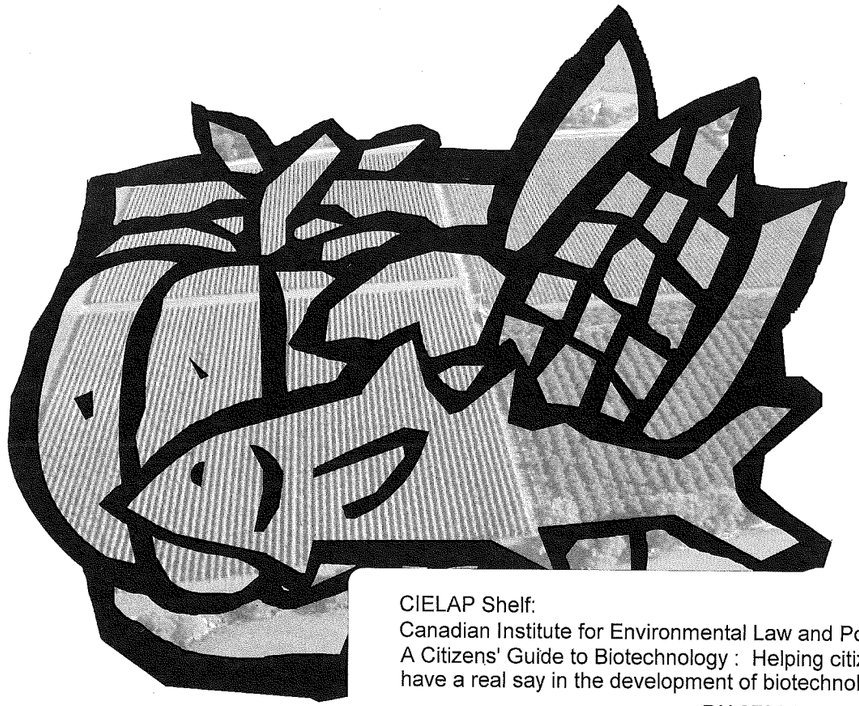
A **CITIZENS' GUIDE** to

Biotechnology

Helping citizens have a real say in the development of biotechnology in Canada



A Project of the
Canadian Institute for Environmental Law and Policy

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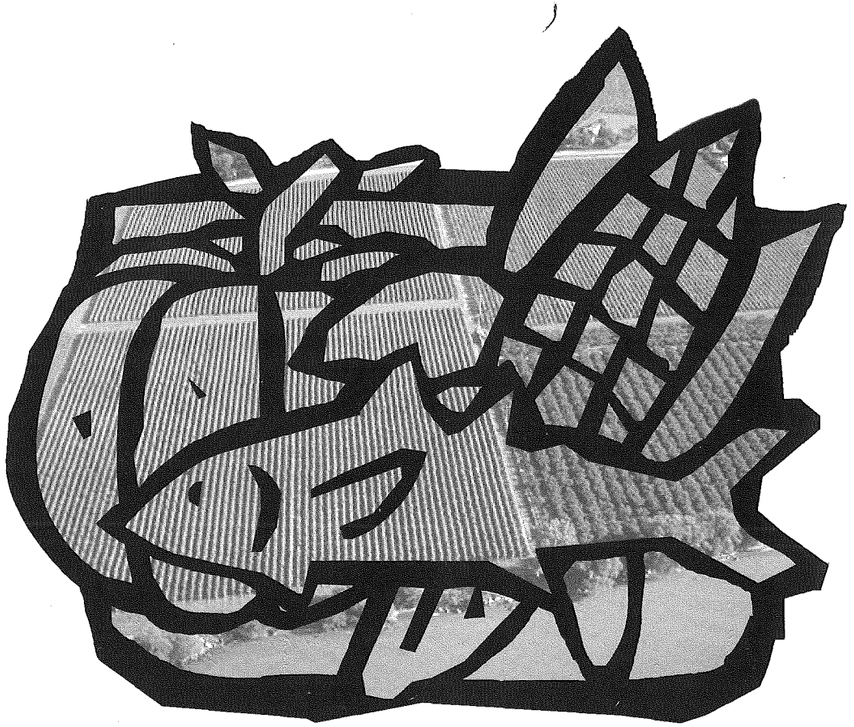

Canadian Institute for Environmental Law and Policy
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About the Canadian Institute for Environmental Law and Policy (CIELAP)

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

CIELAP provides leadership in the research and development of environmental law and policy which promotes the public interest and the principles of sustainability, including the protection of the health and well-being of present and future generations, and of the natural environment.

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1 INTRODUCTION

IN THE LAST DECADE, BIOTECHNOLOGY has become an object of public debate, with stories of significant human and environmental benefits, unintentional contamination of foods, crops and ecosystems, demands for labelling in Europe and Canada, cloned sheep and pigs, patenting of mice for genetic engineering (GE) testing (the Oncomouse trial), and other international news. It has sparked debate between people concerned by the potential risks of biotechnology and those who herald it as a saviour technology for the starving people of the planet.

Clearly, biotechnology is a powerful technology and an issue of great importance. 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." It, like the innovations in chemicals, information, and nuclear technologies, has the potential to significantly change the way that 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 to profoundly improve the lives of people, with applications such as foods that carry vaccines, can grow in salt water or have higher 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. Despite the conclusions of benefits or risks drawn by those for and against biotechnology, we have, in fact, little definitive knowledge of how the technology will impact us.

This uncertainty about biotechnology is a large part of the dilemma it poses and a significant difficulty for citizens trying to draw their own conclusions about its merits. Given such uncertainty, how does a citizen make informed decisions about what to buy or what treatments to undergo? How well does biotechnology solve problems compared to other approaches? How significant are the risks of biotechnology relative to other human and environmental problems? Who really benefits from it? Is it ethical to change the genetic structure of organisms? Can a company own a life form? Do people have a right to know the origins of what they are eating? Who decides what products will be brought to market? Who decides whether or not we need them? Why are products allowed on the market if their impacts are not well understood? There are few obvious answers.

This *Citizens' Guide* explores these questions – what biotechnology is, current trends, potential benefits and risks associated with it, the laws in place to regulate it, and how to express your beliefs concerning biotechnology. Our approach is largely critical. CIELAP is not opposed to biotechnology, but we believe the current applications and the system that regulates them are inappropriate. After some discussion of the science and the current ways biotechnology, especially genetic engineering[1], is being applied, we elaborate extensively on these concerns, looking particularly at how genetic engineering is applied in the food and agriculture system. It is our conclusion that any benefits are generally not

being realized and the regulatory system is not actually capable of properly assessing environmental and human health risks of the technology. Consequently, we propose some significant changes to the way the applications are developed and how they are regulated.

This is not a traditionally balanced approach, but we take it because the critical perspective provided here is largely absent from the information provided to citizens by the federal government and the biotechnology industry. The *Citizens' Guide* comes out of CIELAP's ongoing work on biotechnology. We have been working in this field since 1984, when we organized the first conference in Canada on environmental issues regarding biotechnology. At that time we identified the need for a comprehensive policy framework for the regulation of biotechnology products. Since then we have participated in numerous conferences, workshops, and almost every government consultation on the subject. We have also published a number of documents, including *Enabling Biotechnology; A Review of Biotechnology Regulation in Canada*; a discussion paper on organic agriculture in transition; a paper on the Biosafety Protocol; and the 1995 predecessor to this *Citizens' Guide*.

This *Citizens' Guide* is also the direct result of a project that we began in 1998 in conjunction with the Costa Rican group, Fundacion Ambio, funded by the Canadian International Development Agency (CIDA). The goals of this project are: preventing potential negative environmental and health problems arising from the production and use of genetically modified agricultural products, raising awareness about biotechnology regulation, and promoting organic agriculture as an environmentally sustainable alternative to mainstream agriculture in Costa Rica and Canada.

We hope that you will find this *Citizens' Guide* interesting and informative and that it will help you make informed choices about biotechnologies. As well, we hope that this *Citizens' Guide* will help you engage in the debate in Canada so that we as a society can ensure that the necessary steps are put in place to avoid the risks and distribute equally any benefits as biotechnologies evolve.

Historic Milestones in Genetic Engineering

Year	Event
1973	U.S. scientists perform first genetic engineering experiment
1977	The Canadian Medical Research Council announces laboratory safety guidelines for genetic-engineering experiments
1982	The commercial production of insulin via genetic engineering begins
1982	The first Canadian patent of a living organism is granted to Abitibi-Price
1983	Canada's National Biotechnology Strategy to boost the Canadian biotechnology industry is launched by the federal government
1988	The first 14 tests of GE crops occur on Canadian soil
1990	Canada's Green Plan promises new regulations for biotechnology
1994	Over 700 tests of GE crops occur on Canadian soil
1995	The GE Flavr Savr tomato is approved for sale in Canada and a genetically engineered flax becomes the first crop approved for cultivation
1997	The first cloned animal, Dolly, is announced
2000	Evidence of widespread contamination of non-GE crops with GE varieties begins to emerge
2002	Saskatchewan organic farmers sue two biotechnology companies over contamination of their canola fields

2 THE SCIENCE OF GENETIC ENGINEERING

USING LIVING ORGANISMS TO PRODUCE something – known as biotechnology – is one of the oldest sciences known to humans. The term refers to things like using yeast to make bread, beer or wine. Biotechnology is also used to describe the careful breeding of plants or animals to produce a particular and desired result. Everything from hothouse roses with unique colouring, to cows with increased meat or milk production have been obtained through such breeding. Recently though, the term biotechnology has come to be more familiarly associated with detailed manipulations of biological processes, including the technique of genetic engineering. This "new" biotechnology applies scientific knowledge of cellular and molecular processes to accomplish various ends. Some of the products of recent biotechnology include pesticide-resistant crops and laboratory animals for scientific research.

The use of genetic engineering in biotechnology has become very common, but since this technique alters life at its most basic level, its application has become controversial. In order to better appreciate the implications of this new science, it is important to understand some basic biology.

Genetics

It is no accident that we look like our parents. Our genetic inheritance is carried by a chemical called deoxyribonucleic acid (DNA). Within us, DNA is organized into stringlike molecules that carry critical information about how we look and how our bodies function.

DNA is found in cells, which are the smallest independent structures in organisms. All life forms are made of one or more cells, and adult humans are made up of an estimated 50 million cells[2]. With the exception of red blood cells, all of our cells contain DNA, and all contain the same DNA. This is because DNA is replicated every time a cell divides, and we start off life as a single cell. This is not to say that every cell is the same. Within a human being there are 216 different cell types[3], each of which is specialized depending on where it is and what purpose it serves. Thus, we have heart cells that are distinct from liver cells that are distinct from the cells we have in our brains.

The DNA in cells is organized into packages called chromosomes, and different organisms have different numbers of these packages. For example, bacteria have only one chromosome, while humans have 46 chromosomes. Chromosomes contain a fantastic amount of DNA; if the chromosomes in a single human cell were stretched out and placed end-to-end, the DNA would span 1.8 metres. Some bacteria also have DNA outside of their chromosome. These shorter stretches of DNA are arranged in structures called plasmids.

DNA has some curious properties. Although there is a very large amount of DNA in a human being, about 50 percent of it consists of repeated sequences without functions scientists have been able to determine and is known colloquially as "junk DNA"[4]. Of the rest of our DNA, about three percent is identifiably organized into genes, for a total of about 30,000 genes per human.

Similarly, other organisms contain both "junk DNA" and genes, although their relative proportions vary.

Genes are portions of DNA that can be read like instructions telling cells how to behave and interact with each other. Within different kinds of cells, different complements of genes are read, giving cell types their unique characteristics. Genes work in combination, and often instructions from one can be interpreted in different ways depending on the exact context and the other genes that are also being read. Which genes are active depends on conditions in the cell, and this in turn depends on a number of different factors particular to the organism. The regulation of gene expression is dynamic, and allows cells and organisms to adapt to different situations.

When it is said that genes are "expressed" it refers to the reading of the gene. Once a gene is read, the cell uses this information to make a protein. Proteins are molecules that control biochemical processes in cells, and it is the proteins that actually do most of the work necessary for the business of life. Proteins have a hand in regulating everything about us, from our heart rate to our moods. As different cell types express different genes they also produce different proteins, and these proteins interact with each other to perform a given function.

One of the most fascinating aspects of biology is that all life is made up of virtually the same elements. Every bacterium, plant, animal and fungus has DNA, and it always behaves in essentially the same manner. Indeed, there are even families of genes that are conserved between many diverse life forms, leading some to wonder how such different looking organisms could have such similar families of genes.

In recent years, scientists have discovered ways to manipulate DNA, and it is now common to isolate individual genes for specific study. One aspect of this molecular understanding of DNA is the ability to transfer it from one organism to another, in a process called "genetic engineering". Here, because molecular biologists believe that the fundamental identity of DNA is common across species, a gene is thought to generally be treated in the same way and cause the production of the same protein, whether it is present in a bacteria, in a canola plant or in a mouse. Also, in this view, once foreign DNA is integrated into the chromosome of an organism, it will be replicated with the rest of the DNA complement and can be passed through subsequent generations. As discussed later, there is actually some debate about the validity of this view.

Biotechnology

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."

Traditional Biotechnology

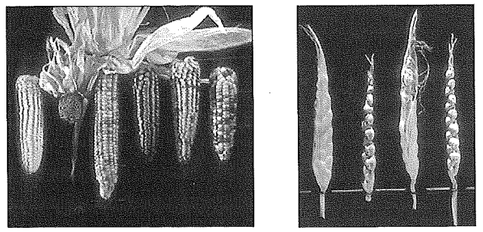
As mentioned above, "traditional" biotechnology has been practised since the first vat of wine was fermented. Traditional biotechnology also includes practices such as selective breeding and induced mutagenesis, where cells are exposed to chemicals or radiation to deliberately generate mutations in cells that might be "useful".

In selective breeding, outstanding individuals in commercially valuable plant and animal populations are used to parent future generations, thus propagating the trait for which they are considered valuable. For example, a corn plant that shows exceptional yield or unusually robust growth will be specifically used for pollination.

Corn (maize) provides an especially dramatic illustration of the effects of selective breeding, as its wild ancestor teosinte has differently arranged sexual structures, considerably smaller kernels, and an overall much lower food yield (see Figure 1). Although obviously grossly different, these traits can be traced to discrete genetic differences. Agricultural livestock have undergone similar alterations, and this has resulted in chickens with increased body weight and cows with enhanced milk production. All of these changes make use of naturally arising genetic variations.

Figure 1

Effects of selective breeding on corn ears and kernels



Corn (photo is at a much smaller scale than the teosinte)

Teosinte

Downloaded pictures: http://cimnts.mnhn.fr

More recently, the rate at which these genetic alterations occur has been increased. This is done through a variety of processes collectively referred to as "mutagenesis". Here, organisms are exposed to chemicals or radiation that encourage mutations in DNA, and the affected population is subsequently screened for traits deemed desirable. This technique was used extensively in the Canadian development of canola.

Modern Biotechnology

Modern biotechnology makes use of the tools and techniques of molecular biology. In this context, the major difference between traditional and modern biotechnology lies with the ability to transfer genes between hugely different species. So it is possible to transfer a gene that allows a herbicide to be metabolized from a bacterium to a plant, and generate a plant that is not killed by the herbicide (known as herbicide tolerance or HT). Such a plant could not arise through either selective breeding or mutagenesis. Some examples of agricultural inventions using genetic engineering (GE) technology are crops toxic to some insects (e.g. Bt corn), herbicide-tolerant crops (e.g. Roundup Ready® canola) and nutrient-enhanced crops (e.g. golden rice).

There are a few different ways to introduce a foreign gene ("transgene") into a multicellular organism. One is to use a "gene gun" to fire small metal particles coated with DNA into cells of plants. Another way to create GE plants makes use of the bacterium *Agrobacterium tumefaciens*, as this microorganism has naturally evolved to insert portions of its own DNA into plant chromosomes. By manipulating the DNA of bacteria, scientists can instead cause the introduction of their particular gene of interest into the plant. Some viruses can be similarly altered and used in the genetic engineering of various plants and animals. The most common method of introducing genes into an animal, however, remains microinjection, where DNA is physically introduced into the nucleus of a progenitor cell with the equivalent of a very small syringe.

It should also be noted that there are uses for molecular techniques within traditional breeding programs as well. Once a desirable trait is identified through GE technology, it can be tracked while traditional selective breeding is under-

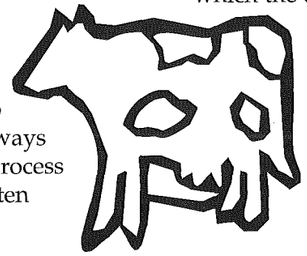
taken, potentially making the breeding work more efficient. This new area of research is known as applied genomics.

Traditional Biotechnology versus Modern Biotechnology

As it relates to plants and animals, traditional and modern biotechnology (genetic engineering) are dramatically different in four main ways.

Trait availability: As modern biotechnology operates at the fundamental level of DNA, there are more possibilities in terms of added traits. Whereas in traditional livestock or crop breeding a characteristic can only be added if it has occurred in a sexually compatible species, with molecular techniques there is the ability to transfer traits from radically different organisms.

Precision: It is often argued by proponents of genetic engineering that there is more precision involved with GE, as a specific protein with desirable characteristics can be selectively expressed in a transgenic organism. However, as the host organism is itself complex, there are other contingencies not addressed by this view. Due to the importance of protein and genetic interactions, a gene introduced into a different environment will not always behave in a predictable way. The process of inserting new gene sequences often randomly creates different results and is therefore a rather imprecise process. As such, after a transgenic organism is made there is a need for screening to isolate those individuals that have the characteristics being sought, as also happens with traditional breeding. Consequently, some argue that genetic engineering is ultimately no more precise than traditional breeding work.



Stability: Because in traditional breeding scientists are moving groups of characteristics around at the same time and not inserting genetic constructs from other organisms, there is a higher level of trait stability than with genetic engineering. There is even now evidence that to maintain their integrity, organisms, when encountering newly inserted transgenes, attempt to eliminate them or silence their functioning[5]. Consequently, the transgenic process can lead to unexpected instability in the modified organism.

Ecological context: For plant and animal applications, in much of traditional breeding the way new traits are expressed is a function of both the new genetic expression and the environment in which the organism is grown. As such, there is an ecological context for the new trait. It has to make sense in its ecological setting. However, with genetic engineering, there is a presumption that the gene sequences behave independently of their environmental setting.

CURRENT APPLICATIONS AND TRENDS

GENETIC ENGINEERING TECHNOLOGY IS being applied in a number of areas. The scientific techniques are generic and can be applied to a number of organisms in different social, economic and environmental contexts. In this section, we review the main applications involving so called modern biotechnology, or genetic engineering. The GE industry is also changing rapidly and the last part of this section looks at some of the economic forces shaping its development.

3.1 Agricultural applications – crops, animals and fish, and the inputs used to produce them

The food and agriculture sector is developing or has commercialized numerous agricultural inputs and food products, including:

- veterinary drugs and biologics (drugs used for the treatment or diagnosis of infectious diseases of animals);
- crops and horticultural plants;
- biopesticides (for insect, disease and pest control);
- biofertilizers (to improve plant growth);
- livestock feed and feed additives;
- insects;
- fish;
- animals;
- foods and food process aids;
- pharmaceutical crops (crops that produce drugs);
- farm animals for xenotransplantation (medical application – using animals to produce organs for human transplant)

Typically, it takes eight to 12 years for a GE food or agricultural product to move from concept to commercialization. The major milestones in this process include:

a) basic research on gene transformations;

b) the application in the laboratory, greenhouse, or confined research or industrial facility of that research to specific organisms (e.g., microbes, crops, animals, fish);

c) regulatory approval for confined research trials (where the level of experimentation moves beyond just the laboratory or very confined research facility, for example, to small exterior research plots on a research farm) and then the carrying out of these trials;

d) collection of data on environmental, human and animal safety;

e) regulatory approval for unconfined release; and then,

f) for some crops, a variety, to be sold under a variety name and used legally in milling, must be approved by a crop variety registration committee that acts under the authority of the Canadian Food Inspection Agency (CFIA) and generally involves three years of cooperative varietal trials.

Table 1. Approved (and in development) food and agricultural GE products in Canada

Type of product	Number of approvals	Examples	Traits
Crops	36	Corn, soybeans, canola, potatoes, tomatoes, squash, cotton	Mostly for herbicide tolerance or toxicity to insects
Animals	None yet, but several at research stage	Pigs, chickens, dairy cows, goats	Mostly to increase growth rates or disease resistance
Fish	None yet, but several at the research phase	Salmon, trout, perch, tilapia	Mostly quality, yield, disease resistance, pollution reduction, enhanced reproduction
Foods	50	Canola oil, soybean products, corn products, potatoes	Same as crops
Animal feeds	31	Canola, corn, soybeans, cottonseed, potatoes	Same as crops
Microbial fertilizers	None yet, but several at the research phase	Mostly nitrogen- fixing bacteria that live symbiotically with plants	Creating relationships with new plant hosts
Veterinary biologicals	Over 60	Modified microorganisms with application to main farm animals	Vaccines, diagnostic tools, growth and development acceleration
Biopesticides[1]	None yet, but several focused on crops at the research phase in the U.S., and on forest pests in Canada	Anti-microbial bacteria and anti-pathogen fungi Viruses focused on common tree pests Modified insects, e.g. cotton bollworm	Gene expressions that are toxic to other microbes Modification to improve effectiveness of viruses Marker gene; eventually genes that kill females
Pharmaceutical crops	None yet, but several at the research phase	Tobacco, potatoes, bananas	To produce industrial quantities of a variety of human drugs, vaccines and enzymes
Xenotransplant farm animals	None yet, but significant research underway	Pigs	Organs for transplant to humans

Source: CFIA http://inspection.gc.ca/english/ppc/biotech/gen/statuse.shtml (As of 2001-02-13)

[1] Note that in the Canadian regulatory context, a biopesticide does not include applications like Bt corn. In Canada, such applications are deemed a novel plant.

