natural gas – are also derived from once-living sources, but have been created in their present form by geological processes over millions of years.) The two most widely used biofuels today are ethanol and biodiesel. Both mainly serve as replacements or supplements for gasoline, diesel, and other transportation fuels. *Ethanol* is sometimes referred to as grain alcohol, and is made by a fermentation process, using crops like corn and sugar beets as the feedstock. It can be blended with gasoline to run today's vehicles, or, with modest engine modifications, can be used as a fuel by itself. *Biodiesel* is plant oil extracted from oil seeds like canola and refined; it can be used as an additive to gasoline or alone as a fuel very similar to diesel. New processes are currently being developed that allow production of bio-based ethanol and diesel fuels to be made from more easily obtained straw, wood, and similar cellulosic materials, rather than from starches, sugars, and oils that have value as human food.

Biotechnology in the broadest colloquial sense means the use of biological processes to create various products, such as cheese or new varieties of plants. Statistics Canada and the OECD also use a broad definition of biotechnology in compiling sectoral economic statistics: "The application of science and technology to living organisms as well as parts, products and models thereof, to alter living and non-living materials for the production of knowledge, goods and services."[1] As we use it here, the term refers to techniques for manipulating tissue, cellular and genetic material, especially transferring genes from one organism to another, sometimes of a different species, in order to create special new characteristics in the genetically treated (or *transgenic*) organism. Biofuels can be made by conventional fermentation and other processes without any use of transgenic biotechnology. However, there can be biotechnology applications used in creating biofuels. These include using transgenic feedstock crops, such as Bt corn or certain GE poplar trees, in order to increase yields or to alter other crop traits to improve processing. As well, biotechnology can be used to produce and modify the enzymes and yeasts used in making ethanol; cellulose-based ethanol from materials like wood chips or sawdust rather than grains greatly increases the potential of the technology.

What potential benefits are claimed for these technologies?

Environmental

The most difficult problem in addressing climate change is replacing the fossil fuels used in transportation. While a hydrogen-based transportation sector is a long-term possibility, it requires a huge and expensive investment in new infrastructure, and is not without potential environmental and other concerns. Biofuels are another option that, by contrast, can be (and

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[1] Munn-Venn, Trefor and Paul Mitchell, *Biotechnology in Canada: A Technology Platform for Growth,* published by The Conference Board of Canada, 2005

are being) used today with relatively minor changes to vehicle engines and fueling infrastructure.

Biofuels would also reduce acid precipitation and a number of air pollutants like carbon monoxide and particulate matter.

Ethanol can replace environmentally problematic anti-knock compounds and increase octane in gasoline.

Socioeconomic
Use of biofuels could support farmers' incomes almost everywhere in the world, since almost all countries can grow feedstock crops. The present transportation fuel supply relies on a globalized system based on unevenly distributed petroleum resources, and biofuel use could lessen risks of interruption because of terrorist actions, war, and storms like Hurricane Katrina.

It is claimed that some 70% of an ethanol plant's revenues are typically spent within 150 km of the facility; rural municipalities would benefit from local economic activity.

What sustainability concerns about biofuels have been raised?

While most of the impacts of these technologies are seen as potentially positive, much depends on specifics.

Environmental
There are questions about how much actual reduction in greenhouse gases would occur if biofuel crops exclusively used fossil fuels for fertilizer feedstock, harvesting equipment, and the like. Badly managed biofuel crops could increase rates of soil depletion and erosion. An important issue relates to land use limits and priorities: will biofuel crops displace native forests and grasslands with genetically engineered monocultures, threatening genetic cross-contamination and diminishing important habitat; and/or displace food crops, reducing food supplies? In part, this depends on the particular technologies used; some recent conversion technologies can make use of waste cellulosic materials like straw and corn husks and can use native species like switchgrass for ethanol production. At present, biofuels production is relatively minor, and would have to increase substantially before large scale competition for land use became a problem. It is clear, however, that simply substituting biofuels for fossil fuels without substantial efforts to curb energy demand and improve efficiency is not a sustainable strategy.