Table 2. GE crops, feeds, and food products approved for unconfined release in Canada

The list of approved crops can be found on the Canadian Food Inspection Agency website at www.inspection.gc.ca/english/plaveg/pbo/pntvcne.shtml. Note that the CFIA includes in its definition of plants with novel traits those plants that are a product of mutagenesis, which is not a transgenic technology. The numbers in this table may not solely represent transgenic applications, although they are the majority. The only approved novel wheat is a product of chemical mutagenesis, so we have not included it in this table.

Crop approved	Number of different varieties approved	Traits	In the food supply?
Corn, field	15 (1 application withdrawn)	• herbicide resistance • Bt expression	Yes. Corn is fed to animals and also appears in many processed foods and beverages as oil, starch, sweetener and processing aid
Sweet corn	1?[1]	• Bt expression	Yes, but in a limited way since not yet widely used by farmers
Soybean	3 (only 1 variety, for glyphosate tolerance, has been registered)	• herbicide resistance • oil characteristics	Yes. Soybeans are fed to animals and appear in many food products as oil, processing aids, tofu and vegetable protein
Canola	12 (note that 2 varietal registrations have been cancelled)	• herbicide resistance • oil characteristics	Yes. Canola is used as an animal feed, and canola oil is used widely in cooking and processed goods
Potato	5	• Bt expression • virus resistance • herbicide resistance	Yes, but not widely since Monsanto has stopped selling them. Available primarily as table potatoes since french fry manufacturers would not buy them
Tomato	3 (none grown in Canada)	• delayed ripening	No. Approved for human consumption, but not on the market in Canada. Product was a market failure
Squash	2	• virus resistance	Perhaps. Approved for human consumption, but grown in U.S. so only available as an import
Cotton seed	4	• Bt expression • herbicide resistance	Yes. Cotton is not grown in Canada, but cotton meal is approved as an animal feed, and cottonseed oil appears in processed foods
Sugar beets	1	• herbicide resistance	No. Variety not registered and sugar manufacturers resistant to commercialization
Flax	1	• herbicide resistance	No. Approved for human consumption (flax oil) and animal feed, but registration withdrawn at request of flax industry

[1] Bt sweet corn is being grown in Canada but it is not clear from the CFIA website how many varieties have been approved. On the immediate horizon are such crops as herbicide-resistant wheat, herbicide-resistant alfalfa, various rice applications, disease-resistant grapes.

For an overview of what has been commercialized and what is in the research and development pipeline, see Table 1.

The first wave of applications have focused primarily on crops and their uses – human and animal feeds (for more details on GE crop approvals, see Table 2). These applications are mostly designed to change farming practices, particularly pesticide-use patterns (over 70 percent of approvals). Many are for herbicide tolerance (or herbicide resistance). This application allows farmers to spray herbicides on a crop that previously would have been killed by the pesticide. They can then use that herbicide, for example Roundup®, more often than in the past to control weeds in the crop. Prior to this development, Roundup® could only be sprayed before the crop had emerged from the ground, or after harvest.

The other significant approvals are for plants that contain a toxin that kills insects. The plant (corn, cotton, soybeans, potatoes) continuously expresses a toxin from the naturally occurring soil bacterium, *Bacillus thuringiensis* (Bt). Different strains of Bt have toxins that are specific to groups of pests, so genetic engineers have inserted different toxins in crops, trying to match the toxin with the pest.

In addition to inserting transgenes for things like herbicide tolerance and insect toxin expression, most GE crops also contain two other transgenes. One is called the marker gene, which helps genetic engineers determine if their insertion process is working. This marker gene usually expresses antibiotic resistance, meaning that many GE crops also are resistant to a particular antibiotic. The second is called the gene promoter, which is designed to enhance the activity of the desired trait. The gene promoter is usually a gene sequence from a virus that commonly infests cauliflower and other plants.

Although these applications are primarily relevant to farmers, the crops are eaten by humans and animals so they have to be approved as food and feeds.

GE crop technology has been adopted very rapidly in four countries: the United States, Argentina, Canada and China. From no acreage in 1994, there were estimated to be 44 million hectares of land in GE crops in 2000, particularly soybeans (59 percent of total area), corn (23 percent), cotton (12 percent) and canola (six percent)[6]. See Table 3 for more details. In Canada, adoption of GE canola has been very extensive (over two-thirds of the canola crop is planted to GE varieties), and more modest in corn (about one-third) and soybeans (about one-quarter).

Table 3. Global planting of GE crops, 2000

	USA	Argentina	Canada	China
Total area in GE crops (million ha)	30	10	3	0.5
% of global total	68%	23%	7%	1%
Growth (million ha), 1999-2000	+1.6	+3.3	-1.0 (declining canola acreage)	+0.2
Dominant crops and trait	HT soybeans Bt corn	HT soybeans	HT canola	GE cotton

Source: James, C. 2000. Global Review of Commercialized Transgenic Crops: 2000. ISAAA Briefs No. 23-2001.

This first wave has also contained some applications with food "quality" characteristics. Many future applications in development focus on these traits. For example, there is a significant amount of research on modifying the milling and baking characteristics of wheat. Other researchers are attempting to shift the nutritional profile of plant foods by, for example, increasing the concentration of nutrients that are thought to play important roles in human health. It also appears that in future GE food products, genetic engineers will try to "stack" different characteristics together, that is provide several new traits within the same plant variety.

3.2 Forestry

No GE trees are on the market in Canada yet, but significant research is underway, some of it carried out by the Canadian Forest Service (CFS) of Natural Resources Canada. Most GE work in forestry is about developing faster growing trees with insect- and disease-resistant characteristics. In 2001, there were four confined field trials of GE trees underway, one involving poplar, one with white spruce, and two with black spruce. All four trials were carried out in Quebec under the sponsorship of the Laurentian Forestry Centre, part of the Canadian Forest Service[7].

Two other significant areas of work focus on:

➤ Developing GE biopesticides to control certain pest problems. For example, the CFS has produced a discussion paper on insect baculoviruses[8] outlining a number of GE virus applications targeted to specific insect pest problems in the forestry sector, such as gypsy moth. Typically, the genetic modification increases the speed with which a virus kills the target organism. The applications are at a research phase.

➤ Using modified microorganisms in the pulp-and-paper manufacturing process for bleaching, for degradation of tough wood components, for wastewater treatment, or for wood protection[9].

3.3 Industrial applications

Genetic engineering can be applied in industry and used in various manufacturing processes. There are numerous applications, both potential and realized. These include roles for microbes, plants and animals, and result in various products, ranging from detergents and food additives to new industrial materials, such as plastics and polymers. Both unmodified and genetically engineered organisms have been exploited for these purposes. In some applications the whole organism is used to fulfill a certain function, while in other processes the organism is harnessed and used for the production of a biological compound that is subsequently isolated.

There are several industries in which genetic engineering is being used in place of more conventional technologies. Some of the major ones are the chemical industry, petrochemical industry, paper-and-pulp industry, textile industry and food industry.

Chemical industry: Increasingly, there is a shift towards using microorganisms to produce organic chemicals[10] (reagents) such as alcohols, thereby providing an alternative to traditional *in vitro* laboratory techniques involving often more laborious procedures[11].

Petrochemical industry: In this industry, some of the most recent research is into the production of so-called "green" plastics. Commonly used plastics are petroleum-based, however there are organisms that are capable of producing either biologic plastics or their precursors.

Textile industry: Novel uses of genetic engineering have been commercialized in the textile industry, most notably in the case of subtilisin, a bacterial enzyme (protease) that is commonly added to laundry detergents to help degrade proteins. There has been a significant amount of research invested in this enzyme. It has been manipulated for increased stability under high temperatures and varying pHs[12], making it more effective. Other roles for genetic engineering in textiles are in the pre-consumer stages, for example in fabric desizing, in aesthetic denim treatments, and in the detoxification and decolourization of effluent discharged from industrial sites. As with the petrochemical industry, most of these applications are still in development[13].

Food Industry: Traditional biotechnology has been in use in the food industry for centuries, in the making of wine, breads and cheeses with the aid of yeast and other microorganisms. Today, GE crops are used extensively in food processing. Some 60 percent of processed foods in the market are now estimated to contain ingredients of GE crops. Genetic engineering is also sometimes used in the production of food additives and nutraceuticals (foods designed with altered nutritional profiles). Certain dietary supplements, flavour agents and enzymes used in food production are made by microorganisms and purified for subsequent use. One example of the latter is chymosin, which is an enzyme used in cheesemaking. Traditionally isolated from a calf intestine as rennet, chymosin is now frequently produced by genetically modified yeast[14].

3.4 Bioremediation

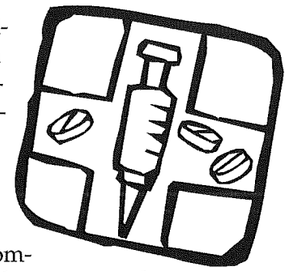
Bioremediation, or the cleanup of contaminated areas using plants and microorganisms, has emerged as a significant area for GE application. Most of the current work is on using modified organisms to carry out cleanup functions. Attention is focused on oil spills and chemical contaminants, like polychlorinated biphenyls (PCBs). The genetic modifications are designed to enhance the capacity of the organisms to capture and breakdown the targeted pollutant. Typically, the genetic modification involves altering a bacterium's pathways for breaking down a toxic chemical, by manipulating their own DNA, or by inserting DNA from other organisms. At this point, no GE organisms for bioremediation have been approved for commercial use in Canada[15].

3.5 Medical applications – pharmaceuticals, reproductive technology, vaccines

Genetic engineering has been used to produce a variety of compounds with use in the area of human health. Products are present in vaccines, diagnostic tests and medicines, and as well in the emerging areas of gene therapy and organ transplantation. There is significant emphasis on the development of genetic engineering applications within the health industry, and the majority of biotechnology money and research is directed towards the development of pharmaceuticals. Upwards of 90 percent of current GE products are related to human health[16]. In general, proponents believe that GE technologies allow for more efficient and precise development of these applications.

Vaccines: Currently, vaccines are an active area of GE research. Vaccines derived with the aid of molecular biology techniques can induce immunity to a bacterial or viral pathogen with potentially less risk of causing infection. This is because these new vaccines can isolate the parts of a pathogen that induce an immune response and can introduce these into the host in the absence of the pathogen itself. This approach has been used for both animals and humans, notably in vaccines for rabies, influenza and hepatitis B. Such vaccination strategies are also being investigated for their ability to prevent diseases such as cancer[17].

Diagnostic tests: Medical facilities are also making use of genetic engineering in the diagnosis of disease and infection. In this capacity, GE contributes molecules, such as antibodies in ways that are seen to be efficient for large-scale production. Antibodies generated and purified in laboratories can be used to detect specific markers of disease or other conditions by being tracked as they bind to identifying proteins. This technique is used by home pregnancy tests, in which mouse-generated antibodies to human chorionic gonadotropin (hCG) react with the hCG present in the urine of pregnant women[18]. Diagnostic techniques, such as the polymerase chain reaction (PCR) and the enzyme-linked immunosorbent assay (ELISA), also use GE technology. PCR, for example, is a way of detecting the presence of aberrant or disease-causing genes, such as those linked to breast cancer or Alzheimer's disease. The ELISA allows laboratory determination of exposure to a pathogen. Among other things, this test is used to diagnose measles, rubella and Epstein-Barr infection.



Medicines: Genetic engineering has provided an alternate way of producing many of the pharmaceuticals used in human treatment. Beginning with the production of insulin in GE *Escherichia coli* bacteria in 1982, recombinant DNA technology has generated drugs used in the treatment of diseases ranging from the genetically inherited (e.g. hemophilia and cystic fibrosis) to the viral (e.g. AIDS and hepatitis). There is also research into the therapeutic use of laboratory-produced antibodies for diseases such as cancer, although nothing is currently available in a clinical setting[19].

Gene therapy: As one of the newest technologies available in the field of medical biotechnology, gene therapy is controversial and not yet commercialized. The idea behind gene therapy is to introduce the normal counterpart of a faulty gene into an individual suffering from a genetically linked disease. Gene therapy approaches have been attempted for many diseases, and treatments have reached the clinical trial stage in some cases (e.g. rheumatoid arthritis, cystic fibrosis and hemophilia[20]). In this area there are success stories and cautionary tales. Severe combined immunodeficiency (SCID), for example, was effectively treated by gene therapy in 2000[21], but this success stands in marked comparison to the tragic death of Jesse Gelsinger who died in 1999 in a gene-therapy clinical trial taking place at the University of Pennsylvania[22].

Xenotransplantation: Work on developing mammals that can be used as a source of organs for human transplantation has received media attention recently, with PPL Therapeutics' development of cloned pigs that are genetically engineered to be more molecularly compatible with humans. Immune rejection is a problem with transplants, and it is hoped that by altering some characteristics of the cells of other animals they can provide acceptable organs[23]. This technology is far from being commercialized, and there is significant concern about passing animal diseases to humans in the process.

Reproductive technologies: Molecular techniques and biotechnology are also put to use in human reproduction. Techniques such as *in vitro* fertilization make use of a scientific understanding of the very early stages of embryo development. One controversial offshoot of this work is the subsequent use of generated embryonic stem cells in medical research and in the development of therapeutics[24]. Debate continues over the ethics of stem-cell research, and whether it should even be permitted. It appears now that the U.S. and Canada will permit such work, with some restrictions.

Other considerations: Biotechnology not only contributes to the generation of novel therapeutics, but it also has a role to play in other related capacities.

Delivery systems: There are ongoing studies that relate to the targeting of the molecular agents used in the prevention or treatment of disease. This is important for localized diseases such as cancer, where delivery of a toxic agent to the whole body in a course of therapy has obvious adverse and widespread effects. Some approaches have been to use specific antibodies linked to toxic compounds[25], or to take advantage of the natural homing abilities of certain proteins or viruses[26].

Means of production: There has also been much effort to find efficient systems for the production of molecular pharmaceuticals. Recently, much discussion has focused on the use of plants as bioreactors in a process dubbed "molecular pharming". To this end, plants have been engineered to express antibodies, subunit vaccines and therapeutic agents[27]. More commonly recombinant products are recovered from microorganisms, laboratory animals or cultured mammalian cell lines. However, the regulatory system is now gearing up for a wave of molecular pharming applications (see section 5).

3.6 Economic trends

3.6.1 A picture of the biotechnology industry[28]

It is estimated that the biotechnology industry will be valued at $50 billion by 2005[29]. However, with the exception of the biomedical sector, the biotechnology industry is in decline relative to the halcyon days of the early 1990s when the applications and investments seemed limitless. Amid slow consumer acceptance, the high costs of research and development, and some restrictive national policies, share values have been falling and most biotechnology companies are failing to show a profit.

Of the 361 biotechnology companies publicly traded in 2000, only 21 percent posted a profit. Only eight of the 10 largest biotechnology companies finished the year in the black. However, that doesn't prevent the industry from spending a great deal of money on research and development. The year 2000 saw biotechnology companies spend a total of $9.59 billion (U.S.) on research and development[30].

Under stiff economic and consumer pressure, companies have been shifting their focus from food crops to products they feel the public is more ready to accept. Nine of the 10 largest biotechnology companies are producers of pharmaceuticals. The rest of the revenue-generating companies focus on early-stage products or platform technologies for pharmaceutical companies or other biotechnology partners.

It is easily seen why the pharmaceutical market is a more attractive sector than food. Looking at Syngenta's total sales in 2000, $6.1 billion was generated from agrichemicals and $958 million from seed sales, while pharmaceuticals generated a total of $27.5 billion. Seed sales, including those with novel traits, account for only two percent of the total, while pharmaceuticals account for 80 percent.

The Canadian biotechnology industry, particularly agricultural applications, is dominated by multinational firms based in other nations (see next section). This reality has complicated Canadian government efforts to develop a made-in-Canada biotechnology sector, with the economic benefits that would flow from a strong domestically owned industry.

3.6.2 Industry consolidation

The result of these difficult economic prospects is an industry in rapid consolidation. Mergers, acquisitions, alliances, and takeovers have become standard business practice in the pharmaceutical, seed, agrichemical and biotechnology sectors. A total of 33 biotechnology companies were lost through mergers and acquisitions from 1999 to 2000.

A brief look at the mergers and acquisitions of one company, Novartis AG, gives an interesting snapshot of this trend (see Table 4).

Investor interest in biotechnology is also on the downturn. This trend is most obvious when one compares the historical stock values of some major biotechnology companies:

As one can see from these charts, they all show a roughly year-long decline in share value. Industry analysts expect this trend to continue in the economically difficult conditions developing in the biotechnology industry.

Table 4. Acquisitions of Novartis AG

December 1996
Novartis formed via merger between Ciba-Geigy and Sandoz

May 1997
Purchased Merck &Co.'s crop protection business

May 1998
Purchase of Oriental Chemical Industries' crop protection division

1998
Purchase of Seoul Seeds Co. Ltd.

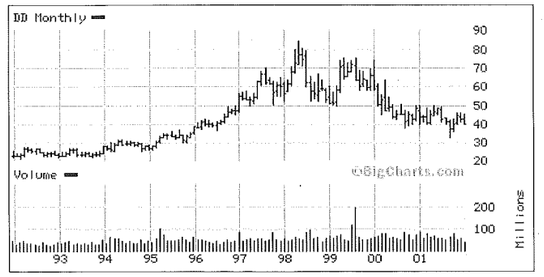
August 1998
Purchase of Agritrading (Italian seed co.)

1998
Acquired 50% equity in Wilson Seeds Inc. (owned by Land O' Lakes)

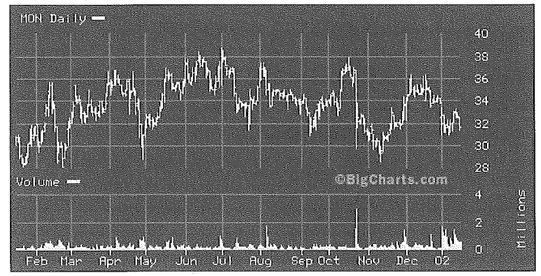
October 2000
Novartis and Zeneca Agrochemicals merge to form Syngenta

From *Transforming Agriculture: The Benefits And Costs Of Genetically Modified Crops*. The Canadian Biotechnology Advisory Committee Project Steering Committee on the Regulation of Genetically Modified Foods, March 2001. Page 28.

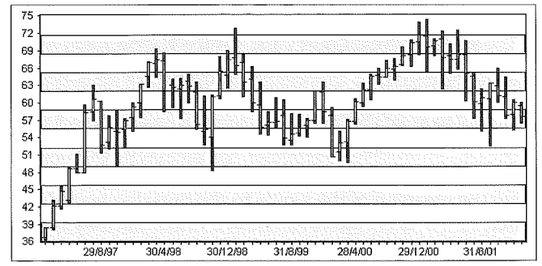
Dupont



Monsanto



Novartis



3.6.3 Patents

Patenting is a central feature of economic development within the biotechnology sector. Companies believe they require patent protection to secure sufficient returns on their investments in research, development, and commercialization. The patent gives the owner the right to practise a monopoly for 20 years from the date of filing of the patent application. In exchange, the owner permits the public disclosure of the invention some 18 months following the application date. This public disclosure permits competitors to attempt to create competitive technologies without infringing on the conditions of the patent. Public disclosure is important because, in its absence, advances in knowledge could be choked off by secrecy.

There are many issues surrounding the patenting of inventions of biotechnology and the Canadian perspective is far from settled. Currently, a variety of biological items including individual proteins and genes, cell lines and single-celled

Oncomouse

The "Oncomouse" is a transgenic mouse developed by Harvard College. An *myc* oncogene inserted into the genome of the mouse predisposes it to cancer, and accordingly it can be used as a model in some cancer research projects. Harvard filed with the Canadian Intellectual Property Office (CIPO) in 1985, and although a patent was granted for the *myc* gene and the involved processes, the parts of the application pertaining to the whole mouse were rejected by the Patent Commissioner in 1995. Harvard College appealed this decision, and since then the case has been heard both by the Federal Court (1998) and the Federal Court of Appeal (2000).

In the Federal Court case, Justice Nadon ruled in favour of the Patent Commissioner, saying that the mouse was not sufficiently reproducible or under the inventor's control to meet the "invention" requirements of the *Patent Act*. He stated that " [a] complex life form does not fit within the current parameters of the *Patent Act* without stretching the meaning of the words to the breaking point," and that if such patents were Parliament's intention they should legislate to this effect.

This finding was overturned in the Federal Court of Appeal by a 2:1 majority. Here, Justice Rothstein found that the Oncomouse itself did fit within the parameters of the term "invention" and there was "no reason in law why the ...oncomouse is not patentable." The Commissioner of Patents has appealed this to the Supreme Court of Canada.

The Supreme Court challenge involves Harvard College and Commissioner of Patents as parties, however there are a number of interveners who were granted leave to make arguments at the hearing. These are divided into three groups and consist of: (1) the Canadian Council of Churches and the Evangelical Fellowship of Canada; (2) the Canadian Environmental Law Association, the Canadian Association of Physicians for the Environment, ETC Group, CIELAP, the Sierra Club of Canada and Greenpeace Canada; (3) the Animal Alliance of Canada, the International Fund for Animal Welfare Inc. and Zoocheck Canada Inc.

Some of the arguments being advanced reflect the concerns mentioned in section 3.6.3.3, however there are other more legalistic concerns as well. For example, there is precedent to suggest that the expertise of the Patent Commissioner should be deferred to and his decision not to patent the Oncomouse respected. As well, there are concerns about the legal validity of interpreting "invention" in a way that could not have been contemplated by the framers of the *Patent Act*.

If the Supreme Court agrees with the Federal Court of Appeal, the ability to patent higher life forms (HLFs) will be "read into" our patent legislation, and will be governed by the terms of the existing *Patent Act*. If Parliament takes an initiative, however, other possible outcomes could include a modification of patent provisions specifically as they apply to HLFs. For example, access to patented goods could be facilitated for use in certain contexts such as research or agriculture. The statute could also be amended to incorporate a discretionary clause to prevent the patenting of certain inventions that offend public morality. CIELAP feels that the extension of patent protection to HLFs is not a step that should be taken without providing an opportunity for a full and vigourous public debate. As such, any decisions would be best made through Parliament.

microorganisms, are eligible for patent protection in Canada[31]. However, there is a line drawn with respect to multicellular plants and animals; the so-called "higher life forms" (HLFs). This line is now being questioned nationally, both in a general way through the pressures of our international trade obligations, and specifically through a particular patent challenge (the Harvard "Oncomouse", see sidebar)[32] that is making its way through the Canadian court system.

3.6.3.1 Current scope of patent protection

Under the *Canadian Patent Act*[33], an invention is a "new and useful art, process, machine, manufacture or composition of matter" (section 2). The *Patent Act* later sets out the additional requirement that inventions be non-obvious to someone skilled in the relevant art or science (section 28.3). Together these criteria mirror the requirements for U.S. patents, and are in keeping with general global guidelines. Improvements on prior inventions are also patentable provided that they demonstrate the criteria of novelty, utility and non-obviousness. The period for patent protection is 20 years from the filing date, after which point the patented invention can be reproduced without penalty. Since the early 1980s, Canada has allowed the patenting of genes and individual cells, including microorganisms; however, to date there have been no patents granted for multicellular organisms[34]. These have been excluded on the grounds that they lack uniformity in their composition and are not sufficiently reproducible. The Canadian Intellectual Property Office (CIPO) is explicit about this limitation in its Manual of Office Practice (section 16.04).

Although HLFs are not currently patentable in Canada, ample protection for transgenic plants and animals is provided through patents on the introduced transgene, individual cells containing the transgene and on the process used for introducing a genetic material into a plant or animal. The generous scope of protection afforded by these means has been demonstrated by successful challenges to patent infringements in the Canadian courts. For example, Monsanto was recently successful in a challenge against Saskatchewan farmer Percy Schmeiser for unlicensed use of their Roundup Ready® canola (Canadian Patent no. 1,313,830)[35] (see sidebar).

Monsanto Canada Inc. v. Schmeiser (2001 F.C.J. No 436) (Federal Court of Canada - Trial Division, Saskatoon)

Percy Schmeiser is a Saskatchewan canola farmer who has been caught in a biotechnology patent dispute with Monsanto since 1998. According to Schmeiser, sometime in 1997 he noticed that isolated canola plants on the part of his land bordering the road were able to withstand treatment with the herbicide Roundup®. He collected some of the seeds from these resistant plants and sowed them the following year alongside his customary canola variety. During this 1998 season Monsanto extensively sampled Schmeiser's crop; testing it for Roundup® resistance, their corresponding patented protein and their patented gene. Several tests done by either Monsanto or the University of Manitoba demonstrated that a large portion of the crop was in fact Monsanto's proprietary Roundup Ready® canola. These results stand in contrast to the outcome of Schmeiser's own tests, which showed much lower proportions of Roundup® resistance. In the ensuing lawsuit, Schmeiser claimed that the Roundup®-resistant plants were an accidental addition to his crop, having been introduced onto his land either by a seed truck using the adjoining roadway or by cross-pollination from neighbouring fields of Roundup Ready® canola. The trial judge ruled in favour of Monsanto, indicating that irrespective of how the contaminating plants arrived on Schmeiser's fields, his saving and sowing the seed infringed on Monsanto's patent rights. In the judge's view, Schmeiser knew, or reasonably ought to have known, that the Roundup® resistance seen was indicative of the presence of Roundup Ready® technology.

The trend in Canada may well be towards extending the scope of patent protection to include broad, whole-organism plant and (non-human) animal protection. In a recent report published by the Canadian Biotechnology Advisory Committee (CBAC), the majority of the committee drafted a recommendation providing for such an extension, subject to limiting provisions with respect to human, animal and environmental health[36]. In contrast, the minority view of CBAC held that there is an intrinsic value to HLFs that is irreconcilable with the idea of patent "ownership". Also, in an ongoing patent dispute between Harvard College and the Canadian Patent Commissioner, the Federal Court of Appeal ruled 2:1 in favour of granting proprietary rights to Harvard over their Oncomouse. This case will be heard by the Supreme Court in the coming year.

3.6.3.2 Arguments for extending the scope of patent protection

There are several arguments in support of extending patent protection to HLFs.

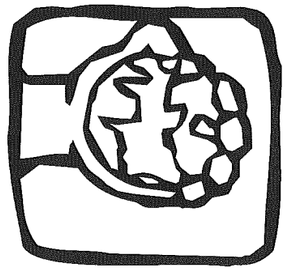
Importance for continued research and development: One of the commonly cited reasons recognizes the role of patents in encouraging scientific research. From this perspective, intellectual property protection is an incentive, as it allows high research expenses to be recouped and enables further investigation. Indeed, in some companies it is reported that 45 percent of revenue from patents is reinvested directly in research and development[37].

Symmetry with trade partners: Another argument points to the provisions in some global trade agreements, and the attitudes of our important trading partners. It is argued that keeping our patent regime in line with those of the U.S., the European Union, Australia and Japan serves to facilitate trade and subsequent economic returns. *Why not?* There is also a passive argument suggesting that the patentability of HLFs would effectively change very little as there is significant protection already afforded applications. This can be seen in the Monsanto Canada Inc. v. Schmeiser case, and through a general assessment of the level of protection afforded by the gene patents already available.

3.6.3.3 Arguments against extending patent protection

The arguments generated against HLF patenting generally reflect dissatisfaction with the patenting of all elements of life, including the genes and cells that are already eligible for intellectual property protection in Canada. Criticisms are often directed not only towards the further extension of patent protection, but also to what is currently available. There are basically two lines through which criticism is levied: one is concerned with the ethics of treating life as a mere commodity for sale in the marketplace, the other considers the social implications of an unequal distribution of the wealth defined by these patents. This latter concern has been loudly expressed with respect to intellectual property protection of crop plants.

Ethical concerns: Fundamentally important to many of the objections to biological patents is the idea that the granting of such protection effectively acknowledges ownership of life. It is for this reason that humans are specifically exempted from patenting under all regimes. There are broad concerns that the possession and profit inherent in patents reduces life to dollars and cents, and animals and plants become objects and commodities. The loss of recognition of the value inherent to life itself could lead to gross abuses of animals and the environment[38]. Another ethical element is the idea that by manipulating life at the basic level of genetics, humans are "playing God" and altering something previously immutable except through nature or divine action. Ethical arguments are difficult to articulate in many cases, and there is hardly a universal consensus on these ideas (see section 4 for further discussion). In some concession to this reality, both the Trade-Related Intellectual Property Rights (TRIPS) (see below under international agreements) and the European Union positions allow the exclusion of inventions from patenting if there is concern that their commercialization would offend morality or *ordre public*.



Distribution of wealth: Many non-governmental organizations, farmers' groups and social activists are raising concerns about the unequal distribution of patented and secured resources. The nature of the global economy is such that most intellectual property is held by corporations and institutions within developed countries and often is inaccessible to developing nations. One situation that recently received media attention is the availability of patented anti-HIV drugs in Africa[39]. The irony here is that a significant number of pharmaceuticals are derived from plants[40], and the vast number of the medicinally valuable species are found in developing countries such as those in South America. Furthermore, the development of novel drugs from these specimens usually relies on the traditional knowledge of indigenous peoples whose contribution is largely unacknowledged and uncompensated[41]. This phenomenon of appropriation has been dubbed "biopiracy" and it is becoming one of the largest problems in global trade.

Another area in which the spectre of biopiracy has been raised is in agriculture. Although intellectual property in plants is generally recognized to some extent under specific international covenants, utility patents for plants are not widely granted. Providing patents for developed crop varieties could dramatically curtail access to germ plasm for farming or breeding. This is already argued to be the case within the United States, where utility patents have been granted for crop varieties since 1985[42]. In contrast, Canada provides protection exclusively under our *Plant Breeders' Rights Act* (*PBRA*), a statute which is distinct from the *Patent Act*. Under the *PBRA* system, plant breeders ("inventors") possess exclusive rights for the sale of plant reproductive material, while the plant itself is readily available for cultivation and further breeding[43]. This allowance is not made under utility patents, and generally licensing agreements are used to restrict access to the plant itself. This extremely limited availability not only threatens future crop improvements but also endangers the livelihood of farmers, especially those in developing countries[44].

According to ETC Group (formerly Rural Advancement Fund International), such a high level of protection creates a situation where farmers are effectively subjected to a regime of "bioserfdom", where they are forced to rent the seeds (or germ plasm) essential to their livelihoods[45]. Furthermore, the economic value intrinsic to food crops makes them appealing targets for the sort of biopiracy mentioned above. For example, a Colorado man recently acquired patent rights for the yellow (Enola) bean after simply buying a bag of beans in Mexico. He was subsequently able to launch lawsuits against 16 small companies and farmers for infringing on his patent and growing "his" bean[46].

3.6.3.4 International agreements

The global nature of trade and the reliance on foreign goods, including crops, has necessitated international discussion on a number of these issues. As a result, there are number of drafted

agreements that reflect trade and intellectual property obligations and, to a lesser extent, environmental and social obligations. The most relevant of these to the patent debate are described briefly below.

North American Free Trade Agreement (NAFTA): NAFTA is a trilateral agreement between Canada, the U.S. and Mexico[47]. Although the implementation of NAFTA imposes a number of obligations on our patenting practices, it provides the option of excluding HLFs from patent protection (Article 1709(3)(b)).

World Trade Organization (WTO) Agreement on Trade-Related Intellectual Property Rights (TRIPS): The TRIPS council is the branch of the WTO responsible for trade in intellectual property (IP)[48]. There are 144 countries party to this agreement and complete alignment between all members is expected by 2006. Like NAFTA, TRIPS currently includes patenting guidelines that allow the exclusion of HLFs from utility patents.

World Intellectual Property Organization (WIPO) Patent Treaty: The WIPO is a specialized agency of the United Nations (UN)[49]. This particular treaty has been drafted and signed by a number of developed countries, but is not yet in force. It aims to standardize requirements and procedures for patent granting mechanisms in member states.

Union for the Protection of New Varieties of Plants (UPOV) Act: This act has been around in various forms and its purpose is to protect international privacy interests in plant varieties[50]. The most recent (1991) act has not been ratified in Canada. Under the 1978 act we abide by, there is no allowance for plant-utility patents, however the more recent 1991 act makes explicit provisions for this.

Convention on Biodiversity (CBD): The CBD has the goals of conserving biodiversity, promoting sustainable development, and ensuring the fair and equitable sharing of genetic resources[51]. As well, this convention anticipates the potential for biopiracy and asserts that each nation has sovereign authority over its flora and fauna. There is an additional supplementary agreement on biosafety (the Cartagena Protocol on Biosafety [CPB]), which aims to protect biodiversity from the threat of contamination by GE products of biotechnology. The CBD has 182 parties to it, while the CPB – although with 103 signatures to the protocol – has only 10 members to date that have ratified or otherwise implemented it (see section 5.2.5 for more on this).

Food and Agricultural Organization (FAO) International Treaty on Plant Genetic Resources: As with the CBD, this treaty's aims are resource conservation, sustainable use and equitable sharing but is specifically with regard to food and agriculture[52]. There are 161 parties to this treaty, although only 113 of these countries (Canada not among them) have actually implemented it. The International Treaty explicitly addresses farmers' rights in the face of increasingly politicized and restrictive trade regimes. It governs the conservation and exchange of valuable crop plants and facilitates availability for developing countries that cannot afford to pay for these resources.

Canada's participation in these international agreements brings a variety of pressures to bear on the patent story in Canada. As a result, the federal government is less likely to forge a uniquely Canadian approach to patents in the genetic engineering arena.

4 CONCERNS ABOUT GE – AGRICULTURE AND FOOD AS A CASE STUDY

CONCERNS ABOUT GE HAVE BEEN RAISED by CIELAP since the mid-1980s[53]. Many critics were concerned even then that GE applications could have extensive negative environmental, social and economic impacts. There were also fears that Canada would not put in place a suitable regulatory framework. Now that the technology has been extensively adopted in the agricultural and food sector, many of these "speculative" concerns are coming true. Some of the main ones are discussed here.

4.1 Meeting its own claims: Do GE crops increase yields, improve financial performance, increase environmental benefits and alleviate hunger?

The "selling" of GE crops and foods to the public has been based on claims of widespread farm and societal benefit, particularly increased yields, significant reductions in pesticide use and associated environmental benefits, improved financial performance, and hunger alleviation in the developing world. When all these benefits are bundled together, the economic benefit has been described as huge. For example, one claim of benefit is that two million farmers worldwide received economic benefits of $700 million (U.S.) in 1999, with consumers receiving additional benefits of $1 billion (U.S.). But industry has actually provided little evidence to support these kinds of numbers. Critics are claiming, in fact, that when performance of GE crops is examined more closely, few real benefits accrue to society. We explore their arguments in the following sections.

4.1.1 Increased crop yields?

Claims of higher yields have not been realized across the board, varying by growing region, commodity and study. Based on data from U.S. state varietal trials, Roundup Ready® (RR) soybean yields in the U.S. are usually five to 10 percent lower than comparable non-GE varieties in comparable tillage systems. The likely causes are the behaviour associated with the gene itself or the gene-insertion process, which may have disrupted metabolic activity in the plant. A third possibility is that the Roundup® (glyphosate) application may have reduced nitrogen fixation, and increased disease pressure[54]. Yields of Bt corn and cotton relative to conventional yields have been both higher and lower depending on U.S. region[55]. Two studies on canola produced conflicting results: one identified no consistent yield advantage for GE canola[56], the other did[57]. From evidence to date, the consistent theme is that GE crops only outperform conventional varieties under particular circumstances (e.g. for Bt corn, under conditions of high European corn borer[58] pressure). The CFIA agrees that many of these GE crops only perform well under stressful conditions[59]. This raises an interesting question: If GE crops only perform well under specific conditions, why are regulators licensing them as if they are universally useful? If the benefits are limited, shouldn't that shift the framework for licensing? This has led some to call for prescription approvals of GE crops – only permitting their use under specific conditions[60].

4.1.2 Reduced pesticide use?

Proponents of genetic engineering claim that farmers will not have to spray their crops as much with herbicides and insecticides. Many farmers believe that GE crops have reduced their pesticide use, but when all farms using this technology are taken into account the story is far less positive. On average, there is no consistent pesticide reduction[61]. Only in the case of Bt cotton have reductions in pesticide use been observed with some consistency in some U.S. states[62]. At best it can be said that pesticide reduction occurs under specific circumstances with specific crops in specific regions.

For example, Bt corn technology appears to result in lower pesticide use to control European corn borer (ECB) in Ontario, where ECB pest pressures are present at least in one of three years, but it does not provide such a result in much of the United States where spraying for ECB control has actually increased[63].

The story so far on herbicide-tolerant (HT) crops shows that reliance on herbicides is not, on average, declining. Growers become more dependent on pesticides like Roundup® and may actually increase their treatments as a result. They find Roundup Ready® crops convenient, since Roundup® is a convenient product to use and the timing of its application often works well with other operations. As well, Roundup® is cheaper than many other herbicides, so herbicide costs may decline. This does not discount the fact, however, that herbicide use is up in RR canola[64] and RR soybeans.

Even worse, a detailed analysis of herbicide use on conventional and RR soybean crops shows that RR soybean systems (and the associated herbicide price wars triggered by the technology's introduction) are encouraging farmers to move away from low-input sustainable soybean systems in favour of those more dependent on herbicides[65].

4.1.3 Improved financial performance?

> *"As of January, 2001 there is no publicly available survey or data on how individual farmers have benefitted from the adoption of GM [genetically modified] crops in Canada. Therefore, it is not possible to say how much economic benefit farmers have experienced from adopting this technology."*[66]

GE crops are expensive relative to traditional varieties. Farmers have to pay companies a fee to use the seed, called the technology-use agreement. When the technology-use agreement is included, the seed can cost several times regular seed prices, and farmers are forbidden from saving and replanting the seed the following year. With no yield increases, and no reductions in pesticide input costs, GE crops are proving to be no more profitable than many conventional varieties[67] and perform particularly poorly when compared with low-input systems. Where economic benefit has been concluded, such as in a Canola Council of Canada study of transgenic canola[68], it is primarily due to cheaper pesticide costs associated with the GE crop technology, not a result of reduced reliance on pesticides.

But why have certain GE crop technologies been adopted by farmers at such a rapid rate? Some economists now speculate that GE technology is adopted primarily for its convenience[69] and as insurance against the possibility of major pest infestations[70]. These conveniences result from the use of fewer kinds of pesticides, ease of harvest, flexibility, and less time carrying out certain field operations. Yet such conveniences do not necessarily result in greater financial returns to labour and management. In fact, these returns can be decidedly lower for GE varieties[71].

It may be a short-lived convenience if the effectiveness of the technology is quickly eroded by pesticide resistance to weeds and increased management problems and expenses associated with gene flow to weeds and crops. One Canadian study suggests that gene flow of any significance from canola to wild mustard (a weed and relative of canola) would quickly eliminate any financial benefits associated with GE canola[72]. And GE technology, because of resistance pressures, is likely to reduce the effectiveness of traditional control agents. This loss will impose significant economic costs that someone will be forced to pay.

Emerging evidence suggests that the effectiveness of Roundup® in RR soybean systems is slipping as weed tolerance increases and growers are forced to increase rates, numbers of treatments or use tank mixes with other products[73]. Although resistance to Bt crops has yet to be confirmed in the field, most believe it to be inevitable[74]. Widespread resistance to Bt due to the proliferation of Bt crops will render Bt spray useless as a control strategy[75]. Because it is naturally occurring, Bt is arguably the most important insecticide discovered in recent times and its loss would cause growers to switch to more harmful synthetic pesticides.[76] Used as a spray, Bt is critical for many organic farming and integrated pest management programs and has been identified by the U.S. Environmental Protection Agency (EPA) as a safer approach than chemical pesticide alternatives. The EPA has concluded that should resistance develop, Bt pesticides have low dietary, worker, and ecological risks compared to the alternatives that might replace Bt.[77] The regulatory system takes no account of this problem. In fact, CFIA is not concerned with the loss of Bt technology, only with extending its lifespan[78]. When Bt is lost as a control option, it is unlikely the companies who created Bt crops will have to compensate farmers for its loss.

Consumers do not receive many benefits from this first wave of GE applications that focus on farmer needs. Since the farm price of commodities like corn, canola and soybeans is generally below farmers' costs to produce them, and is also such a small percentage of the retail price, even if farm costs were reduced by GE crops it would have no bearing on retail prices. Several economists studying this question have concluded that it is primarily seed companies and biotechnology firms that are receiving economic benefits from the technology, not farmers and consumers[79]. This may explain, in part, why consumer opinion on the technology is divided, as surveys in Canada consistently show a questioning of the risks and benefits of the technology[80] and significant interest in labelling.

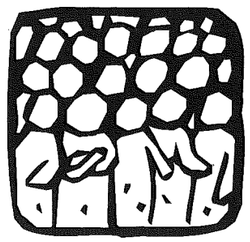
4.1.4 Hunger alleviation?

A typical rationale for higher yielding crop technologies, including GE, is captured in a quote from a report of the Global Crop Protection Federation (GCPF)[81], now known as CropLife International (the global trade association of the pesticide industry):

> The demands of a growing world population for food and fibre require world agriculture to produce higher yields from cultivated land. Feeding future populations with today's crop yields is not viable; it would require a drastic expansion of planted acreage. In many parts of the world additional land is unavailable. In others, an expansion of cropped area would be environmentally and socially unacceptable. To increase yields from existing land requires good crop protection against losses before and after harvesting.... Less land per person requires more high-yielding agriculture.

The assumptions of such a statement are that the world population will rise dramatically and that the underlying problem of hunger and food insecurity is production, rather than distribution and equitable access to food resources. These assumptions are largely incorrect.

The United Nations estimated[82] that by the year 2000 the world population would be below earlier estimates, at approximately 6.09 billion. Population will peak, in the medium scenario[83], in the year 2050 at about 9.3 billion and then go into a long-term decline, dropping below today's population by the year 2150. Already, more than 50 countries, including China, have birth rates below replacement levels. These estimates stand in stark contrast to the 11-12 billion figures frequently put forward by proponents of chemical agriculture, high-yield farming and biotechnology.



Although the popular view is that the world has a food-production problem, in a 1994 report on food insecurity the World Bank stated, "had the world's food supply been distributed evenly in 1994, it would have provided an adequate diet of about 2350 calories a day per person for 6.4 billion people, more than the actual population."

It's also important to remember that conventional farming has itself systematically reduced productivity on millions of hectares of agriculture land[84], land that would still be in use were it not for destruction of soil and water resources. For example, some 550 million hectares of the world's agricultural lands lose topsoil or undergo degradation as a direct result of poor agricultural methods[85]. The vast majority of this would be the result of unsustainable agricultural practices imposed directly or indirectly on farmers. In the U.K., some six percent of the agricultural land base is at high or very high risk of soil erosion, all associated with high-yield agricultural practices[86]. Conventional farming practices in Canada create soil erosion and cost billions of dollars annually in lost incomes and cleanup expenses[87]. Regarding water resources, "chemical contamination and eutrophication (from runoff of excess nutrients, mainly nitrogen and phosphorous, from cropland) threaten the productivity of the marine and aquatic systems from which a substantial portion of the world's food supply derives."[88]

Also, much of what high-yield agriculture produces does not contribute directly to the nourishment of people but instead is being used for flowers, sugar and corn syrup for soft drinks, and cotton. A significant percentage of agricultural resources is devoted to production of foods that are overconsumed by many. For example, over 70 percent of the U.S. grain crop goes to feed animals[89] at a time when overconsumption of animal protein is thought to be a significant health issue[90].

There does not appear to be a population-based imperative to dramatically increase yields. There is an enormous need to reduce the loss of productive agricultural land, and to ensure access of the world's population to the existing food supply. GE crops and food do not provide a solution since they are an expensive technology to which most of the world's farmers will not have access. Even if they were given the technology free of charge, given the earlier discussion about yields and pesticide use, there is little reason to be optimistic that the food supply would increase. In contrast, the adoption of sustainable-agricultural practices in the developing world consistently produces yield improvements without compromising local environments[91].