What is the status of biofuels technology in terms of commercialization?
Biofuel technology has been in use since World War II. In the 1970s, responding to dramatic global jumps in oil prices, Brazil undertook a major initiative to reduce its oil dependence by developing an ethanol-based transportation system. Using its sugar cane as a feedstock, and a variety of policy instruments from subsidies and tax breaks to mandated requirements for biofuel use, by the mid-80s almost all new car sales were ethanol vehicles. Ethanol use there declined with falling oil prices in the following decade, but a decision in 2003 to require flexible-fueling capability in vehicles changed the economics significantly and ethanol

production and vehicle use once again expanded. Global production of ethanol has doubled since 2000, and biodiesel nearly tripled. After Brazil, the U.S. comes second in ethanol production, chiefly using corn, while Europe produces almost all of the world's biodiesel, largely from rapeseed and sunflower seeds.[2] Canada produced 245 million litres of ethanol in 2004, and renewable fuels associations would like to double that by 2010.

Specifically in the biotechnology resource sector in Canada, there are some 21 biotechnology companies (though not necessarily involved with biofuels), with about $13 million invested in R&D.[3]

What about government oversight and policy?

Biofuels policy
In Canada, there are modest initiatives to support quality and availability of biofuels through an online supplier registry by Natural Resources Canada. Saskatchewan, and, more recently, Ontario have developed programs to support ethanol production; Ontario has a target of 5% ethanol in gasoline by January 1, 2007.

Federal biotechnology policy and support for Research & Development
The Canadian Biotechnology Strategy of 1998 proposes as its main theme that Canada should position itself to be a responsible world leader in biotechnology, including explicit attention to ethical and social responsibilities. The Strategy sets up the Canadian Biotechnology Secretariat (CBS), which assists an external advisory committe, the Canadian Biotechnology Advisory Committee (CBAC) and a federal ministerial committee of the main departments involved, which are Industry; Agriculture and Agri-Food; Health; Environment; Natural Resources; Fisheries and Oceans; and International Trade. In Canada, total federal expenditures for biotechnology R&D nearly tripled between 1997-98 and 2003-04, going from $254 million to $717 million.[4] Canada's federal tax credit program for scientific research, the Scientific Research and Experimental Development (SR&ED) program, is considered one of the best such mechanisms in the world for supporting biotechnology research.

Regulation
Regulation of biotechnology in Canada is a confusing patchwork of legislation originally created for controlling other products, substances, and processes. The main departments responsible include Health Canada, Environment Canada, the Department of Fisheries and Oceans (DFO), and the Canadian Food Inspection Agency (CFIA). For biofuels, relevant regulations might include laboratory biosafety guidelines, CFIA environmental regulations

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[2] Hunt, Suzanne C. And Janet L. Sawin and Peter Stair, "Cultivating Renewable Alternatives to Oil," Ch. 4 in *State of the World 2006* by Worldwatch Institute (New York: W.W. Norton & Company, Inc., 2006).

[3] In *Biotechnology in Canada,* above, Reference 1

[4] Statistics Canada, *Canadian Trends in Biotechnology, 2nd edition,* 2005

dealing with field trials (for feedstock crops), or the *Canadian Environmental Protection Act* (CEPA) regulations for Living Modified Organisms (for yeasts).

There is no legislated liability regime in Canada. In Canada, those who promote biotechnology are subject to the traditional common law rules of civil liability. If the use of biotechnology causes damage to a person, their property or their economic interests, the producer or user of that biotechnology may or may 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 unique and novel challenges raised by the potential for harm that biotechnology may cause. Biotechnology raises general policy issues that should be resolved by legislators rather than judges. A strict liability regime, entrenched in legislation, would hold producers of biotechnology responsible for damage to human or environmental health.

What international implications are there?

The widespread introduction of biofuels worldwide would have positive implications for national security for many countries, and could contribute significantly to meeting the international targets in the Kyoto agreement for reducing greenhouse gas emissions.

Additional sources of information specific to biofuels and biotechnology

- The Canadian Biotechnology Secretariat's website, www.biogateway.gc.ca
- Worldwatch Institute's *State of the World 2006,* Chapter 4 (see **References** - endnote 2)
- The Canadian Institute for Environmental Law and Policy's *A Citizens' Guide to Biotechnology* (March 2002)

Nanotechnology

What is nanotechnology?