4.1.5 Benefits of future applications?

Second-wave technologies will focus more on perceived consumer benefits – characteristics of processed foods and "improvements" in the nutritional profile of foods. The truth of such claims is difficult to assess at this point since few applications are currently on the market. Given the gap between the claims and realities of first-wave applications, there is reason to be critical of assertions of future benefits. As well, any health benefits that might result will be almost impossible to document under the current regulatory regime, since there is no mandatory identification of GE foods in Canada (see section 5.2.5). Without identification of GE foods, consumers will not be able to document what they are eating, which is essential to most health benefit studies. Only in highly controlled experiments in which humans take the place of test animals would it be possible to determine whether there are any resulting benefits. Most people would be unwilling to subject themselves to such experimentation, and the ethical questions surrounding such experiments are significant (see section 4.4).

4.2 GE foods and potential health impacts

As discussed in section 3.1, most GE food applications currently on the market are designed to address farm issues. Only a few have direct health-related purposes, although many in development focus on altering the nutritional profile of foods or removing anti-nutritional factors.

The debate about the human safety of these current GE foods centers around four questions:

- ➤ Do GE foods introduce new food constituents that might be toxic?
- ➤ Do GE foods introduce new food constituents that might cause allergies in some people?
- ➤ Do GE foods have new anti-nutritional factors that may be problematic?
- ➤ Do GE foods contribute to the creation of antibiotic-resistant bacteria[92]?

There are currently no clear answers to these questions. Industry and regulators claim that a substantial body of evidence from eminent scientists and scientific panels worldwide shows that GE foods are safe for human consumption. However, there is actually very little literature in the scientific journals on the subject, especially studies that feed GE food diets to test organisms. In a 2000 *Science* article that followed detailed database searches, the author found just eight referenced journal articles dealing with any aspect of the safety of GE foods and only four were actual feeding trials. Three of these were from Monsanto research teams[93]. Most of the other evidence was generated in industry applications to regulators. However, these studies are not subject to broader scrutiny (as discussed further in section 5), and there are serious questions about the quality of the data. The rest of the "studies" actually do not contain data but rather scientific opinion, much of it referring to these confidential industry studies that are not available for public review. Other scientific opinions are formed around theoretical considerations that lead scientists to conclude no negative impacts could be expected. These conclusions are not generally based on any real evidence of safety.

While there is no definitive evidence of problems, there are disturbing signs. For example:

▽ One feeding study in the scientific literature showed mild and significant changes in the structure of the digestive system of rats fed a type of Bt potatoes[94].

▽ There is some evidence that the gene-insertion process can produce effects that alter the structure and function of the inserted gene sequence, and this in turn can affect its behaviour in humans[95].

▽ In the U.K., an Aventis feeding trial submitted to regulators involving GE corn and chickens was reviewed by researchers working on studies for the Ministry of Agriculture, Fisheries and Food. They found what appeared to be higher death rates among chickens that ate the GE corn during the study, results that Aventis scientists did not further investigate or adequately explain[96].

▽ Nutritional composition studies funded or carried out by industry frequently have statistically significant variability in some nutritional parameters that are not explained, or deemed biologically insignificant in the face of competing study data that suggest otherwise[97].

▽ Some studies have shown that it is possible for the antibiotic-resistant gene sequences in the crop-marker genes to pass to bacteria in the guts of animals. Since many of these genes express resistance to antibiotics used in human treatment, the fear is that human disease treatment with these antibiotics could ultimately be compromised. This has caused several bodies, including the British Medical Association[98], an Organization for Economic Cooperation and Development (OECD) group[99], and the Royal Society of Canada[100] to conclude that, based on potential risks, these antibiotic markers should not be used in producing GE crops.

Because of the problems with the regulatory process (see section 5), these results may serve as indicators of significant problems that are not being detected by industry or regulators.

4.3 GE crops and impacts on biodiversity

GE crops can have negative impacts on biodiversity in a number of ways: the GE crop itself may become invasive in wild ecosystems; it may pass introduced traits to other plants (gene flow) that may increase the invasiveness of these other plants; the GE crop may have direct and indirect negative impacts on non-target beneficial organisms; and the use of GE crops may simplify crop rotations that would trigger a series of negative consequences for soil and water quality and habitat.

4.3.1 Invasiveness of GE crops

Many crops are so domesticated that they are not able to survive in wild ecosystems. Others, however, are still closely related to their wild weedy relatives and are much more viable outside of farm fields. This has led some ecologists to worry that some GE crops could become problematic plants in wild ecosystems. A recent study in *Nature* concluded after 10 years of investigation, that the studied GE crops could not survive in natural ecosystems in the U.K.[101] The study has been held up by proponents of GE crops as confirming evidence that these crops do not have greater weediness potential. However, the study only examined four GE crops in a limited number of ecosystems. No studies have been carried out that project how millions of seeds dispersed into ditches and field borders will behave. So, although the chances of many GE crops surviving in the wild and having a competitive advantage over other plants is small, it is too early to say that this cannot happen, especially for crops like canola, alfalfa, carrots and many grasses that are better adapted to wild ecosystems than other crops such as corn and soybeans.

4.3.2 Passing introduced GE traits from crops to other plants and organisms (gene flow)

One of the main ecological risks of GE crops is the flow of the "foreign" inserted gene sequences from crops to other organisms. Gene flow may occur from plant to plant, from plant to bacteria, and from plant to virus[102]. The gene sequence that moves may be the novel trait itself, or it can be other sequences that are inserted in the crop as part of the engineering process (e.g., antibiotic-resistant genes, gene promoters that are usually virally derived). Of particular concern for pesticide use is the flow of herbicide-tolerant genes from a crop to a close relative.

Of the crops currently on the market, canola presents a significant problem in Canada as it is very closely related to many plants that are considered weeds. The main canola variety, *Brassica napus (B. napa)*, is very prone to gene flow. It has out-crossing (cross-pollination) rates of up to 30 percent with other plants of the same species, and also with other related plants (frequently weeds in canola fields)[103]. This means that genetically modified versions are at significant risk of gene flow. In fact, gene flow from GE canola to closely related canola varieties and weeds has already been documented[104]. For instance, in 1998, Canadian farmers reported Roundup® (glyphosate)-resistant "volunteer" (weed) canola plants on fields where none had been grown, the result of gene flow from transgenic to conventional canola plants. As a result, farmers are forced to use chemicals other than glyphosate to control the volunteers and of the available options, some are environmentally more problematic (such as 2,4-D)[105]. If a related weed that is already hard to control such as wild radish acquires herbicide-tolerant traits, then it will be even more difficult to manage.

GE crops in development – for example, carrot, squash, sunflower and alfalfa – also present concerns similar to canola because they have close relatives that are common weeds. In Canada and the U.S.A., corn, soybeans and cotton have no close relatives, so herbicide-tolerant gene

Fears about gene flow to the "homes" of agricultural crops

Agricultural crops have "genetic homelands", the regions of the world in which they evolved. These are known as Vavilov Centres, named after a Russian scientist. For example, the home of corn is Mexico and the home of wheat is Eastern Turkey and surrounding area.

These homelands have historically been important sources of plants for both local agriculture and traditional crop-breeding programs because they contained many close relatives of North American agricultural crops. Plant breeders return frequently to these regions to identify closely related plants with desirable yield and disease-resistance traits. They would then cross-fertilize crop plants with these close relatives.

Because they are close relatives, these wild plants can readily acquire the GE traits of GE crop varieties once exposed to their pollen. Some preliminary investigations in Mexico suggest that this process has already started there, with GE traits from GE corn transferring to local relatives of corn[1].

Should this be confirmed in subsequent investigations[2], the implications are potentially profound. If traits for herbicide tolerance or insect toxicity are passed through local corn varieties and wild corn populations, local and international plant breeding could be compromised and ecological disruption could be significant. The story could potentially be repeated in each of the homelands of the main agricultural crops as GE versions of them are commercialized.

[1] Quist D and Chapela IH. 2001. Transgenic DNA introgressed into traditional maize landraces in Oaxaca, Mexico. Nature 414: 541-543.

[2] There is considerable debate in the scientific literature about both the merits of the study and the implications should the results be confirmed.

flow is considered unlikely in these crops. However, the possibility that GE traits have appeared in Mexican corn, even though GE corn has not been approved for release there, is testimony to the power of GE material to move, either through ecological means or illegal plantings. The Mexican story is of concern because it is the genetic "home" of corn (see sidebar).

4.3.3 Negative impacts on beneficial organisms that help control pests and cycle nutrients

Several studies indicate that populations of bees, lacewings, ladybugs, butterflies, and soil organisms may be reduced by exposure to GE crops[106]. These negative effects may result directly from the toxicity of the GE crop or indirectly from how the GE crop affects food sources and habitat.

Harm to lacewings and ladybugs is of particular significance since reducing the populations of beneficial insects means reduced levels of natural pest control. Research conducted at the Swiss Federal Research Station for Agroecology and Agriculture found that green lacewings, an important predator of many agricultural pests, were killed by both direct exposure to Bt corn [107] and also after eating European corn borers (ECB) fed on Bt corn[108].

Researchers from the Scottish Crop Research Institute found that female ladybugs that ate aphids fed genetically modified potatoes laid fewer eggs and lived only half as long as ladybugs feeding on aphids fed non-GE potatoes[109]. The potatoes were genetically engineered to include a toxin found in the plant snowdrop – GNA lectin[110] – which kills potato aphids. While the transgenic potatoes suffered reduced attacks, reductions were insufficient to compensate for the decreased aphid control performed by ladybugs feeding on the green peach aphid. This is significant because ladybugs prey on a wide variety of aphids that are serious pests in corn, alfalfa, canola, wheat, flax, peas, apples and potatoes. A single ladybug larvae can eat 800-1,000 aphids before pupating and an adult can eat 3,000-4,000 during its lifetime.[111] Reducing such beneficial insect populations means more difficulty controlling aphids and a greater likelihood of spraying.

Planting GE varieties of food crops as a pest-management strategy as opposed to multi-tactic integrated pest management, which is designed to work with beneficial organisms, has an additional pest-control cost that has not been calculated in the expenses of using GE technology. The loss of pest control associated with reducing beneficial insect populations is not subtracted from the economic benefits assigned by industry to the use of GE crops.

4.3.4 GE crops reinforce poor crop rotation practices

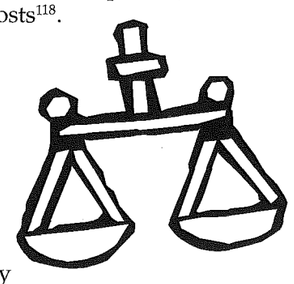
In the short term, some GE applications may help some farmers reduce pesticide use. But this single tactic approach is not sustainable and may even undermine one of the key approaches to sustainable pest and environmental management – crop rotation. Crop rotation is critical to pest management because changing the kind of crop grown in a field every year creates a different, less hospitable, habitat for pests. It is more difficult for pest populations to build up and therefore the need to spray pesticides is reduced.

Many growers have not been practising appropriate crop rotation and have turned to GE crops in the hopes of continuing what are fundamentally unsustainable cropping practices. Soybean farmers currently experience more weed-management problems than they did several decades ago, likely because many practices, including longer crop rotations, have been abandoned.[112] Rather than recognize that longer crop rotation is a root solution to this problem, farmers use GE soybeans. Similarly, simplified crop rotation is also blamed for increases in European corn borer populations in corn production. Again, rather than practising crop rotation to solve this problem, growers turn to Bt corn.[113]

GE canola provides an example of how a GE crop can "inadvertently" shorten a farmer's rotation. Farmers are very concerned about how to manage Roundup Ready® canola plants when they appear in their fields the next year as weeds, or "volunteers" as they are known in farming[114]. Volunteer canola plants resistant to one, two or three herbicide-tolerant traits at the same time have already been found[115]. Dealing with RR canola volunteers requires, relative to conventional canola volunteers, that glyphosate spray tanks be spiked with additional products. Adopting this practice was already underway because of weeds glyphosate did not control well, but RR canola volunteers have made it a requirement. The product used with the glyphosate can limit rotational options. For example, 2,4-D is probably the most popular tank-spiking option because it is cheap and effective against broadleaf weeds and volunteer RR canola. But if it is applied before planting to clean up weeds remaining from the previous year, the herbicide residue on the surface can have a negative impact on broadleaf crops planned for the next phase of the rotation. If the timing and moisture conditions are not optimal, growers may be forced to grow a cereal crop like wheat, which is not affected by 2,4-D residue. Or growers may have to use a more expensive and possibly less effective herbicide in the mix with glyphosate[116].

All this complicates management, particularly if the rotation has to be changed, since rotational changes may have other environmental implications, including effective management of nutrients and diseases. One study has found that growers using GE canola have shorter rotations than those using non-GE canola[117], although it isn't clear from the study whether these problems are the cause. These rotational complications can also add to production costs[118].

4.4 Ethical concerns



Ethical concerns about genetic engineering, particularly transgenic technology, have not received much attention in agriculture[119]. Industry and policy makers have framed the discussion as primarily a "utilitarian" one – if we can do these things and provide some social benefits at minimal costs, why shouldn't we do it?

Ethicists, however, are raising larger questions:

- Do we have the moral authority to alter the blueprint of life of other species?
- Is it right that there be ownership of genetic information?
- Is it right to use animals, plants and microorganisms as bioreactors?
- How widely are the potential benefits of genetic engineering distributed? Do many benefit or just a few?

These and other questions have been imbedded in an ethical framework for assessing GE products presented in Table 5. Although many frameworks for ethical assessment exist, this one is

useful because it has been adapted from one already used in the medical field for some time[120]. It can also be seen as a middle-ground framework, one that attempts to consider the interests of numerous stakeholders, falling somewhere between purely spiritual and purely pragmatic considerations. A preliminary analysis by the matrix's author of one GE crop application in Europe suggests that more elements of the matrix are being violated than adhered to.

Unfortunately, no framework of any kind is being applied by Canadian legislators or regulators. Using different ethical frameworks, other countries are attempting to integrate these larger ethical considerations into their assessments of GE applications. Some, including Norway, Britain, France and Australia, have established advisory bodies that provide ethical interpretation of GE applications to government[121]. See the next section for a discussion about why the Canadian system is deficient in this area and the implications.

TABLE 5. The Ethical Matrix

From: Mepham, B. 2000. *A framework for the ethical analysis of novel foods. J. Agricultural and Environmental Ethics* 12:165-176.

Respect for:	**Well-being**	**Autonomy**	**Justice**
Treated organism	e.g., Animal welfare	e.g., Behavioural freedom	Telos
Producers (e.g., farmers)	Adequate income and working conditions	Freedom to adopt or not adopt	Fair treatment in trade and law
Consumers	Availability of safe food; acceptability	Respect for consumer choice (e.g., labelling)	Universal affordability of food
Biota	Protection of the biota	Maintenance of biodiversity	Sustainability of biotic populations

The table illustrates, in the 12 cells of the Matrix, the specification of the three ethical principles for four interest groups.

5 CANADA'S REGULATORY SYSTEM

THE GENETIC ENGINEERING INDUSTRY and government regulators believe that Canada has one of the most sophisticated and scientifically sound GE regulatory systems in the world. In their view, it assures minimum risk for significant benefits. It properly balances the need for public safety with opportunities for commercialization of a beneficial technology. The system, they believe, has been assembled by many of the best minds in the world. Its effectiveness is demonstrated, they state publicly, by the absence of definitive evidence of harm associated with approved GE applications.

In this section, we explore the nature of Canada's GE regulatory system and whether the confidence expressed by industry and regulators is warranted. Understanding the regulatory system is critical to the debate about GE applications, because it is the regulatory system that acts as the gatekeeper of safety and suitability for the market.

5.1 A general overview of the system

It generally takes 10 years for a GE application to move from concept to regulatory approval. Companies do most of the development work, although university and government researchers often play significant roles as well[122]. The federal government is the primary regulator and its role is: to provide guidance to the research and development phases so that the research process follows best practices; to regulate the way research is carried out once it is out of the laboratory and greenhouse and into the general environment; and then to evaluate the final set of data submitted by industry applicants for the product's efficacy, and health and environmental safety[123].

Genetically engineered products are regulated and evaluated primarily through existing pieces of federal legislation administered primarily by Health Canada, the Ministry of the Environment, the Department of Fisheries and Oceans, and the Canadian Food Inspection Agency. These pieces of legislation include the *Food and Drugs Act*, the *Canadian Environmental Protection Act*, the *Fisheries Act*, the *Feeds Act*, the *Fertilizers Act*, the *Seeds Act*, the *Plant Protection Act*, the *Pest Control Products Act*, and the *Health of Animals Act*. Depending on the GE application, different pieces of legislation apply. For example, for regulating GE crops – whether they be for food or pharmaceutical production – the *Seeds Act* and the *Plant Protection Act* are particularly important. For GE foods and human drugs, the *Food and Drugs Act* is the key piece of legislation. The *Canadian Environmental Protection Act* (*CEPA*) is the catch-all legislation for GE, covering anything that has no applicable legislation. This is an odd situation since *CEPA* is actually the only Canadian legislation having any specific references to environmental and health aspects of biotechnology[124]. But it only has limited impact on the current regulatory process (except as noted below), since for most applications, other legislation takes precedence over *CEPA*[125]. See Table 6 for an overview of all the pieces of legislation and departments that are involved in the regulation of biotechnology.

Not all legislation and regulations are currently in place, even though products are in development and even commercialized[126]. For example, new legislation has been proposed for human reproductive technologies, including genetic engineering technologies[127]. Regulations under existing legislation have yet to be finalized for transgenic

animals and fish and other aquatic organisms. Molecular-farming regulations (pharmaceutical products of crops) are not yet in place[128]. Environmental-assessment rules for GE foods (as opposed to human-safety assessments that are already in place) are also being developed. The federal government claims that in such cases products are currently regulated under *CEPA*, but *CEPA* (and the New Substances Notification Regulations adopted in 1997 and amended in 2000) provides few details on how such products should be regulated. Detailed guidelines to instruct industry and regulators on GE applications covered under *CEPA* were only published in December 2001[129], several years after GE applications were first submitted to regulators.

Given this lengthy list of application pieces of legislation and regulations, it is apparent that Canada has no specific comprehensive legislation governing the regulation of GE products. Using a single new legislative framework to regulate GE organisms was considered in the 1980s, but ultimately rejected[130]. The rationale for using existing legislation and institutions rather than developing a new legislative or regulatory framework was:

- it would build upon existing expertise in specific product areas and would speed up the regulatory process;
- it would permit regulation of GE products in the same way as traditional products;
- it would evaluate the product that was produced by biotechnology, and the process of creating that product (the genetic engineering itself) would not be subject to evaluation.[131]

Since the legislative framework for GE products is not unified and provides little specific instruction to applicants or regulators, new regulations, directives and guidelines have been created to bring meaning to specific pieces of legislation. For example, Part V of the *Seeds Act* regulations, first adopted in 1996, deals with release of Plants with Novel Traits (PNTs), the designation that includes GE crops and trees. However, these regulations do not provide sufficient instructions to industry on data requirements, so such requirements are subsequently spelled out in more detailed directives and guidelines (see Figure 2 for a fuller picture of how different crops and foods are evaluated under different acts, regulations and directives). When applicants carry out tests for biosafety, these are usually guided by Organization for Economic Cooperation and Development (OECD) testing protocols. Finally, regulators, when reviewing data packages from industry applicants, have protocols and decision trees to follow that help them decide whether to approve or reject an application. Regulators do not generate their own independent data.

5.2 How is the regulatory system deficient? A case study of food and agriculture

There are five main deficiencies with the Canadian regulatory system that call into question the system's ability to protect human and environmental health.

Table 6 Endnotes

[1] Adapted from the Biotechnology Gateway, Industry Canada, http://strategis.ic.gc.ca/SSG/bo01376e.html and Environment Canada CEPA registry, http://www.ec.gc.ca/ceparegistry/regulations/FINAL-RoadMap_e.pdf

[2] Includes imports of plant material with novel traits (PNT) intended for direct use as food, non-livestock feed, or for processing into food or industrial products and not covered by either the *Seeds Act* or the *Feeds Act* and Regulations; Genetically modified microorganisms not covered by other legislation and regulations; Novel feeds for non-livestock animals (e.g. new substances in pet foods); New substances in fertilizers and novel supplements manufactured for export only; New substances used as intermediates to manufacture pest-control products; New substances in drugs (human and veterinary), human biologics, cosmetics, medical devices

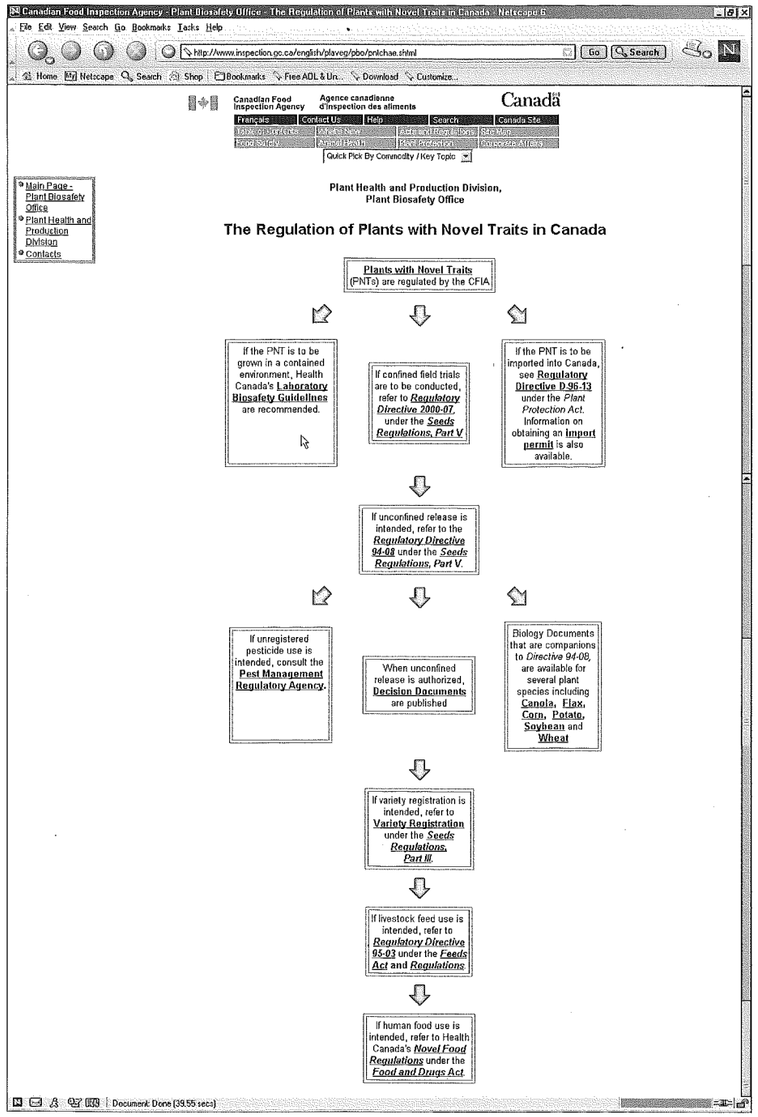
Table 6. An overview of the main federal laws and agencies currently involved in biotechnology regulation[1]

Biotechnology products/organisms	Relevant laws and regulations	Primary departments / agencies involved
Animals, animal pathogens, veterinary biologicals, animal products and by-products	• *Health of Animals Act* and regulations; regulation of GE animals still in development so covered by *Canadian Environmental Protection Act* (*CEPA*) and New Substances Notification Regulations	• Canadian Food Inspection Agency (CFIA); Agriculture and Agrifood Canada (AAFC); Health Canada; Environment Canada
Bioremediation, industrial enzymes and waste disposal	• *CEPA* and regulations • *Seeds Act* and regulations	• Environment Canada • CFIA
Chemical products	• *CEPA* and regulations	• Environment Canada; Health Canada
Consumer and health products	• *Hazardous Products Act* and controlled products regulations, cosmetics regulations • *Food and Drugs Act* and regulations, and medical devices regulations • Environmental assessments in development, so covered by *CEPA*	• Health Canada; Environment Canada
Energy	• *CEPA* and new substances notification regulations • Oil-and-gas legislation and regulations	• Environment Canada • Natural Resources Canada
Feeds and feed additives	• *Feeds Act* and regulations	• CFIA; AAFC
Fertilizers / supplements	• *Fertilizers Act* and regulations	• CFIA; AAFC
Fish	• *Feeds Act* and regulations • *Health of Animals Act* and regulations • *Fisheries Act*, general fish regulations and fish health protection regulations • *Pest Control Products Act* and regulations • Since fish regulations in development, covered by *CEPA* and new substances notification regulations	• CFIA • Department of Fisheries and Oceans • Health Canada • Environment Canada
Foods (including meat and fish) and food additives	• *Food and Drugs Act* and regulations, novel foods regulations; many regulations still in development, especially for animal and fish products	• Health Canada
Forestry	• *Seeds Act* and regulations • *Plant Protection Act* and regulations	• CFIA
Mining	• *CEPA* and new substances notification regulations • *Nuclear Energy Act* and uranium mines and mills regulations	• Environment Canada • Natural Resources Canada
Pest control products	• *Pest Control Products Act* and regulations	• Pest Management Regulatory Agency of Health Canada
Plant pests	• *Plant Protection Act* and regulations	• CFIA
Plants / seeds	• *Seeds Act* and regulations	• CFIA
Other applications not elsewhere covered[2]	• *CEPA* and regulations	• Environment Canada

(See page 32 for endnotes.)

Figure 2

How different crops and foods are evaluated under different acts, regulations & directives



Source: Canadian Food Inspection Agency's website at http://www.inspection.gc.ca/english/plaveg/pbo/pntchae.shtml

1. The absence of a legislative framework reduces public oversight of GE regulation; the absence of public oversight means that a full range of societal concerns about the technology are not part of the decision-making process.

2. The ideological, regulatory and scientific assumptions of the regulations, directives, protocols, guidelines and data requirements do not stand up to close scrutiny; this means that the underpinnings of the regulatory system do not accurately reflect how GE applications behave in the real world.

3. The quality of data and how regulators interpret them demonstrates a deep lack of understanding of health and ecology.

4. The culture and organization of the regulatory agencies reduce the efficiency of the review and assessment process.

5. The Canadian regulatory system does not comply with our international obligations and this has health, environmental and economic implications.

We briefly address each of these deficiencies using food and agricultural GE regulation as the case study, since this part of the regulatory system, although not yet complete, has been further developed than most other areas.

5.2.1 The absence of a legislative framework reduces public oversight of biotechnology regulation

The acts that guide biotechnology regulation were adopted in much earlier regulatory eras, long before the application of genetic engineering to plants, animals and foods was imagined. In fact, most of these statutes were written with the primary objective of preventing fraud[132], or evaluating agronomic, production or quality aspects of products. Evaluation of environmental or human health risks is not part of these acts and there is no clear legislative authority for the evaluation of GE crops or foods from an environmental or human health perspective[133]. As discussed later, this deficient legislative framework explains why much of the data submitted to regulators is primarily agricultural in nature, and not helpful for assessing environmental and health risks.

Since there is no legislation, elected officials have never had a significant debate on the subject[134]. Without parliamentary debate, public access to the decision-making process is curtailed. The absence of public discourse means that a narrower range of issues are applied. Public participation has been limited to consultations on specific components of the regulatory system. These consultations have been controversial because of the dominant position occupied by the GE industry. The rules of GE regulation have been developed within the federal civil service, relying particularly on rules set out by some other western countries[135]. These rules and their adequacy are discussed in the next section.

5.2.2 The ideological, regulatory and scientific assumptions of the regulations, directives, protocols, guidelines and data requirements do not stand up to close scrutiny

Since the legislative framework for genetically engineered organisms (GEOs) is not unified and provides little specific instructions to applicants or regulators, new regulations, directives and guidelines have been constructed. In Canada, these regulations, directives and guidelines for crops, foods and feed are designed around the concepts of familiarity and substantial equivalence. Both these concepts have been adapted to GEO environmental regulation, familiarity from the chemical industry and substantial equivalence from food-safety regulation.

If there is "knowledge of the characteristics of a plant species and experience with the use of that plant species in Canada"[136], and their characteristics do not differ from the parent, then the GEO is deemed "familiar". Regulators are confident that there will be no adverse effects specific to the GEO. If the characteristics are familiar, then existing legislative and regulatory frameworks can be used to assess them. Familiarity with the introduced trait, the environment, the crop plant and the interactions between them can all be used to justify a decision to permit widespread release of a GE crop[137].

This approach, however, denies the possibility that the process of inserting genes can change the behaviour of the GEO relative to its familiar conventional analog. Insertion techniques are sufficiently imprecise that the placement of the transgenes is haphazard, unpredictable, and frequently unrepeatable. Reliable targeting techniques are not yet available in recombinant DNA technology[138]. This imprecision leads to unstable genetic constructs within plants that

companies try to weed out. They are not always successful, leading to unpredictable alterations and potential risks from problematic plant behaviour[139]. Although federal government officials claim otherwise, Canada's system effectively does not require examination of such possibilities and it is only in the post-release period, as primarily university-based scientists examine GEOs, that such effects are being identified. The federal government's post-release monitoring capacity is very weak, something implicitly acknowledged in the government's response to recent criticisms of the regulatory process[140].

Used with familiarity is the concept of substantial equivalence. If the molecular, compositional and nutritional characteristics of both GEOs and their conventional counterparts are comparable, then the GEO will be considered "substantially equivalent"[141]. If deemed substantially equivalent by regulators, a GEO does not have to undergo safety and environmental testing beyond that used to determine whether substantial equivalence exists. Using information on conventional crops or foods establishes the baseline for comparison.

However, critics believe the relationship between genetics, chemical composition, and toxicological and ecological risks is largely unknown. The biochemical or toxicological effects of a GE food cannot be predicted from its chemical composition. Seemingly minor changes in foods can have significant nutritional implications. If relationships are largely unknown, critics argue, how can similarity in composition be a predictor of equivalent ecological or toxicological behaviour as regulators presume?[142].

Working together, these regulatory concepts assume that single-gene changes resulting from genetic engineering result in well-characterized responses. In fact, say critics, single genes can affect many traits and produced unexpected expressions[143]. If the responses are often unpredictable, then substantial equivalence has no merit as a trigger for environmental and human health assessments. The Expert Panel of the Royal Society of Canada was particularly critical of the use of substantial equivalence as a decision threshold – the determination of whether a full risk assessment is required – and proposed that it be abandoned as a determination approach[144]. Although regulatory theory suggests otherwise, these concepts of familiarity and substantial equivalence are used in Canada as substitutes for environmental risk assessment[145]. The federal government agrees these concepts should not be so used but will not acknowledge that it currently does so, and consequently has no plans to modify this approach to regulation[146].

Critics believe that a regulatory system operating in this way is about limiting the scope of environmental and human health assessment in order to facilitate commercialization of GEOs[147].

A second important area of assumption is limiting assessment to the direct environmental and health risks of GEOs; assessments of the broader long-term social, economic, and ethical implications of these products are not required. The regulatory system determines whether a product is effective, but it does not evaluate benefits in any broader sense. For example, the system evaluates whether a variety expresses Bt toxin as claimed, but not whether broad social benefits result from the use of Bt crops. The government view is captured in this quote:

> No socio-economic assessments [are conducted] .... whatever assessments are conducted are strictly science-based. In terms of potential management issues arising from the environmental release of GMOs, the marketplace does its own cost/benefit analysis. Policy makers at AAFC [Agriculture and Agri-Food Canada] deal with rural issues, not with cost/benefit analysis issues.[148]

In fact, government officials have actively discouraged socio-economic criteria, describing them as a slippery slope leading to religious and environmental considerations determining GE crop and food approvals[149]. Since markets are traditionally incapable of determining broad benefits to society[150] and government will not do it, there is no way of assessing whether these products actually provide any.

There is, however, precedent in the Canadian agricultural regulatory system for socio-economic criteria. The Pest Management Regulatory Agency requires that pesticides be evaluated for their "economic value"[151]. The provision is not well applied by the agency but it exists, and it's reasonable to argue that if pesticide companies must demonstrate prior to approval that their product has value, then why should not GE crop varieties be subject to the same test?

5.2.3 The quality of data and how regulators interpret them demonstrates both a deep lack of understanding of health and ecology, and unsound scientific practice

It is frequently claimed that Canada's regulatory system relies on sound science. Government does not generate its own data, so application assessments are based on its evaluation of industry data and the international scientific literature. The most widely accepted measure of scientific soundness is review by peers, but industry applications are not reviewed publicly and it is only through Access to Information requests that some of the applications have become public. As they become available, a disturbing pattern is emerging. The data submitted by applicants are of such poor quality that they would not likely pass a peer review. Regulators accept these data as sound and as demonstrating there are no environmental risks.

One industry application that has been thoroughly analyzed is a Roundup Ready® canola (GT73) developed by Monsanto[152]. The regulators determined substantial equivalence based on the company's submitted data, so no full safety assessment was required. However, there are major deficiencies in the application, so much so that the analysts[153] doubt the usefulness of the data for determining risk. Oddly, the statistical treatment of the data by Monsanto appears not to meet the standard imposed by CFIA in its 1996 revisions to field trial guidelines – that the designs be sufficiently statistically valid to be acceptable for inclusion in peer-reviewed journals.

Some examples of the problems:

▽ many of the tests were poorly performed, with a lack of duplicate measurements, small sample sizes, uneven comparative scales, inappropriate data pooling, comparison of the parent with varieties other than that subject to the application, a lack of statistical consistency, indiscriminate use of data from trials to support the applicant's claim of substantial equivalence, and conclusions that are not supported by the actual data;

▽ some studies contained only one year of data, which is far too limited;

▽ methodologically unsound field studies were performed, and most of them are agronomic studies not ecological ones;

▽ insufficient scope in the studies to adequately assess environmental safety – many of the studies, particular those looking at effects on soil, assume that a limited number of tests can be taken as examples of a full range of environmental phenomena. This is a critical flaw because independent scientists have already demonstrated that GE crops can have negative effects on soil organisms in a variety of unpredictable ways[154];

▽ studies of such limited surface area that they have no hope of predicting how the GE crop will behave once planted on millions of acres;

▽ failure to adequately explain variability in the results when in fact the variability could result from the insertion of the gene expressing the herbicide tolerant trait; strong tendency to treat variability as natural and to ascribe unusual results to "outlier effects".

Several other studies have identified similar problems with the quality of environmental data – and the conclusions drawn from them – submitted by the industry to U.S. and European Union regulators[155].

Similar problems appear to exist with the quality of data submitted by industry to governments for food-safety assessments[156]:

▽ Governments have minimal requirements of industry to provide data on toxicity. Of the 27 food-safety assessment decisions available (as of 2000) on Health Canada's website, 17 submissions did not present any evidence of laboratory or feeding trial measurements of toxicity[157]. The Royal Society of Canada concluded that regulatory requirements for toxicological assessment appear to be *ad hoc*, and that there did not appear to be any validated study protocols available to assess GE foods in their entirety[158]. This problem is endemic within GE food assessment as very few peer-reviewed feeding trials have been published[159].

▽ Allergenicity testing is undertaken mostly by comparison to known allergens. While this approach may be reasonable for known allergens, it is thought by many to be wholly inadequate for assessing products with no current history of allergenicity[160].

▽ The data sets of industry applications are very inconsistent. Doses, durations and other aspects of experimental design appear to be at the discretion of the applicant, not determined by the regulatory protocols. This raises questions again about whether the data are of peer-review quality[161].

Given these problems with the data, the ability of regulators to carry out good risk assessments is in serious question.

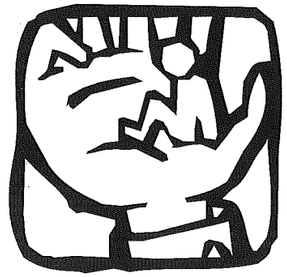
5.2.4 The culture and organization of the regulatory agencies reduces the efficiency of the review and assessment process

Although much of the information on the workings of the main departments and agencies responsible for GE food and agriculture regulation is confidential there are indications of the following dysfunctions that limit the capacity of these bodies to do effective review.

1. Regulatory bodies have been underfunded relative to the complexity of the task. There are now attempts to redress this deficiency as additional resources have recently been allocated to the CFIA and Health Canada to increase their capacity.

2. Staff morale is low. This problem has come to light in Health Canada because of a series of complaints launched by staff scientists against Health Canada management. As well, the CFIA Human Resource Strategy[162] suggests, based on the solutions it proposes, that there are significant challenges retaining qualified staff. Morale is frequently a problem in such circumstances.

3. Regulatory bodies may not have people on staff with ecological expertise. About 20 evaluators are the core evaluation staff (10 in Health Canada and 10 in CFIA) and another 20 or so scientists within the federal system participate in assessments on a periodic basis[163]. While considerable molecular and agronomic expertise is available, the ecological assessment side appears weak. These weaknesses are implicitly acknowledged in the Health Canada response to the Expert Panel of the Royal Society of Canada when the department talks about how it will enhance multidisciplinary and expert discussion of applications[164]. The interim report of the Canadian Biotechnology Advisory Committee (CBAC) also identifies this lack of expertise as a problem.



4. Regulators have no substantial rebuttals to criticisms of the regulatory system and appear disconnected from the critical literature[165]. Typically, officials reiterate the official position on how the system works, deny that familiarity and substantial equivalence act as decision thresholds, and highlight how the Canadian system is based on principles used in all OECD countries. Officials seem unaware of much of the literature calling into question the regulatory process. Critics are left wondering whether the absence of substantial rebuttal is a result of contempt for critical views, lack of knowledge, isolation from contrary views and critical data that sometimes occurs in institutional settings, incompetence, or deliberate efforts to protect the interests of those commercializing the technology. When regulators do require further study of a potential problem brought to light by independent researchers (for example whether Bt corn has negative impacts on beneficial organisms), they assign the research task to scientists who have already published studies favourable to the technology[166].

5. Regulatory agencies are evaluating scientific information provided by their colleagues in other departments, an apparent conflict of interest. For example, CFIA staff, when evaluating GE canola applications, have been reviewing work carried out by their colleagues in Agriculture and Agri-Food Canada for the company making the application. CFIA staff have expertise in molecular biology, but not necessarily in canola agronomy and ecological behaviour. For that expertise, they would normally rely upon the same groups of scientists who would be involved in carrying out the studies that were part of the application submitted by industry.

6. CFIA has a mandate to further market access of Canadian food products, an apparent conflict with regulatory functions. Is it feasible for truly objective assessments to be carried out in this situation? Both the Canadian Biotechnology Advisory Committee and the Royal Society of Canada have questioned these circumstances and make recommendations to separate more rigorously development, promotion and regulatory functions. The official government position is that such separation already exists, but a review of CFIA documents suggests that this is not yet true[167].

5.2.5 The Canadian regulatory system does not comply with our international obligations and this has health, environmental and economic implications

Canada is a signatory (April 19, 2001) to the Cartagena Protocol on Biosafety (or Biosafety Protocol or BP) and participates in the working groups designed to further its implementation[168]. Although the Biosafety Protocol is intended to govern transboundary movement of living modified organisms (LMOs), domestic GE regulatory systems are intertwined with the provisions of the protocol. If the principles underlying its domestic regulatory system are fundamentally at odds with the principles of the protocol it will be difficult, given global trade in food, for any nation to fully implement its commitments under the protocol, or avoid export losses. But this is the situation currently facing Canada. Several concepts that underlie the BP are at odds with the central tenets of Canada's system for regulating GEOs. These contradictions revolve around:

- the precautionary approach,
- the role of sound science in risk assessment, and
- identification of LMOs to be used directly for food, feed or processing.

Failure to comply with the first two principles will have significant consequences for export and for Canada's reputation as a participant in international agreements. Contradiction within the third issue area will have domestic political consequences. As the problems of unsound science have been discussed in section 5.2.3, we focus in this section on the absence of precaution in GE regulation and the failure to identify LMOs.

The absence of precaution

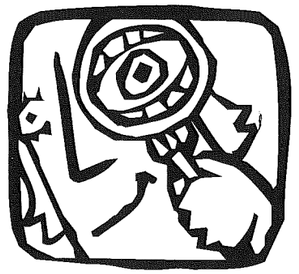
As discussed in section 5.2.1, Canada has no specific comprehensive legislation governing the regulation of GE products. Instead, pieces of legislation adopted before the development of genetic engineering are used, governing plants, foods, animals and drugs[169]. None of these acts have the precautionary approach as an objective. Only the *Canadian Environmental Protection Act* (*CEPA*) mentions the precautionary approach in its preamble. This mention does not, however, have weight in *CEPA* provisions and this legislation has only a limited impact on the current regulatory process (see section 5.2.1 for more).

The federal government released in late 2001 a discussion paper on the precautionary approach[170]. From the wording and analytical framework used in this document it appears that the federal government wants to restrict the application of the principle; it does not wish it to be an integral part of the scientific assessment and policy development process. This approach remains inconsistent with the approach taken in the Biosafety Protocol.

No mandatory provisions identifying LMOs for food, feed or processing

In the Canadian system, there are no regulated requirements at any level – farm, warehouse, broker (domestic or export), wholesale, processor (food or feed), retail – to identify LMOs destined directly for food, feed or processing, except consumer labelling when the LMO has not been deemed substantially equivalent (see below), and a health risk.

At a retail level, under the Guidelines for the Safety Assessment of Novel Foods[171], labels identifying GE foods are only required when the food has characteristics that generate a safety hazard or nutritional or compositional change relative to its conventional analog. But since all applications to date for unconfined release have been deemed substantially equivalent, there are no GE foods on the market that require consumer labelling. Voluntary positive or negative labelling is permitted as long as the claim is not misleading or deceptive and is factual. Very few companies have voluntarily used a positive label (i.e., identifying the food as coming from a GE crop or having ingredients derived from GE), despite poll results that consistently show a large number of Canadians want GE foods to be clearly labelled.



Regarding GE feeds[172], although there are extensive rules on labelling of feeds, there is no requirement that GE crops or microbes used in feeds be identified as derived from genetic engineering, for either domestic or imported feeds. All feeds on the market have been deemed substantially equivalent to their conventional analog. A few feed manufacturers have voluntarily identified GE feed ingredients, usually microbes.

Canada's domestic system is at odds with the intent of the Biosafety Protocol, which states that LMOs used directly for food, feed or processing have a "may contain" identification. The article also states that the details of this identification are to be worked out and since formal negotiations on it have not yet commenced, Canada's position is not clear. It is conceivable, given that the BP does not require consumer-level identification, but only identification for transboundary movement, that the federal government might only implement identification provisions at levels in the food and feed chain below the consumer level. Their contention has always been that consumers have no reason to be informed about LMOs in their diet unless there is something different about their safety or composition. However, to comply with the BP, industry will have to do the work of establishing segregation and traceability systems. They will put in place the basic systems they currently claim – when explaining their opposition to consumer-level information – are impossible to implement or overly costly. Refusing to then go the next step and provide consumer-level information would likely be a significant public relations problem, and leave Canada open to criticisms that it has more concern for trade than the information needs of its own citizens.

6 WHAT KIND OF REGULATORY SYSTEM DO WE NEED?

AS DISCUSSED THROUGHOUT THIS GUIDE, there are significant concerns about the risks that GE applications are posing and the ability of the regulatory system to identify them and then control commercialization of suspect applications. Although the evidence of problems cannot yet be described as iron-clad, there are very troubling signals emerging from the studies carried out by independent scientists, particularly those with expertise in ecology and evolutionary biology.

These disturbing signals have pushed many organizations to call for a thorough overhaul of GE regulatory systems, both domestically and internationally (see the appendix for an example of what is being called for by Fundacion Ambio for Costa Rica). CIELAP has been proposing alternative approaches to Canadian GE regulation since the mid-1980s. The organization has never called for a ban on GE technology, believing that some applications may have merit if properly assessed. CIELAP is suggesting, however, that a moratorium may be appropriate while a more rigorous regulatory system is put in place. The regulatory frameworks of other nations, particularly several European ones (see sidebar), and the recently adopted Biosafety Protocol identify other approaches to GE crop and food regulation and highlight some of the limitations of Canada's system. This section presents some broad options that are under discussion elsewhere and should be implemented in Canada. These proposals have overlapping components but are presented independently for sake of clarity.