Nanotechnology includes a variety of techniques that are used to manipulate materials at the nanoscale, the scale of atoms and molecules. One nanometre (nm) equals one billionth of a metre, about the width of 10 hydrogen atoms; a DNA molecule is 2.5 nm wide, and a red blood cell is about 5,000 nm across. A human hair is about 80,000 nm in diameter.[5] "Atomic force" microscopes are needed to "see" material at this extremely small scale.

The building blocks for nanotechnology are simply the chemical elements and compounds which make up all materials. However, substances at the nanoscale (that is, 1 - 100 nm) have very different properties, such as changed colour, elasticity, strength, chemical reactivity, and electrical conductivity, from those they have in everyday human experience at the macroscale or even the microscale. Developing ways to use and control these novel properties is what nanotechnology is about.

For example, some molecules can be configured in unusual ways that give them attributes almost like comic book super-heroes. Buckyballs (also called fullerenes, and technically referred to as nano-C60) were discovered in 1985 and are hollow spheres of 60 carbon molecules. They can withstand enormous pressure and could be used as nano-containers, for instance for delivering drugs to highly specific sites in the body. Carbon nanotubes are like stretched-out buckyballs, with single- or multiple-sheeted walls; they are six times lighter and many times stronger than steel, and can be either semi-conductors or insulators. They may be used in energy-related applications, or added to materials to improve strength without increasing weight. Quantum dots are semi-conductor nanoparticles that emit different colours depending on their size; they can be used to track or monitor various substances, such as biological materials in medical research.

What potential benefits are claimed for nanotechnology?

Coatings and powders containing nanoscale particles are now being used in consumer products to make fabrics stain-resistant or for ultraviolet protection in sunscreen and cosmetic creams. Nanoscale silver inhibits bacterial growth and is used to coat wound dressings.

Promoters are predicting huge future breakthroughs in many beneficial fields. There is an enormous and ever-growing number of potential applications in the near-term in medicine, electronics, energy and materials conservation and environmental clean-up. These include such things as highly targeted delivery of medications (for example, anti-cancer drugs going directly to the interior of cancer cells, killing those cells without the side effects associated with chemotherapy today), better water filtration, energy-saving improvements in batteries and fuel cells, and diagnostic sensors to detect pathogens and chemical contaminants.

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[5] Shand, Hope, and Kathy Jo Wetter, "Shrinking Science: An Introduction to Nanotechnology," Ch.7 in *State of the World 2006* by Worldwatch Institute (New York: W.W.Norton & Company, Inc., 2006)

Further down the road, researchers are working on molecular nanotechnology, aiming to make self-assembling nanoscale molecules for creating devices like electronic circuitry actually manufactured at the molecular level. Nanobiotechnology takes the technology even further, and is about developing engineered organic-inorganic hybrids: DNA, living cells, viruses, or microbes that can be made to incorporate or utilize synthetic components to perform some human-directed function. For example, researchers at MIT reported in the April 2006 on-line journal *Science* that they have used genetically modified viruses to assemble a positive electrode that works as a component of a conventional lithium-ion battery. However, this electrode can outperform those used in today's commercial batteries in that it can store up to three times the energy. To make the electrode, the researchers first engineered viruses, which are made of proteins, to incorporate some additional DNA sequences. These genetic sequences direct the viruses' proteins to form with a new amino acid that binds to cobalt ions. The genetically altered viruses then can, in a solution, coat themselves with cobalt ions. After reactions with water, cobalt oxide, an advanced battery material, can be produced. The MIT scientists hope to make negative electrodes as well, and eventually to have viruses actually assemble the positive and negative electrodes into a high-capacity battery.

What sustainability concerns about the technology have been raised?

It should be noted that nanoscale particles can be found in the natural environment under certain conditions, such as salt nanocrystals in ocean air or nanoparticles that result from nearly all combustion. However, with the exploding growth in nanotechnology, exposures to synthetic nanomaterials for researchers, workers, and consumers will certainly increase, with unknown results.