Create a comprehensive legislative framework for GE crops and foods

Although Canada has no specific legislative framework for genetic engineering adopted by Parliament, other nations do. For example, Germany has the "Act on Genetic Engineering" (Gentechnikgesetz - GenTG), which came into force in 1990, and has since been amended. It contains regulations on safety measures to be taken for operations involving GMOs in closed systems (laboratory and production areas) as well as on field experiments with genetically modified organisms and on the placing on the market of products containing such organisms. In particular, it contains provisions on safety measures for genetic engineering installations and regulations on application and notification documents. Much of the work of safety assessment and monitoring is not carried out by government officials but by the Robert Koch Institute, the designated competent German authority. Market releases are not governed by the *Act on Genetic Engineering* but rather by the European Union according to the provisions of Directive 90/220 and more recently enacted Directives. The existence of federal legislation has allowed the German public to participate in policy development.

European Union Directives

In Europe there are a number of directives which govern GE foods. Fresh GE plant foods and other GE plant foods that contain transgenic DNA and its gene products are not considered "substantially equivalent" to a conventional food. Therefore two types of permission have to be obtained: First, a permit for the cultivation and/or import of the crop (Directive 2001/18); second, an additional permit for its use as a "novel food". Medicinal claims for GE foods are not allowed (Directive 2001/13). Since April 2000, all GE food additives introduced to the market must be labelled as such. The EU's definition of a food additive is a substance that does not naturally occur in food (Directive 89/107).

The European Commission has proposed two new regulations that could be made law by 2003. One will specifically focus on GE foods, food ingredients and animal feed. Its scope will be broad encompassing the GE components of all other food items, including additives, flavourings, supplements and dietetic foods. The second proposed regulation describes a mandatory labelling and documentation system of any GE food throughout the food production chain.

To create a new legislative framework, Canadian parliamentarians should have a full-blown debate on how GE applications should be regulated. Similarly, there should be full parliamentary debate about patenting and GE applications. However, to inform that debate, broader public discussion is warranted. One way to generate discussion, used extensively in western Europe, is "consensus conferences". This approach was first adopted in the late 1980s by the Danish Board of Technology (DBT) to engage interested citizens in debates and discussion of technology assessments. The Dutch held a consensus conference on animal biotechnology in 1993 and the British on plant biotechnology in 1994. The process is unique in a number of ways. While the government makes provisions for the conference, it does not attempt to guide the process in any way. "Experts" would be chosen by participants and not government; the participants – who are lay members of the general public – would prepare questions for and consult with the experts and then prepare a report for government and the public.

In countries in western Europe where consensus conferences have been held, there have been a number of practical results: citizens were better informed; citizens expressed a higher degree of satisfaction with their government's policies regarding biotechnology; and elected officials found conference reports to be very helpful when formulating policy and regulations. Industry has also benefitted from early public involvement and have been able to incorporate public opinion earlier in the product development process. A consensus conference was held at the University of Calgary in 1999, from which a useful report was produced. Using a formal consensus conference procedure gives credibility to citizen's sensible questions and views and re-legitimizes the social and ethical debate around the technology being assessed. Apart from the one attempt at the University of Calgary, the Canadian government has not pursued the consensus conference idea[173].

Incorporate the precautionary principle into Canada's regulatory framework

The precautionary principle first emerged in Germany in the 1970s. "At the center of the precautionary principle is the concept of taking anticipatory action in the absence of complete proof of harm, particularly when there is scientific uncertainty about causal links[174].

Canada's current regulatory system is essentially antithetical to the precautionary principle. Although the precautionary principle is named in CEPA, it currently has no bearing on the design of the Canadian GE crop-and-food regulatory system. As discussed above, it is based on an approach to science and regulation that focuses on avoiding regulatory action until the scientific evidence of a problem is irrefutable. Instead, the

Table 7. Steps to implement the precautionary principle

Adapted from: Barrett, K and Raffensperger, C. (forthcoming). *From Principle to Action: Applying the precautionary principle to agricultural biotechnology*. International J. Biotechnology

1. Set clear goals for the food and agriculture system.
2. Do comparative assessments of different approaches to achieving those goals, and assess GE crops, animals and foods within that framework.
3. Where GE technology appears to have value, adopt transparent and open processes for evaluation and regulation.
4. Define the parameters of harm in the GE assessment process:

   a. To what extent does risk assessment address the following levels of potential impacts?

   - ❖ individuals
   - ❖ populations
   - ❖ ecosystems

   b. To what extent does current risk assessment deal with the extent of harm? The precautionary principle says that when the potential for harm is serious, preventive action must be taken. These are some of the kinds of harms that may result from GE introduction and would require preventive action:

   - ❖ The harm is not reversible – an irrevocable loss of ecosystem function or biodiversity. Note that if the harm is reversible, this doesn't provide automatic assurance that the harm is not significant.
   - ❖ The harm is widespread, extending beyond agricultural landscapes in which a product is applied.
   - ❖ The harm is cumulative.
   - ❖ The harm is involuntary – those exposed have little opportunity to mitigate or avoid being exposed.
   - ❖ The harm is unfairly distributed – certain organisms or people are more likely to suffer than others, and the benefits of the product's use are concentrated within a small group.
   - ❖ The harm is portentous – mitigating it will require additional commercialization of related products causing harm.
   - ❖ The harm is restrictive – use of the product causing harm forecloses other options that are less likely to generate harm.
   - ❖ The harm is avoidable using other approaches that are readily available.
5. Analyze uncertainty in the scientific data – use statistical methods to clarify what is uncertain and how much error and bias there is in the data.
6. Use the weight of evidence approach – do not rely on the science being absolutely definitive, instead look at how different lines of investigation lead to related conclusions.
7. Shift the burden of proof of the safety of GE products from the public sector to the companies that want to commercialize them.
8. Take precautionary action when many of the elements outlined here reveal there are significant reasons to be concerned.

regulatory system will have to develop different tools, especially the use of precautionary science. Such science is rarely practised in the Canadian food-and-agriculture system, but the basics of it are reasonably well understood[175].

Although critics of the precautionary principle claim it is too vague and cannot be implemented, it is already an operational part of the European GE regulatory framework, and is a major component of the Biosafety Protocol. Work continues on how to bring the precautionary principle to the level of detailed regulatory implementation. To that end, two long-time students of the principle have developed an eight-step process for its implementation (see Table 7). We elaborate on some of Canada's challenges and opportunities in implementing the precautionary principle in the rest of this section.

Setting goals for the food and agriculture system

Canada would have to develop a goals-based approach to food-and-agriculture development. Such an approach would result from a public discussion about the kind of food-and-agriculture system Canada wishes to have, with specific targets and resources dedicated to achieving them. Canada has never applied this approach to the entire food-and-agricultural system, only to certain economic components such as the growth in trade of Canadian commodities. Setting goals would place the role of genetic engineering – which is essentially a tool – in a broader context.

Performing comparative technology assessments

Regulators would carry out comparative technology assessments to identify which approaches to solving problems in agriculture are most likely to produce optimal societal benefits with minimal risks. Currently, the regulatory system has no capacity to do this. Such assessments have been carried out by independent researchers[176] so methodologies have been established.

In a comparative assessment, the product is compared to other products, practices or systems to determine whether:

1. it presents significantly less risk to human health, wildlife or the environment;
2. it is relatively effective, also taking into account the risk of acquired product resistance;
3. it has relative economic or practical benefits for the user;
4. it provides broad social benefits that are well distributed.

There are four main outcomes from a comparative analysis:

1. The product is found to be superior, and is approved.
2. The product is found to be at least as good as other options and is approved with no impacts on other registered products.
3. The product is found to be useful in certain circumstances, requiring some limitations on its use.
4. The product is found to be unacceptable because it does not add anything to the existing toolbox of options.

This kind of assessment is already part of the U.S. and European pesticide regulatory systems. In Europe, some of this thinking has been incorporated into GE regulatory decision making. Broader societal assessments of benefit have been used to keep GE products such as recombinant Bovine Growth Hormone off the market on the grounds that the restructuring that would occur in the European dairy sector would have adverse affects on farmers. The recently negotiated Biosafety Protocol permits countries to use as part of their process for reviewing trade in living GMOs, "socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities."

The need to revise assessment processes

Many critics call for an overhaul of the safety-testing process, much of it within a precautionary approach. For example, a team of Swiss scientists[177] has concluded that testing procedures should be expanded to include multitrophic interactions over more than one generation, with chronic and sublethal toxicology tests in addition to short-term, acute toxicity testing. Others have

laid out a full suite of risk-assessment parameters that should be fully examined before approvals for release are granted[178]. The Expert Panel of the Royal Society of Canada has called for major revisions to the allergenicity testing protocols and guidelines[179]. The Edmonds Institute has produced a two-volume biosafety assessment manual that elaborates on all the review and evaluation procedures to be followed if regulators are serious about integrating the precautionary principle into the safety evaluation of GE foods[180]. In their view, "a precautionary approach to the release of GEOs therefore requires shifting the burden of proof from those charged with post-release monitoring and management to those seeking approval for the release of new products. That is, the manufacturers and producers of GEOs intended for release must demonstrate that their products conform to the highest standards of human health and environmental safety." (xi)

Creating open and transparent processes

As described earlier, much of the scientific data submitted by industry would not likely pass a scientific peer review. Interestingly, one of the only GE food-related products to be denied approval to date was a growth hormone for dairy cows produced by modified microbes, recombinant Bovine Growth Hormone (rBGH). Only after significant public pressure was brought to bear did Health Canada agree to submit data and studies on the application to expert panels. These panels carried out some of the functions of peer review and the one examining animal health concluded that the drug should not be approved because of negative health effects on cows[181]. This is the only application to date, however, that has received this kind of public scrutiny and all the other applications that have reached the final assessment stage have been approved.

The rBGH experience shows what can happen if a wider body of expertise is brought to bear on the decision-making process. The other possible model to be considered is the Proposed Regulatory Decision Document (PRDD) process used for pesticide registration. In this process, the Pest Management Regulatory Agency publishes a proposed decision and invites comment from the public for a 45-day period. On occasion, comments have resulted in additional requests for data from registrants. For this process to be useful however, it requires that more detailed data sets be made available to the public than are currently provided. This kind of process is used more widely in the U.S. and Australia[182].

Make labelling of GE foods mandatory

Given a new regulatory system based on the precautionary principle, a mandatory system of labelling foods derived from genetic engineering or containing constituents derived from GE foods should be established. It should be guided by the following concepts:

➤ A process-based system, i.e., labelling is required not only where GEOs are detectable, but also where they are derived through the process of genetic engineering.

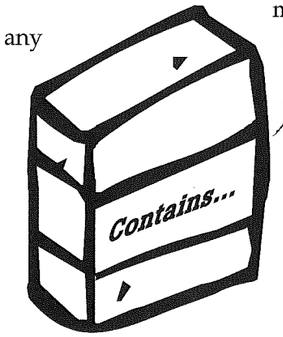
➤ Labelling is required for all crops and foods of rDNA technology (not as broad as the Novel Food or Plant with Novel Traits definition currently used).

➤ GE foods require a full audit trail and segregation.

➤ Positive claims are mandatory but provisions are made for voluntary negative claims.

➤ No deliberate inclusion of GEOs is the threshold for voluntary negative claims; however recognizing that accidental/adventitious contamination occurs, a level of inadvertent contamination between 0.1-1 percent as verified through the audit trail (requiring further study to determine precisely which level), would be an acceptable threshold.

➤ For mandatory positive claims, any deliberate inclusion of a GE material or material derived from a GE process would trigger the mandatory label provision; the mandatory provision would also be triggered with accidental/adventitious contamination above the determined threshold.



➤ The cost of positive labelling and segregation would be borne by the developer, farmer or manufacturer bringing the GE crop or food to market.

If adopted, this package of reforms would produce a much more robust regulatory system. The quality of experimental data would improve, and more information on potential benefits and environmental and human health risks would be generated. It is very likely that many current and developing applications would not pass the standard for utility and safety. For those that did, society could have a much greater assurance that the applications would not cause harm.

7 WHAT CAN YOU DO?

WHEN A SUBJECT IS AS COMPLEX AS GENETIC engineering, it's easy to feel that outcomes are determined by forces beyond our control. But as individuals, we actually have tremendous power to influence how genetic engineering is used. That power comes particularly to us when we eat, and since most of us eat every day, there are opportunities each day to send a message to governments and industry.

➤ Think of each mouthful you take and dollar you spend on food as a vote for what you want. Local retailers are highly dependent on volume business to make a profit. It doesn't take too many shoppers talking to a sales clerk or the local store manager about what they want and don't want, before someone's on the phone to head office trying to get something changed. Eaters have changed the landscape in Europe, where food companies have been falling over themselves to go GE-free and organic. The same can happen in Canada.

➤ Tell your grocery store that you won't buy food that is genetically engineered and ask them to require labelling from their suppliers. Call directly to companies; most provide a 1-800 customer service number on the back of food products. Ask if their products contain GEOs; put pressure on companies to manufacture GEO-free food or insist that they provide a label stating use of GEOs. Encourage companies that do not use GE crops to stand behind their policy; this may begin a trend for other food producers to follow.

➤ Try to buy organic food items when possible since the use of GEOs is not permitted in organic farming. The following two websites provide a list of GEO-free food products that can be found in your local supermarket or alternative health food stores:

- www.greenpeace.ca
- www.keepnatural.org

➤ Write letters to the editor with requests for more stories about genetically modified food and recent biotechnological developments.

➤ Write your federal MPs and ministers. Tell them you want stringent laws to regulate genetic engineering. Also, ask them to make sure that all genetically engineered food is so labelled. You can find your local MP's name and address at:

- www.parl.gc.ca/36/senmeb/house/MemberList.asp?Lang=E
- www.canoe.ca/CNEWSPolitics/mplist.html
- canada.gc.ca/directories/direct_e.html

➤ Write a letter to the Prime Minister (see sidebar for a sample letter).

➤ Write to the agencies listed below. Ask for information, input into the decisions to be made, and how the agencies will address your concerns.

Sample Letter to Jean Chrétien

(Don't forget, letters sent to the House of Commons do not require postage. This letter is available on the CIELAP website at www.cielap.org/whatsnew/bioletters.html)

The Right Honourable Jean Chrétien
Prime Minister
House of Commons
Ottawa, Ontario
K1A 0A6

Dear Mr. Chrétien:

As a Canadian taxpayer, I am writing to express concern about the regulation of genetic engineering and the labelling of genetically engineered foods.

While genetic engineering may offer some potential to benefit our lives, there are many social, ethical, economic and environmental issues that must first be considered. I am requesting, therefore, that the Canadian government hold a full parliamentary debate on genetic engineering and impose stringent new laws to regulate biotechnology in order that these issues are wisely dealt with.

I would also like to request that laws be established for the mandatory labelling of food that has been genetically engineered. As consumers, we should have the right to choose whether or not to purchase such products. This choice can only be made if genetically engineered foods are clearly labelled.

I look forward to your response.

Sincerely,

Copy this letter to the relevant government ministers and send to: House of Commons, Ottawa, Ont., K1A 0A6

➤ The Honourable David Anderson Minister of the Environment; anderd@parl.gc.ca

➤ The Honourable Allan Rock Minister of Industry; rocka@parl.gc.ca

➤ The Honourable Lyle Vanclief Minister of Agriculture; vancll@parl.gc.ca

➤ The Honorable Anne McLellan, Minister of Health; mclela@parl.gc.ca

Canadian Food Inspection Agency

Veterinary Biologicals: Executive Director, Animal Health and Production Division, Canadian Food Inspection Agency (CFIA), 59 Camelot Dr., Ottawa, Ontario, K1A 0Y9; telephone (613) 225-2342; fax (613) 228-6631. (Also for veterinary drugs, Chief, Veterinary Drugs Directorate, Health Canada, 11 Holland, Ottawa, Ontario, K1A 0K9.)

Livestock Feeds: Feed Section, Animal Health and Production Division, Canadian Food Inspection Agency (CFIA), 59 Camelot Dr., Ottawa, Ontario, K1A 0Y9.

Plants and Crops: Director, Plant Health and Production Division, Canadian Food Inspection Agency (CFIA), 59 Camelot Dr., Ottawa, Ontario, K1A 0Y9.

Health Canada

Drugs and Cosmetics: Chief, Drugs Regulatory Affairs Division, Drugs Directorate, Tunney's Pasture, Ottawa, Ontario, K1A 0K9.

Food and Food Additives: Director, Food Directorate, Health Canada, Tunney's Pasture, Ottawa, Ontario, K1A 0K9.

Medical Devices: Director, Medical Devices Bureau, Health Canada, Tunney's Pasture, Ottawa, Ontario, K1A 0K9.

Pest Control Products: Pesticide Directorate, Pest Management Regulatory Agency, 2720 Riverside Dr., Ottawa, Ontario, A.L. 6606D2, K1A 0K9.

Reproductive Technologies: Director, Biologics and Genetic Therapies Directorate, Health Canada, Tunney's Pasture, Ottawa, Ontario, K1A 0K9.

Environment Canada

All products not covered by other departments: Environment Canada, Biotechnology Section, 351 St. Joseph Boulevard, Hull, Quebec, K1A 0H3.

See the sidebar for a sample letter to the Department of Agriculture and Agri-Food Canada.

➤ Many websites provide petitions that support GM food labelling that you can fill in and send on-line. Or create your own petition by collecting signatures and sending it to the government ministers and your MP.

For additional information, visit the following websites:

- www.cielap.org
- www.agbios.com
- www.agcare.org
- www.biotech.ca
- www.inspection.ge.ca
- www.gmotesting.com
- www.fishtomato.com
- www.pwgsc.gc.ca/cgsb
- www.greenpeace.ca
- www.farmingsolutions.org

Finally, support the many organizations that are widening the discussion about genetic engineering.

CIELAP has been engaged in this debate since the mid-'80s. We are working nationally and internationally to ensure that as these technologies evolve, the public interest is central to the policy debate. Help us to stay involved to ensure that the ethical and societal, as well as the long-term ecological and health concerns, are addressed in the public interest. Cheques can be sent to CIELAP or contact us to find out how you can help us.

Sample letter to the Canadian Food Inspection Agency

(This letter is available on the CIELAP website at www.cielap.org/whatsnew/bioletters.html)

Director
Plant Biosafety Office
Canadian Food Inspection Agency
59 Camelot Dr.
Ottawa, Ontario
K1A 0Y9

To whom it may concern:

I am writing to express my concerns about genetically engineered organisms. I believe that they:

(Here are some concerns you could mention)
- are not properly assessed by your agency and other departments for human and environmental safety;
- are of minimal benefit to society;
- represent unknown risk to human health;
- represent unknown risks to the environment;
- represent an ethically inappropriate approach to food production;
- will not solve environment problems or hunger.

I ask that you: *(here are some possible things to request)*
- implement a mandatory labelling scheme;
- provide more supports to farmers adopting organic practices that do not permit the use of GMOs;
- assist Parliament in creating a new law to govern the use of genetic engineering in Canada;
- make industry applications publicly available for peer review and public comment.

Until my concerns are addressed I am: *(you could indicate which of the following actions you are taking)*
- not buying products containing soy, corn and canola unless I can be sure they are not derived from GMOs;
- telling my local store manager to stock more organic foods;
- enlisting my friends in these same activities.

I look forward to receiving your reply.

Sincerely,

8 GLOSSARY OF TERMS[1]

Acute toxicity: Usually a short-term but high level of exposure to a toxic agent.

Antibodies: Proteins produced in animals in response to the presence of alien proteins.

Anti-nutritional factors: Components of foods that reduce the value of nutrients or ability of the body to properly absorb them.

Bacterium: Any of a large group of single-celled, microscopic organisms with a very simple cell structure. Some manufacture their own food, some live as parasites on other organisms, and some live on decaying matter.

Biodegrade: To break down by the action of living organisms.

Biodiversity: The diversity or variety that exists within a natural environment, in terms of both the types of species present and the amount of variety within each species. Biodiversity depends on genetic diversity (see below).

Bioreactors: The use of living organisms, rather than industrial processes, as "vessels" for the creation of chemicals.

Bioremediation: To break down polluted areas using plants and bacteria.

Bt *(Bacillus thuringiensis)*: A bacterium that produces a protein called Bt toxin, a biological insecticide. When ingested, Bt toxin kills certain insect larvae, but is regarded as mostly harmless to humans, pets and most beneficial insects such as bees. Inserting a copy of the Bt gene into plants enables them to produce Bt toxin protein. Such plants can resist some insect pests.

Cell: The smallest structural unit of living organisms that is able to grow and reproduce independently.

Chromosomes: Thread-like components in the cell that contain DNA and proteins. Genes are carried on the chromosomes.

Chronic toxicity: Regular and usually low level exposure to a toxic agent over a long period of time.

Confined field trials: The release of a Plant with Novel Traits (PNT), for research purposes, under terms and conditions of confinement designed to minimize any impact the PNT may have on the environment. These terms and conditions include reproductive isolation, site monitoring, and post-harvest land-use restrictions.

Crop rotation: Changing the crop that appears in any given field over several years. Most good crop rotations have different crops in a given field for each of three to five years.

Deoxyribonucleic acid (DNA): The molecule that carries the genetic information for most living systems which, through many steps, can help to determine the structure, function and development of an organism. DNA can replicate itself and is passed form generation to generation.

DNA sequence: The order of the subunits in a DNA molecule. This order determines what function, if any, a segment of DNA will have.

Double helix: A term often used to describe the structure of double-stranded DNA, a structure that consists of two spiraling strands of DNA wound around one another.

[1] Adapted from Canadian government documents, the University of Wisconsin Biotechnology Center (http://www.agen.ufl.edu/~foodsaf/wi008.html), Glossary of Biotechnology Terms (http://biotechterms.org/sourcebook/index_kc.phtml), and Barrett, K. and Raffensperger, C. 1999. Precautionary science. In: C. Raffensperger and J. Tickner (eds.). Protecting Public Health and the Environment: implementing the precautionary principle. Island Press, Washington. Pp. 106-122.

Ecosystem: A term used to denote a natural area with respect to all that it contains (e.g., geographic features, plants, animals) and all the processes that occur within it (e.g., climate, nutrient transport, water movement, reproduction).

Familiarity: The knowledge of the characteristics of a plant species and experience with the use of that plant species.

Gene: The smallest portion of a chromosome that contains the hereditary information for the production of a protein.

Gene flow: The movement of genetic sequences from one organism to another, often, but not always, by sexual reproduction.