Toxicity

Toxicity studies on engineered nanoparticles are now underway. In general, substances at the nanoscale are more reactive and toxic than at the micro- or macro-scale. Tissue damage to lungs, brains, and hearts has been found in animal species exposed to carbon nanotubes and buckyballs. One concern is that nanoscale particles could be able to penetrate barriers in the body that exclude larger particles. A German product described as "nano" – Magic Nano, a protective sealant for glass and ceramics – was introduced as an aerosol spray for the first time in March 2006. It was withdrawn after two days when a number of consumers who used it reported coughing and breathing difficulties; six people were hospitalized with pulmonary edema, but all were released within a few days. The product had previously been marketed for four years in a pump container with no reported problems. However, aerosols alone can sometimes cause respiratory distress, and since the product's recipe is secret it is not proven that it actually contains nanomaterials or that they are the sole source of the problem.

Ecological

A 2004 report on nanoscience and nanotechnology by The Royal Society and The Royal Academy of Engineering in the U.K. stated that almost nothing is known about the behaviour of nanoparticles in environmental media, and recommended that until more is known, the release of manufactured nanoparticles and nanotubes into the environment be avoided as far as possible. Two years later, research has barely begun on ecological effects, but a 2005 study of buckyballs in the environment discovered that they are toxic to soil bacteria, and that in water they clump together, forming nanoparticles that are soluble, a strange property since buckyballs individually are insoluble.[6] The above-mentioned Royal Society report makes a distinction between nanoscale materials that are incorporated into parts of products like computer chips and the free release of nanoparticles and nanotubes. The latter seems potentially more risky, and even with the present limited production raises questions about nanomaterials in the waste streams from laboratories, industrial and medical facilities.

There is also concern about potential dangers of nanobiotechnology or synthetic biology if engineered "biological machines" are released into the environment – as they might be for environmental remediation or to mitigate climate change, for example. Possible hazards related to control or misuse of such synthetic life forms have not been addressed.

Equity and social issues
Many countries in the South are afraid that their traditional commodities or natural resource industries could become unnecessary, and that they will face massive industry disruption and worker displacement.

Military applications
In 2002, MIT established the Institute for Soldier Nanotechnologies. Battlesuits to improve "soldier survivability" are being designed to incorporate sensors and protective fibres and coatings to allow the suits to detect and neutralize chemical and biological agents.

What is the status of nanotechnology in terms of commercialization?

As noted above, consumer applications in cosmetics, sunscreens, paints, sports equipment such as tennis racquets, fabric treatments, and medicine are already in commercial use. The Project on Emerging Nanotechnologies (given below as an additional source of information) has an inventory of over 200 such products, and that is not considered an exhaustive list. The scale of R&D aimed toward near-future commercial use is enormous and growing rapidly; the rush to patent nanoscale products and processes has been likened to "biotechnology on steroids."

What about government oversight and policy?

Federal nanotechnology policy and support for research and development (R&D):
In policy statements, Industry Canada and other agencies have stated that nanotechnology will be vitally important for Canada's future economic development. The National Research Council (NRC) in conjunction with the University of Alberta in Edmonton established the National Institute for Nanotechnology (NINT) in 2001. Because there is no single window for information and policy on this wide- reaching technology, it is difficult to discover just how much is being spent in total on R&D. Policy comments are almost entirely about research and business opportunities, with little or no official discussion of health, environment, or social issues.

[6] Press release on website, Center for Biological and Environmental Nanotechnology (CBEN), Rice University, June 23, 2005

Transparency and citizen engagement
There is no formal ongoing mechanism for civil society input about nanotechnology policies in Canada.

Regulatory framework and labeling requirements
Canada and other governments have so far taken the position that a nano-scale material is still the same substance as at the micro- and macro-scales, and does not need any additional regulation beyond what is required for ordinary uses of that substance. (This is despite the fact that the novel properties exhibited at the nano-scale are precisely why these applications are useful.) Even cosmetics, which Canada has recently required for the first time to label all their ingredients, do not have to reveal that nano-scale particles of compounds are used. Neither do other products, including food. Some governments, however, have begun to consider possible approaches to potential regulatory or labeling initiatives; in 2005, for instance, the European Commission asked for public comment on nanotechnology risk assessment.

Liability regime
There is no legislated liability regime in Canada. In Canada, those who promote biotechnology are subject to the traditional common law rules of civil liability. If the use of biotechnology causes damage to a person, their property or their economic interests, the producer or user of that biotechnology may or may 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 unique and novel challenges raised by the potential for harm that biotechnology may cause. Biotechnology raises general policy issues that should be resolved by legislators rather than judges. A strict liability regime, entrenched in legislation, would hold producers of biotechnology responsible for damage to human or environmental health.

What are the international implications?

There is a rush to control the burgeoning patent rights in what is likely the next "technology platform" – that is, an innovation like electricity, which is central to further developments in many diverse fields. Control over nanotechnology's fundamental tools and processes will be very important for shaping applications, having access to benefits, and avoiding and mitigating health, environmental, and other problems. China is already playing a very significant role in nanotechnology development, as is India. The poor and politically disadvantaged, both countries and individuals, should be concerned about being left out of this new knowledge- and technology-based revolution. Since nanoscale technologies also have the potential to revolutionize design and manufacturing of new materials across many sectors, developments could cause disruption and dislocation to workers and economies that depend on traditional commodities.

Additional sources of information specific to Nanotechnology

- Worldwatch Institute's *State of the World 2006*, Chapter 5 (see **References,** endnote 1)
- The Massachusetts Institute of Technology (MIT) journal *Technology Review* in its online edition at www.technologyreview.com frequently reports on nanotechnology developments

- The Woodrow Wilson International Center for Scholars in partnership with the Pew Charitable Trusts launched the Project on Emerging Nanotechnologies in April 2005; its website is www.nanotechproject.org
- The Royal Society and the Royal Academy of Engineering of the U.K. produced a major report in July, 2004, which is available online at www.nanotec.org.uk/finalReport.htm

Plant Molecular Farming (PMF)

What is plant molecular farming (PMF)?

Plant molecular farming is the use of genetically modified plants to produce pharmaceutical products or industrial chemicals. These "plants with novel traits" (PNTs) have been developed by inserting new genes, usually from other species, that instruct the plant to produce the desired substance. The plant can be directed to make that substance accumulate in specific parts of the plant, such as seeds or leaves. The compound can then be extracted from the "platform" plant species crop and refined for use; the remaining plant material is destroyed. Platform species commonly used in the research today include corn (maize), tobacco, tomatoes and potatoes; these are advantageous because their production techniques are well known and their genetics have been well-studied. More recently, non-crop species like duckweed and mouse-eared cress (Arabidopsis) have also been used in research trials.

What potential benefits are claimed for PMF?

Socioeconomic

A major claim is that much pharmaceutical production done in this way would be substantially cheaper and would result in significantly increased availability and lowered drug costs and prices. This is because the source of many products used in medicine, including drugs, diagnostic materials, blood products and hormones, is biological in origin and expensive to produce in conventional ways from plants, animals, or from microbes in bioreactors. Using plants to manufacture these compounds could increase the quantities produced, and do it more quickly and cheaply. This technology could also be used for many industrial chemicals. For example, the enzyme used in cheese production originally came from the stomachs of calves; since the 1990s, almost all of North American production of this enzyme has been from microbial bioreactors, but this is generally a fairly expensive technology. PMF alternatives could lower these production costs, although this does not necessarily translate into lower prices for consumers.

Better patient care

As well, some promoters envision using PMF to produce vaccines and other drugs that can be given orally, rather than by using syringes, thus making their use easier on patients and also cheaper to administer. Production in plant-based systems also eliminates the risk of contamination of the final product with animal viruses and prions that constitute a potential threat to human health.

What sustainability concerns about PMF have been raised?

Human health

Because the reason for this particular application of biotechnology is to produce plants that produce biologically active substances, there are strong concerns about inadvertent human exposure to these plants and the compounds they are programmed to make. Among other possible ways, such exposure could happen through contaminated harvesting equipment, intermixing of transgenic plants or seeds with those intended for the food supply, or worker exposure directly. Even if such transgenic crops are grown in greenhouses, it is possible for natural disasters and accidents to occur that could result in unforeseen paths of exposure or contamination.