Gene splicing: Inserting new genetic information into a chromosome using recombinant DNA techniques.

Genetic diversity: The variety that is present within a given species with respect to the genetic makeup of the individual organisms. The more genetic differences that exist from organism to organism, the greater the genetic diversity of the species.

Genetic engineering: Using recombinant DNA (rDNA) techniques and related methods to move one or several genes from one organism to another, to rearrange one or several genes within a cell, or to alter gene-controlled processes. Transferring a DNA segment from one organism and inserting it into the DNA of another organism to modify, amplify, transform and express genetic information.

Genome: The genetic information contained in one complete set of chromosomes.

Hormone: A chemical that acts as a messenger within the body, relaying instructions to stop or start certain bodily activities. Hormones are synthesized in one type of cell and then released to direct the function of other cell types.

Hybrid: The offspring of genetically dissimilar parents, such as a new variety of plant or animal that results from the cross-breeding of two different existing varieties, or a cell formed by fusing two unlike cells as in the production of monoclonal antibodies.

Integrated pest management (IPM): The use of multiple tools and tactics to prevent pest attack, with synthetic chemicals only used as a last resort if more ecological approaches fail.

Invasiveness: The ability of an organism to move into a new habitat and dominate other organisms.

In vitro: Actions that occur within an artificial system (such as a lab test tube) as opposed to within a living organism.

Living modified organisms (LMOs): "Living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids.

Marker gene: A gene that is easy to find or observe attached to another that is hard to detect. Marker genes are often resistant to antibiotics or herbicides.

Mutagen: An agent that causes biological mutation. Examples include chemicals, radioactive elements and ultraviolet light. The process of using mutagens is known as mutagenesis.

Multitrophic interactions: In ecosystems, there are webs and layers of interactions between different organisms. What happens in one layer or web, may have an impact on activities in another web or layer.

Mutation: Sudden random change in genetic material that may cause that cell and all cells derived from it to look or behave differently.

Novel food: A food derived from a plant, animal or microorganism that has been genetically modified so that: (i) the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism, (ii) the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or (iii) one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism.

Pathogens: Disease-causing organisms.

Plant with Novel Traits (PNTs): A plant variety/genotype possessing characteristics that demonstrate neither familiarity nor substantial equivalence to those present in a distinct, stable population of a cultivated species and that have been intentionally selected, created or introduced into a population of that species through a specific genetic change.

Plasmid: A small circular form of DNA that carries certain genes and is capable of replicating independently of chromosomal ("regular") DNA. Plasmids, as well as some viruses, can be used to carry new DNA into a cell.

Precautionary principle: Asserts that parties should take measures to protect public health and the environment, even in the absence of clear scientific evidence of harm.

Pre-market assessments: The government's review of the safety of a GE food prior to its sale to consumers.

Progenitor cells: Progenitor cells are cells which, after being isolated, can reproduce themselves and be used as founders for subsequent cell culture.

Promoter: The promoter "promotes" the expression of a gene. The promoter controls where (e.g., which portion of a plant, which organ within an animal, etc.) and when (e.g., which stage in the lifetime of an organism) the gene is expressed.

Proteins: A large class of molecules of which there are many types. Proteins carry out a number of different functions essential for cell growth and reproduction.

recombinant DNA (rDNA): Technique of isolating DNA molecules and inserting them into the DNA of a cell. This technique includes taking copies of genes from one organism and inserting them in another organism. The two organisms can be totally unrelated.

Safety Assessment: In the Canadian government, it encompasses hazard identification, risk estimation, and risk evaluation and management.

Species: A level in the classification system for living creatures. A group of closely related, structurally similar individuals that are capable of successfully interbreeding.

Stem cell: A stem cell is a relatively undifferentiated (unspecialized) cell from an embryo, fetus or adult that has the capability to reproduce itself and can give rise to several distinct cell types.

Sublethal effects: Effects that damage the health of an organism but do not kill it.

Substantial Equivalence: Equivalence of a plant with a novel trait, within a particular plant species, in terms of its specific use and safety to the environment and human health, to those in that same species, that are in use and generally considered as safe in Canada, based on valid scientific rationale. The concept of substantial equivalence embodies the idea that existing organisms used as foods, or as a source of food, can be used as the basis for comparison when assessing the safety of human consumption of a food or food component that has been modified or is new.

Toxin: A substance, in some cases produced by disease-causing microorganisms, that is poisonous to other living creatures.

Transgene: A gene from one organism inserted into another, using rDNA technology.

Transgenic: Carrying one or more genes introduced using recombinant DNA technology.

Unstable genetic construct: An engineered DNA fragment (e.g. plasmid) that contains the DNA sequences integrated into a target plant's genome, which does not express itself in expected ways.

Variety: A level of plant classification below the species. In agriculture, cultivated varieties are known as cultivars.

Virus: Microscopic particle that contains genetic information but must invade a cell to reproduce.

Xenotransplantation: Transplanting organs from other creatures into humans.

APPENDIX – COSTA RICA'S MODEL LAW ON GENETIC ENGINEERING

This model law on genetic engineering is proposed by Fundacion Ambio in Costa Rica.

DECREE No.

THE PRESIDENT OF THE REPUBLIC, THE MINISTER OF HEALTH AND THE MINISTER OF THE ECONOMY, INDUSTRY AND COMMERCE

In use of the faculties conferred in article 140 section 3 and 18 of the Political Constitution; article 28, 2b of the General Public Administration Law, articles 206, 207, 210, 211 proceedings and agreements and 352 of the General Health Law (Law 5395); Promotion of Competition and Effective Defense of the Consumer Law (Law 7472); Industrial Standards Law (Law 1698); International Systems of Units and Measures Law (Law 5292); Organic Law of the Ministry of Industry, Economy and Commerce (Law 6054); Execution of the Agreements of the Uruguay Round Law (Law 7473); the Convention on Biological Diversity;

Considering:

(1) That the protection of human health and of the environment demands that attention be given to controlling the risks derived from the intentional release into the environment of genetically modified organisms (GMOs);

(2) That, in order to protect public health, it is necessary to guarantee that foods and food ingredients be subjected to an evaluation of security before becoming available on the national market; that in the case of foods or food ingredients substantially equivalent to existing foods or food ingredients, it is convenient to undergo a simplified procedure;

(3) That it must be considered that the introduction of any product that contains or is composed of GMOs and that is destined for intentional release be previously subjected to satisfactory tests in the research and development phase in the ecosystems that could be affected by their use;

(4) That it is possible that there are associated risks to the environment from new foods or food ingredients that contain or consist of genetically modified organisms;

(5) It is advisable that specific requirements for labeling be established; that these requirements must be precise orders to guarantee to the consumer the necessary information; it is advisable to inform determined groups of the population that are associated with well-established eating habits when there is a new food of materials not found in the existing equivalent food product, using a warning of an ethical nature for these groups of the population; that the foods and the food ingredients that contain genetically modified organisms that are available on the market must be safe to human health;

(6) That this security is guaranteed by a specific evaluation procedure established in the present Regulation; that, with respect to labeling, consumer information regarding the existence of an organism that has been genetically modified constitute an additional requirement applicable to those foods and food ingredients referred to in this Regulation;

(7) Considering that, with regard to the foods and food ingredients that are destined to go on the market for the final consumer and that can contain genetically modified products as well as conventional products, and without harm to the other labeling requirements established in the present Regulation, it will be considered, with exceptions, particularly with regard to bulk goods, that the consumer information about the possibility that the foods and food ingredients can contain genetically modified organisms comply with the requirements of article 11;

DECLARE the following

Regulation on the commercialization of foods and food ingredients consisting in, or products of, genetically modified organisms

Article 1. Scope of the standards

1. The present Regulation, conforming with the focus on precaution that figures in Principle 15 of the Rio Declaration on Environment and Development, has as an objective the regulation of the release onto the market of foods and food ingredients included in the following categories:

   a) Food and food ingredients and primary material that contain genetically modified organisms, or that consist of such organisms, except those foods and food ingredients obtained through traditional practices of reproduction and selection and which have a safe history of alimentary use;
   b) Foods and food ingredients produced from parts of genetically modified organisms but that do not contain them.

Article 2. Exclusions

1. The present Regulation will not apply to foods and food ingredients obtained through the following techniques:

   - In vitro fertilization;
   - Conjugation, transduction, transformation or any other natural process;
   - Polyploid induction (on the condition that a GMO is not used as a parent or receptor);
   - Mutagenesis;
   - Cellular fusion (including the fusion of the protoplast) or plant cells in which the resulting organisms can also be produced through traditional crop improvement methods.

1. Will also not apply to those food products that have been legally fabricated, imported and labeled before this present Regulation has taken effect. Will not apply to:

   a) Live modified organisms that are pharmaceutical products;
   b) Live modified organisms in transit;
   c) Live modified organisms destined for contained use;
   d) Live modified organisms that have been declared safe by the Conference of the Parties of the Cartagena Protocol on Biosafety.

1. In each case, it can be determined according to the procedure established in article 9 if a type of food or food ingredient is included in article 1.

Article 3. Necessity for Authorization

The commercialization of products that contain or are composed of GMOs will only be authorized when a notification of conformity with the contents of the present Regulation has been approved in writing and consequently the Ministry of Health has proceeded to register the food.

Article 4. Guarantees to the Consumer

1. The foods or food ingredients contemplated in the present Regulation must not:

   - Suppose a risk to the consumer;
   - Wrongly persuade the consumer;
   - Substitute for other foods and food ingredients whose replacement is such that normal consumption implies disadvantages for the consumer from the point of view of nutrition.

1. To put foods and food ingredients included within the jurisdiction of this present Regulation on the national market, the procedures established in articles 5,7,8,9 and 14 will apply, based on the criteria defined in section 1 of the present article and other pertinent factors mentioned in the above articles.

2. Not withstanding those foods and food ingredients contemplated in this present Regulation and derivatives of plant varieties subject to the ordinances of Title VIII of the Plant and Animal Sanitation Protection Law, the decision to authorise examined in article 7 of the present Regulation will be adopted after the food or food ingredient obtains a certificate of sanitation for release into the environment according to the procedures established in the above Law, and when the

evaluation principles established in the present Regulation are taken into account, as well as the criteria contemplated in section 1 of the present article, except the ordinances related to labeling of said food and food ingredients which will be established in conformity with article 14, according to the procedures established in article 9.

3. Section 2 will not apply to those foods and food ingredients examined in letter b) of section 2 of article 1 when the genetically modified organism is used in the fabrication of a food or food ingredient that has been put on the market in conformity with the present Regulation.

4. Not withstanding that of section 2, the procedure examined in article 6 will apply to those foods and food ingredients mentioned in letter b) of section 2 of article 1 that, based on available and generally recognised scientific data, are substantially equivalent to existing foods or food ingredients with regard to their composition, nutritional value, their metabolism, their intended use and their content of undesirable substances. As cases arise, it will be determined, according to the procedure established in article 9, if a type of food or food ingredient is included in the present section.

Article 5. Application and Information Required

1. The person responsible for putting the product on the national market, hereafter denominated the "applicant", will present a notification to the Ministry of Health.

2. Each new product, if they have different uses, must be notified separately even if they contain or are composed of the same GMO(s) o combinations of GMOs.

3. The application contemplated in section 1 of article 5 will contain, in addition to the specified requirements in Appendix I (sic). The applicant can also make reference to data and results from previous notifications presented by other applicants, provided that the latter had given their agreement in writing.

4. In the case of foods or food ingredients derived from varieties of plants subject to the ordinances of Title VIII of the Plant and Animal Sanitation Protection Law, the procedure that establishes this law in relation to importation, release and/or mobilisation must first be followed. Once these procedures are completed, a copy must be presented of the sanitation certificate for release into the environment together with an account of the release results with regard to any possible risk to human health and the environment.

5. In the case of food ingredients consisting of additives, the information required in Article 6 of Decree No. 26725-S, Regulation for the Registration and Commercialisation of Foods, must also be contributed.

6. Before the date that the present Regulation takes effect, the Ministry of Health will publish recommendations with respect to scientific aspects related to:

   - Information that will facilitate an application, as well as the presentation of the same;
   - Making the initial evaluation reports required in article 6.

Article 6

In the case of foods or food ingredients referred to in section 4 of article 4, the applicant will notify the Ministry of Health that the product is on the market. The pertinent elements that are mentioned in section 5 of article 4 would accompany the notification.

Article 7. Initial Evaluation and Decisions

1. Once the application is received, the Ministry of Health will carry out an initial evaluation. For this, the Ministry will solicit the collaboration of the Biosecurity Commission and any other organisation competent in the material.

2. Once the initial evaluation is concluded, the Ministry of Health will inform the applicant through an established procedure:

   a) That it authorizes the commercialization;
   b) That a complementary evaluation is necessary in conformity with article 8;
   c) That the proposed release does not comply with the present Regulation and, therefore, the commercialization is not authorized.

1. The authorization for commercialization will establish the scope and will determine precisely at least:

   - The conditions of use of the food or food ingredient;
   - The name of the food or food ingredient, as well as its description;
   - The specific requirements of the material for labeling examined in article 11.

1. The report of the initial evaluation and the decision will be developed in a period of three months from when the application was received. In the case of a complementary evaluation and the respective final decision, a period of six more months can be expected. These calculated time periods do not take into account the lapses in which the Ministry of Health has to wait for additional information that was required of the applicant.

Article 8. Complementary Evaluation and Authorization

When a complementary evaluation is necessary according to letter b of section 2 of article 7, a decision regarding authorization will be adopted as per the procedure established in article 9.

Article 9. Additional Evaluation

1. In case the procedure defined in the present article must be applied, the Ministry of Health will be assisted by the Biosecurity Commission.

2. The Commission will present to the Ministry a plan of additional evaluation measures that must be taken in a period of two months.

3. The Ministry will adopt these measures when they conform to the judgment of the Committee.

4. The applicant will have a period of two months to realize a complementary evaluation and to present the results.

5. The Ministry will have a period of two months from the delivery of the complete results to definitively decide upon the application for commercialization.

Article 10. On the Assignment and Use of a Registration Code

The foods that comply with all the requirements established in the present standards will be recorded and the Ministry of Health will assign them a registration number.

Article 11. On the Publication and Operation of Registration

The application for commercialization as well as the final decision that authorizes the application through registration must be published in a journal of national circulation at the cost of the interested party.

Article 12. On Operation of Registration

The registration will be in effect for five years, except cancellations anticipated by infractions or by new information that indicates that the food or ingredient constitutes a danger to public health.

Article 13. The Release from Storage of Foods

The authorization of the Ministry of Health to release foods from storage will be realized by checking the validity of the respective registration number.

Article 14. Labeling

In addition to the name of the product, name and address in the country of the manufacturer or distributor, the label will inform the final customer of the following characteristics or nutritional properties (together with an indication of the method through which the said characteristic or property has been obtained):

a) The composition and names of the GMOs that the food contains, indicating if it may have health consequences for certain members of the population;
b) Specificity of the product, exact conditions for its use, including (when relevant) the type of environment and geographic zones of the country for which the product is appropriate;
c) The nutritional value and the nutritional effects.

When a new food or food ingredient has been made it is no longer equivalent to an existing food or food ingredient.

1. For the purposes of this article, a new food or food ingredient will no longer be considered equivalent if a scientific evaluation based on an adequate analysis of existing data demonstrates that the characteristics studied are distinct from those present in a conventional food or food ingredient, keeping in mind the accepted limits of natural variation for those characteristics.

2. Lacking an existing equivalent food or food ingredient, appropriate arrangements will be adopted when necessary in order to guarantee that the consumer is informed in an adequate manner of the nature of the food or food ingredient.

3. In addition to the information acquired in section 1, it will be indicated where pertinent:

   a) The measures that must be taken in case of unintentional release or improper use;
   b) The specific instructions and recommendations for storage and manipulation.

1. The registration number.

Article 15. Labeling Exceptions

1. The foods and food ingredients will not be subject to the additional specific requirements in labeling material when:

   a) Neither in each of the food ingredients nor in those foods that contain a unique ingredient, there is the presence of DNA nor proteins derived from genetic modification. In order to facilitate the application of this ordinance, a list (not exhaustive) will be developed of food ingredients or foods containing a unique ingredient in which there are neither proteins nor DNA derived from genetic modification.
   b) The presence of a material originating from a genetically modified organism together with other commercial materials originating from genetically modified organisms in food ingredients or in those foods that contain a unique ingredient does not exceed the limit of 2% in each one of the food ingredients nor in the foods that contain a unique ingredient, provided that the presence is accidental.
   c) To establish that the presence of this material is accidental, the applicant must be able to provide convincing proof to the Ministry of Health that opportune measures were taken to avoid using genetically modified organisms.

Article 16. Change of Circumstances

1. When, as a consequence of new information or a new evaluation of existing information, there are well-founded motives to consider that the use of a food or a food product that complies with the contents in the present Regulation places human health or the environment in danger, the commercialization or use of the food or food ingredient in question can be limited temporarily or suspended within the territory.

2. If the applicant is in possession of new information regarding the risks of the product to human health, be it before or after the written authorization, the applicant must:

   a) Immediately revise the information presented in the initial application;
   b) Immediately inform the Ministry of Health;
   c) Immediately adopt the necessary measures to protect human health.

Article 17. Confidentiality of Information

1. The competent authorities will not communicate to third parties any confidential information notifying or exchanged in conformity with the present Regulation, and will protect the intellectual property rights related to data received.

2. The applicant can signal within the notifications conforming with the present Regulation which information would damage competitiveness if revealed and, therefore, must be considered confidential. In these cases, a verifiable justification must be offered.

3. The competent authority will decide, after previous consultation with the applicant, what information will remain secret and will inform the applicant of its decision.

4. In no case will the following information remain secret:

   - The description of the GMO or the GMOs, name and address of the applicant;
   - The methods and plans for controlling the GMO or GMOs and emergency procedures;
   - The evaluation of the foreseeable effects, in particular any pathogenic effect.

1. If, for whatever reason, the applicant withdraws the notification, the competent authority must respect the confidential nature of the information provided.

Article 18. Compliance

As regards compliance, the contents of articles 9, 10 and 12 of Decree No. 26725-S, Regulation for the Registration and Commercialization of Foods will be applied.

Article 19.

Will be in force from its publication.

Annex I: REQUIRED INFORMATION

a) The name and address of the applicant of a decision for national use.
b) The name and address of the authority in charge of the decision.
c) The name and identification of the live, modified organism.
d) The description of the modification of the gene, the technique employed and the resulting characteristics of the live, modified organism.
e) Any exclusive identification of the live, modified organism.
f) The taxonomy, the common name, the place of collection or acquisition and the characteristics of the receiving organism or organisms.
g) Centre of origin and centres of genetic diversity, if known, of the receiving organism and/or the parent organisms and a description of the habitat in which the organisms can persist or proliferate.
h) The taxonomy, the common name, the place of collection or acquisition and the characteristics of the donor organism or organisms that are related to biotechnological security.
i) The approved use of the live, modified organism.
j) A report on the risk evaluation that has been completed and any other available element to demonstrate that the food or food ingredient complies with the criteria established in section 1 of article 4, including the information obtained in the research and development phase surrounding the impact of release on human health and the environment.
k) A proposal on the presentation and labeling of the food or food ingredient conforming to the fixed requirements in article 14.
l) Suggested methods for the manipulation, storage, transport and safety, including the packaging, labeling, documentation, elimination and emergency procedures, as appropriate.
m) Certification from a professional faculty and authorization by the respective College Professional, that the product complies with the general physical, chemical, microbiological and macroscopic characteristics established by sanitation standards and the quality of innocuous material in foods.
n) A photocopied certificate of Sanitary Operation Permit.
o) In the case of imported products, a certificate from the Costa Rican consulate that indicates that the sale, use and consumption of the product is permitted in the country of origin. In addition, the applicant must include, even if not considered in the application for certification of the consulate, data and results of releases of the same GMO or same combinations of GMOs that the applicant has notified or is notifying, and/or that has effect or will have effect inside as well as outside the country.

ENDNOTES

[1] Certain terms like genetic engineering, genetic modification, novel foods and traits, and genetically engineered organisms (GEOs) are used regularly and somewhat interchangeably in this guide. See the glossary for more information on the meaning of these terms.

[2] See http://www.sciencenet.org.uk

[3] See the Medical Research Council website: http://www.mrc.ac.uk

[4] See the National Human Genome Research Institute website: http://www.nhgri.nih.gov/

[5] Kumpatia, S.P. et al. 1998. Genome intruder scanning and modulation systems and transgene silencing. Trends Plant Sci. 3(3):97-104.

[6] James, C. 2001. Global review of commercialized transgenic crops: 2000. ISAAA Briefs No. 23-2001.

[7] From the CFIA website: http://www.inspection.gc.ca/english/plaveg/pbo/triesse.shtml

[8] Canadian Forest Service. 1997. Genetically engineered baculoviruses for forest insect applications. Natural Resources Canada, Ottawa.

[9] Bourbonnais, R. et al. 1991. Biotechnology in the Pulp and Paper Industry. Report for Industry, Science and Technology Canada.

[10] Note that the use of the term in organic chemistry is different from its use in organic farming. Organic chemistry refers to the study of chemicals with a carbon molecule. The term organic used in organic farming comes from the term "organism" – managing the farm as an organism.

[11] For example see: Bennett, G.N., and K.Y. San. 2001. Microbial formation, biotechnological production and applications of 1,2-propanediol. Applied Microbiology and Biotechnology, 55(1):1-9; Gapes J.R. 2000. The economics of acetone-butanol fermentation: theoretical and market considerations. Journal of Molecular Microbiology and Biotechnology 2(1): 27-32.

[12] Wolff, A.M. et al. 1996. Laundry performance of subtilisin proteases. Advances in Experimental Medicine and Biology 379:113-120.

[13] Gubitz, G.M. and Cavacco-Paulo, A. 2001. Biotechnology in the textile industry - perspectives for the new millennium. Journal of Biotechnology 89(2-3):89-90.

[14] Yu, P.L. 1994. Production of chymosin for the dairy industry by recombinant DNA technology. Australasian Biotechnology 4(1):19-23.

[15] Applicants are required to notify Environment Canada of their intention to release GE microrganisms for bioremediation. At this point no such notifications have been received (Nigel Skipper, CEPA New Substances office, Environment Canada, personal communication, March 1, 2002).