Ecological and economic issues
Field crops are always invaded by disease, insects (whether pests, pollinators, or just local inhabitants), weeds, deer, raccoons, and other animals. And the soil ecosystem involves earthworms, insects, and bacteria. All these living organisms could be affected by ingesting pollen or plant material that is biologically active. As well, genetic contamination of food crops or closely related wild species through wind-borne pollen is a concern. All of these scenarios could have severe economic implications for farmers and society in general.

What is the status of PMF in terms of commercialization?

Currently there are no commercial applications approved for use in Canada. Only confined field trials have been allowed here. Some pharmaceutical PMF products in the U.S. have reached the stage of clinical trials.

What about government oversight and policy?

Research and development (R&D)
The bulk of Canada's millions of dollars spent on biotechnology research is in the health field.. More than half of its biotechnology companies are in this sector, and in 2003 there were over 10,000 health-related biotechnology products or processes that were at some stage of approval. However, little of this health-related biotechnology R&D is specifically for PMF applications.

Regulatory framework
Health Canada and the Canadian Food Inspection Agency (CFIA), along with Environment Canada and possibly other government departments that make up the patchwork of Canadian agencies responsible for different aspects of biotechnology regulation have key roles for PMF applications.

Liability regime
Canada does not have a legislated liability regime for any biotechnology applications, including PMF. In Canada, those who promote biotechnology are subject to the traditional common law rules of civil liability. If the use of biotechnology causes damage to a person, their property or their economic interests, the producer or user of that biotechnology may or may 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 unique and novel challenges raised by the potential for harm that biotechnology may cause. Biotechnology raises general policy issues that should be resolved by legislators rather than judges. A strict liability regime, entrenched in legislation, would hold producers of biotechnology responsible for damage to human or environmental health.

Transparency and citizen engagement
The formal avenue of public input into government policy is the Canadian Biotechnology Advisory Committee, though its involvement from civil society has primarily been from the scientific community and commercial interests. Because of potential benefits and the

possibility of indoor production in greenhouses, there is probably less opposition from environment and other groups to PMF applications, despite their risks, than to genetically modified trees and food crops intended for widespread, unconfined use.

What are the international implications?

The potential for more widely available and much cheaper pharmaceuticals offers promise from this technology to many poorer countries. However, the risks to biodiversity and human health are also arguably great, particularly if PMF is practiced in countries with less capacity for scientific monitoring and stringent regulatory oversight.

Additional sources of information specific to PMF

- The Canadian Food Inspection Agency website at www.inspection.gc.ca

Additional Sources of Information

Government of Canada

The Government of Canada's BioPortal - the online gateway to the latest government information on biotechnology
http://www.bioportal.gc.ca/

The Government of Canada's BioStrategy – offers information about Canada's strategy for Biotechnology
http://biostrategy.gc.ca/

Canadian Biotechnology Advisory Committee - CBAC provides advice to the federal government on ethical, social, regulatory, economic, scientific, environmental and health aspects of biotechnology
http://www.cbac-cccb.ca/

Concerned about Biotechnology

Union of Concerned Scientists - an independent nonprofit alliance of more than 100,000 concerned citizens and scientists.
http://www.ucsusa.org/

Greenpeace Canada – an independent not-for-profit organization concerned about Genetic Engineering
http://www.greenpeace.ca

ETC group – a charity dedicated to the conservation and sustainable advancement of cultural and ecological diversity and human rights
http://www.etcgroup.org/

Pro-Biotechnology

Biotechnology – Good to Grow – a corporate sponsored organization that advocates the positive aspects of biotechnology
http://www.biotechgoodtogrow.com/

BIOTECanada – a not-for-profit, industry-funded association promoting public awareness and acceptance of biotechnology
http://www.biotech.ca/

Council for Biotechnology Information – an organization that communicates the benefits and safety of agricultural and food biotechnology
http://whybiotech.com/