[16] Canadian Biotechnology Advisory Committee. 2001. Biotechnology and Intellectual Property Patenting of Higher Life Forms and Related Issues (Interim report to the Government of Canada Biotechnology Ministerial Coordinating Committee), November 2001.

[17] Trends in Biotechnology 19(8):286.

[18] See: http://health.yahoo.com/health/pregfaq/how_do_pregnancy_tests_work_.html; also, Chard, T. 1992. Pregnancy tests: a review. Human Reproduction 7(5): 701-710.

[19] Humphreys, D.P. and Glover, D.J. 2001. Therapeutic antibody production technologies: molecules, applications, expression and purification. Current Opinion in Drug Discovery and Development 4(2): 172-185.

[20] For example, see: Evans C.H. et al. 2001. Gene therapy for rheumatoid arthritis. Expert Opinion on Biological Therapy 1(6):971-978; Cockett, M.I. 1999. Technology evaluation: CF therapy. Genzyme: Current Opinion in Molecular Therapeutics 1(2):279-285; Lynch C.M. 1999. Gene therapy for hemophilia. Current Opinion in Molecular Therapeutics 1(4):493-499.

[21] Cavazzana-Calvo, M. et al. 2001. Gene therapy of severe combined immunodeficiencies. The Journal of Gene Medicine 3(3):201-206.

[22] Stolberg, S.G. 1999. The biotech death of Jesse Gelsinger. N.Y. Times Magazine Nov 28: 136-140, 149-150.

[23] See: http://www.ppl-therapeutics.com/Welcome/Products/Xenotransplantation/xenotransplantation.html; http://www.agbiotechnet.com/topics/Database/newsarticle.asp?id=991&name; and Igaz, P. 2001. Recent strategies to overcome the hyperacute rejection in pig to human xenotransplantation. The Yale Journal of Biology and Medicine 74(5):329-340.

[24] For further information see the U.S. and Canadian government websites addressing science and policy with respect to stem-cell research: http://www.nih.gov/news/stemcell/; http://www.cihr.ca/governing_council/ad_hoc_working_groups/preamble_stem_cell_e.shtml

[25] Hudson, P.J. and Souraiu, C. 2001. Recombinant antibodies for cancer diagnosis and therapy. Expert Opinion on Biological Therapy 1(5):845-855.

[26] Wildner, O. 2001. Oncolytic viruses as therapeutic agents. Annals of Medicine 33(5):291-304.

[27] Carrick, J.W. and Thomas, D.W.. 2001. Producing proteins in transgenic plants and animals. Current Opinion in Biotechnology 4:411-418.

[28] For more on economic relations in the biotechnology sector, see the recent popular guide from the Polaris Institute. Sharratt, L. 2002. Regulating Genetic Engineering for Profit: a guide to corporate power and Canada's regulation of genetically engineered foods. Polaris Institute, Ottawa. February 2002.

[29] National Biotechnology Advisory Committee. 1998. Leading in the Next Millennium, 6th report. Industry Canada, Ottawa.

[30] ETC Group. 2001. Globalization, Inc.: Concentration in corporate power: the unmentioned agenda. ETC Group Communique #71. July/August.

[31] CIPO Manual of Patent Office Practice (March 1998), section 16.

[32] President and Fellows of Harvard College v. Canada (Commissioner of Patents); [2000] 4 F.C. 528

[33] *Patent Act* (R.S. 1985, c. P-4), online at http://laws.justice.gc.ca/en/P-4/index.html

[34] Canadian Biotechnology Advisory Committee. 2001. Biotechnology and Intellectual Property Patenting of Higher Life Forms and Related Issues. Interim report to the Government of Canada Biotechnology Ministerial Coordinating Committee. November 2001, p v.

[35] Monsanto Canada Inc. v. Schmeiser [2001] 3 F.C.D. 35.

[36] Canadian Biotechnology Advisory Committee. 2001. Biotechnology and Intellectual Property Patenting of Higher Life Forms and Related Issues. Interim report to the Government of Canada Biotechnology Ministerial Coordinating Committee. November 2001, p v, *supra* note 4. Harvard College v. Canada.

[37] National Biotechnology Advisory Committee. 1998. Leading in the Next Millennium, 6th report. Industry Canada, Ottawa.

[38] See Schrecker, T. et al. 1997. Ethical Issues Associated with the Patenting of Higher Life Forms. Study for Industry Canada, http://www.ic.gc.ca

[39] See generally: http://dailynews.yahoo.com/fc/World/Africa_AIDS_Epidemic/

[40] By some estimates 25 percent of U.S. and U.K. pharmaceuticals contain active molecules derived from flowering plants. See, Farnsworth, N.R., 1984. The role of medicinal plants in drug development. In: P. S. Krogsgaard-Larsen et al. (Eds.). Natural products and drug development. Baillière, Tindall and Cox, London. Pp. 8-98.

[41] For a somewhat novel corporate take on this see http://www.shamanbotanicals.com and http://www.netsci.org/Science/Special/feature11.html. Shaman Pharmaceuticals, a start-up U.S. company overtly relying on indigenous knowledge, discusses its practices and some compensation mechanisms.

[42] Mendelson, J. and Kimbrell, A.C. 2001. Brief Amici Curiae of American Corn Growers Association and National Farmers Union; May 4, 2001. (Brief for U.S. Supreme Court hearing of J.E.M. Ag Supply Inc. and Others v. Pioneer HiBred International Ltd.)

[43] *Plant Breeder's Rights Act*; http://laws.justice.gc.ca/en/P-14.6/80544.html

[44] For further information and discussion see the ETC Group website: http://www.etcgroup.org

[45] New Enclosures: Alternative Mechanisms to Enhance Corporate Monopoly and Bioserfdom in the 21st Century ETC group Communique, November/December 2001.

[46] Proctor's Gamble: Yellow Bean Patent Owner Sues 16 Farmers and Processors in U.S. ETCgroup News Release, 17 December 2001.

[47] See generally: http://www.nafta-sec-alena.org/english/nafta/toc.htm

[48] See generally: http://www.wto.org

[49] See: http://www.wipo.int

[50] See: http://www.upov.int

[51] See: http://www.biodiv.org

[52] See: http://www.fao.org/ag/cgrfa/default.htm

[53] In addition to a conference on GE regulation held in 1985, CIELAP has produced a number of reports and briefs, including, Comments to Agriculture and Agri-Food Canada Regarding the Environmental Assessment of Genetically Engineered Plants. Brief 1994-6; Bjorkquist, S. and Winfield, M. 1999. The Regulation of Agricultural Biotechnology in Canada. Canadian Institute for Environmental Law and Policy, Toronto. MacRae, R. 2001. Mixed Messages. CIELAP, Toronto.

[54] For evidence of effects of the gene itself or the gene insertion process, see Elmore, R.W. 2001. Glyphosate-resistant soybean cultivar yields compared with sister lines. Agronomy Journal. 93:408-412. For an interpretation of data from many sources and the possible effects of Roundup® itself, see Benbrook, C. 2001. Troubled Times Amid Commercial Success for Roundup Ready Soybeans: Glyphosate Efficacy is Slipping and Unstable Transgene Expression Erodes Plant Defenses and Yields Northwest Science and Environmental Policy Center, Sandpoint Idaho. May 3, 2001.

[55] Klotz-Ingram, C. et al. 1999. Farm level production effects related to the adoption of genetically modified cotton for pest management. AgBioForum 2(1):24-32. Available at: http://www.agbioforum.org/archives.htm

[56] AAFC. 2000. Benefits of HT canola systems vary, system shows. Lethbridge Research Centre Report. Jan. 13, 2000. Available at: http://res2.agr.ca/lethbridge/rep0113.htm

[57] As reported by growers in a survey conducted for the Canola Council. Serecon Management Consulting Inc. and Koch Paul Associates. 2001. An Agronomic and Economic Assessment of Transgenic Canola. Prepared for the Canola Council of Canada. January 2001.

[58] European corn borer, or ECB, is one of the most common corn pests in North America. The worm bores into the ear of the corn, sometimes reducing yield, other times, causing consumers anxiety if they find a worm in the corn.

[59] Dr. John Larsen, CFIA, personal communication, March 13, 2000.

[60] Gray, M. 2000. Prescriptive Use of Transgenic Hybrids for Corn Rootworms: an ominous cloud on the horizon? Crop Protection Technology Conference, University of Illinois, Champaign-Urbana. January 5-6, 2000 . Available at: http://www.biotech-info.net/mgray.pdf

[61] For an overview of why this occurs, see Benbrook, C. 2001. Do GM crops mean less pesticide use? Pesticide Outlook Oct:204-207; World Wildlife Fund (WWF). 2000. Do Genetically Engineered Crops Reduce Pesticides? The Emerging Evidence Says Not Likely. WWF, Toronto.

[62] Benbrook, C. 2001. Do GM crops mean less pesticide use? Pesticide Outlook Oct:204-207.

[63] Benbrook, C. 2000. Comments submitted to Docket Number OPP-30487a: registration application for Cry3Bb transgenic corn modified to control the corn rootworm. Submitted to the Environmental Protection Agency March 20, 2000.

[64] Serecon Management Consulting Inc. and Koch Paul Associates. 2001. An Agronomic and Economic Assessment of Transgenic Canola. Prepared for the Canola Council of Canada. January.

[65] Benbrook, C. 2001. Troubled Times Amid Commercial Success for Roundup Ready Soybeans:Glyphosate Efficacy is Slipping and Unstable Transgene Expression Erodes Plant Defenses and Yields Northwest Science and Environmental Policy Center, Sandpoint Idaho. May 3, 2001.

[66] Furtan, H. and Holzman. J. 2001. Ch. 4. Agronomic costs and benefits of GMO crops: what do we know? In: Richard Gray et al. (ed). Transforming Agriculture: The Benefits and Costs of Genetically Modified Crops. Report Commissioned by the Canadian Biotechnology Advisory Council. http://www.cbac.gc.ca/documents/Richard_Gray_English.pdf

[67] See, for example, Duffy, M. 2001. Who benefits from biotechnology? American Seed Trade Association Meeting, Dec. 5-7, 2001. Chicago.

[68] Serecon Management Consulting Inc. and Koch Paul Associates. 2001. An Agronomic and Economic Assessment of Transgenic Canola. Prepared for the Canola Council of Canada. January.

[69] See, for example, Ewins, A. 2001. Study will help farmers with economics of GM production. Western Producer. January 18, 2001.

[70] Duffy, M. 2001. Who benefits from biotechnology? American Seed Trade Association Meeting, Dec. 5-7, 2001. Chicago.

[71] Duffy, M. 2001. Who benefits from biotechnology? American Seed Trade Association Meeting, Dec. 5-7, 2001. Chicago.

[72] Mayer, H., and Furtan, W. H. 1999. Economics of transgenic herbicide-tolerant canola: the case of Western Canada. Food Policy 24:431-442.

[73] Benbrook, C. 2001. Troubled Times Amid Commercial Success for Roundup Ready Soybeans:Glyphosate efficacy is slipping and unstable transgene expression erodes plant defenses and yields. Northwest Science and Environmental Policy Center, Sandpoint Idaho. May 3, 2001.

[74] For a discussion, see Tabashnik, B. 1997. Seeking the root of insect resistance to transgenic plants. Proc. Nat. Academy Sci. 94:3488-3490.

[75] Note that the toxin expressed in Bt crops is not the same as the toxin produced from naturally occurring Bt. The GE version, exists in a truncated and more active form, does not require the highly alkaline gut of susceptible insects for activation. This means that the GE version is much less selective, and can potentially have an impact on a wider range of non-target species. See Hilbeck, A. et al. 1998. Toxicity of Bacillus thuringiensis Cry1Ab Toxin to the predator Chrysoperla carnea (Neuroptera: Chrysopidae). Environmental Entomology 27:1255-1263.

[76] Gianessi, L. 1995. An Economic Profile of the U.S. Crop Protection Pesticide Industry. National Center for Food and Agricultural Policy, Washington, DC.

[77] Janet L. Anderson, Acting Director Biopesticide and Pollution Prevention Division, Decision Memorandum, Consideration of Section 3©)(7)(B) Conditional Amendment for Northrup King's Bt Corn Plant-pesticide, August 2, 1996 at 2.

[78] Dr. John Larsen, CFIA Plant Biotechnology Office, personal communication, March 13, 2000.

[79] Duffy, M. 2001. Who benefits from biotechnology? American Seed Trade Association Meeting, Dec. 5-7, 2001. Chicago; Fulton, M. And Giannaskis, K. 2001. Chapter 2: Biotechnology and industry concentration. In: Richard Gray et al. (ed). Transforming Agriculture: The Benefits and Costs of Genetically Modified Crops. Report Commissioned by the Canadian Biotechnology Advisory Council. http://www.cbac.gc.ca/documents/Richard_Gray_English.pdf

[80] There appears to be a shift in Canada towards growing concern about food safety and environmental risks. See Hobbs, J.E. 2001. Chapter 5: Consumer responses to food quality, food safety and health concerns. In: Richard Gray et al. (ed). Transforming Agriculture: The Benefits and Costs of Genetically Modified Crops. Report Commissioned by the Canadian Biotechnology Advisory Council. (http://www.cbac.gc.ca/documents/Richard_Gray_English.pdf)

[81] Global Crop Protection Federation. 1997. IPM: the way forward for the crop protection industry. Global Crop Protection Federation, Brussels.

[82] United Nations. 1998. World Population Projections to 2150. UN Population Division, New York; Homer-Dixon, T. 2002. Standing room only. Globe and Mail, March 9, 2002. A17.

[83] In the low projection, population peaks at around eight billion. The upper projection is the one biotechnology industry proponents focus on.

[84] See, for example, Pingali, P. 1994. Technological prospects for reversing the declining trend in Asia's rice productivity. In: J.R. Anderson (ed.). Agricultural Technology: policy issues for the international community. CAB International, London. Pp. 384-401.

[85] Oldman, L.R. et al. 1991. The extent of human-induced soil degradation. In: L.R. Oldman et al. (eds). World Map of the Status of Human Induced Soil Degradation. UNEP and Int. Soil Ref. and Info. Centre, Wageningen, Netherlands.

[86] Evans. 1990, cited in Pretty, J. 1995. Regenerative Agriculture. IIED, London.

[87] Science Council of Canada. 1986. A Growing Concern: soil degradation in Canada. Supply and Services, Ottawa.

[88] Hewitt, T.I. and Smith, K.R. 1995:3. Intensive Agriculture and Environmental Quality: examining the newest agricultural myth. Henry A. Wallace Institute for Alternative Agriculture, Washington.

[89] Rifkin, J. 1992. Beyond Beef: the rise and fall of the cattle culture. Dutton, New York.

[90] Toronto Food Policy Council (TFPC). 1997. If the health care system really believed you are what you eat: strategies to integrate our food and health systems. TFPC Discussion paper #3, Toronto; Toronto Food Policy Council and Toronto Department of Public Health. 1998. Cutting out the fat: food and agriculture policies, programs, regulations and pricing mechanisms that promote the production and distribution of fat in our food system. TFPC Discussion paper #6, Toronto.

[91] Pretty, J. et al. 2000. An assessment of the external costs of UK agriculture. Agricultural Systems 65:113-136.

[92] The problem arises from the use of so-called marker genes, genes that tell genetic engineers whether their efforts to introduce new a new trait has been successful. Antibiotic resistance genes are frequently used and there is concern that these genes can flow to bacteria. Since many of the resistance genes are for antibiotics used in human therapy, the fear is that human treatment may ultimately be compromised.

[93] Domingo, J.L. 2000. Health risks of GM foods: many opinions but few data. Science 288(June):1748-1749.

[94] Fares, N.H. and El-Sayed, A.K. 1998. Fine structural changes in the ileum of mice fed on endotoxin-treated potatoes and transgenic potatoes. Natural Toxins 6(6):219-233.

[95] Hansen, M. 2000. Comments on the human health and product characterization sections of EPA's *Bt* Plant-Pesticides Biopesticides Registration Action Document. Consumer Policy Institute/Consumers Union. Presented to the EPA Science Advisory Panel Arlington, VA. October 20, 2000.

[96] Vidal, J. 2000. Scientists question safety of GM maize risk test. The Guardian Nov. 4, 2000. http://www.guardian.co.uk/gmdebate/Story/0,2763,392703,00.html

[97] For a review of this with soybean data, see Benbrook, C. 2001. Troubled Times Amid Commercial Success for Roundup Ready Soybeans: Glyphosate efficacy is slipping and unstable transgene expression erodes plant defenses and yields. Northwest Science and Environmental Policy Center, Sandpoint Idaho. May 3, 2001.

[98] British Medical Association. 1999. The Impact of Genetic Modification on Agriculture, Food and Health: an interim statement. May 1999.

[99] OECD Council. 2000. GM Food Safety: facts, uncertainties and assessment. The OECD Edinburgh Conference on the Scientific and Health aspects of Genetically Modified Foods. Chairman's Report and Rapporteurs Summary. 28 Feb- 1 March, 2000.

[100] An Expert Panel Report on the Future of Food Biotechnology Prepared by the Royal Society of Canada at the request of Health Canada, Canadian Food Inspection Agency and Environment Canada. 2001. Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada. January 2001.

[101] Crawley, M.J. et al. 2001. GM plants make weedy weeds. Nature 409 (8 Feb. 2001):682-683.

[102] See, for example, Mikkelsen, T.R. et al., 1996. The risk of crop transgene spread. Nature 380:31; Stephenson, J.R. and Warnes, A. 1996. Release of genetically modified microorganisms into the environment. J. Chem. Tech. Biotech. 65:5-16; Ho, M.-W. et al. 1999. Cauliflower Mosaic Viral Promotor – A recipe for Disaster? Microbial Ecology in Health and Disease 11.

[103] Taken from Monsanto's submission to the Canadian government for unrestricted field release of Roundup Ready® canola.

[104] Jorgensen, R. and Andersen, B. 1995. Spontaneous hybridization between oilseed rape (*Brassica napus*) and weed *Brassica campestris*: A risk of growing genetically engineered modified oilseed rape. American Journal of Botany 81: 1620-1626; Mikkelsen, T.R. et al. 1996. The risk of crop transgene spread. Nature, 380: 31; Eber, G. et al. 1994. Spontaneous hybridization between a male-sterile oilseed rape and two weeds. Theor. App. Gene. 88:362-368; Damency. 1994. The impact of hybrids between genetically

modified crop plants and their related species: introgression and weediness. Mol. Ecol. 3:37-40; Lefol, E. et. al. 1996. Gene dispersal from transgenic crops: II. Hybridization between oilseed rape and the wild hoary mustard. Sexual plant reproduction 9(4):189-196.

[105] Environmental problems of pesticides are measured by a number of indices. For a review, see Levitan, L. 1997. An overview of pesticide impact assessment systems (a.k.a. Pesticide Risk Indicators) based on indexing or ranking pesticides by environmental impact. OECD Bacground Paper, Paris, France. Available at: http://www.pmac.net/lois.htm

[106] Crabb, Charlene. 1997. Sting in the tale for bees. New Scientist 14; Compeerapap, J. 1997. The Thai debate on biotechnology and regulations. Biology and Development Monitor, 32: 13-15. In: M. Hansen and J. Halloran. Jeopardizing the Future? Genetic Engineering, Food and the Environment. http://www.pmac.net/jeopardy.html; Hilbeck, A. et. al. 1998a. Effects of transgenic *Bacillus thuringiensis* corn-fed prey on mortality and development time of immature *Chrysoperla carnea* (Neuroptera: Chrysopidae). Environl. Entomol. 27(2): 480-487; Hilbeck, A. et. al. 1998b. Toxicity of *Bacillus thuringiensis* Cry1Ab Toxin to the Predator *Chrysoperla carnea* (Neuroptera: Chrysopidae). Environ. Entomol. 27(5): 1255-1263; Birch, A.N.E. et al. 1997. Interactions between plant-resistant genes, pest aphid populations and beneficial aphid predators. Scottish Crop Research Institute Annual Report, pp. 68-72; EPA MRID No. 434635; Dunfield, K.E. and Germida, J.J. 2001. Diversity of bacterial communities in the rhizosphere and root interior of field-grown genetically modified *Brassica napus*. FEMS Microbiology Ecology, Vol. 38 (1):1-9; Tapp, H. and Stotzky, G. 1998. Persistence of the Insecticidal Toxin from *Bacillus thuringiensis* Subsp. Kurstaki in Soil. Soil. Biol. Biochem. Vol. 30, no. 4, p. 471-476; Saxena, D. et al. 1999. Transgenic plants: Insecticidal toxin in root exudates from Bt corn. Nature 402:480; Losey, J.E. et al. 1999. Transgenic pollen harms monarch larvae. Nature 399, 214.

[107] Hilbeck, A. et al. 1998b. Toxicity of *Bacillus thuringiensis* Cry1Ab Toxin to the Predator *Chrysoperla carnea* (Neuroptera: Chrysopidae). Environ. Entomol. 27(5): 1255-1263 1998.

[108] Hilbeck, A. et al. 1998. Effects of transgenic *Bacillus thuringiensis* corn-fed prey on mortality and development time of immature *Chrysoperla carnea* (Neuroptera: Chrysopidae). Environl. Entomol. 27(2):480-487.

[109] Birch, A.N.E. et al. 1997. Interactions between plant resistance genes, pest aphid populations and beneficial aphid predators. Scottish Crop Research Institute Annual Report, pp. 68-72.

[110] These same GNA lectins are being used in GE experiments with grapes, canola, rice, sweet potato, sugar cane, sunflower, tobacco, walnuts and tomato.

[111] World Wildlife Fund. 1999. Beneficial Bugs at Risk From Pesticides. Toronto, WWF.

[112] Benbrook, C. 1999. Evidence of the magnitude and consequences of the Roundup Ready® yield drag from University-based varietal trials in 1998. AgBiotech InfoNet Technical Paper #1. July 13, 1999.

[113] Note that GE proponents claim that crop rotation no longer works. However, they are referring to very simplified corn-soybean rotations where the European corn borer has adapted to living with soybeans and then has higher populations in the corn crop that follows. Corn requires a minimum three-to-four year rotation if these kinds of pest pressures are to be avoided. There is ample evidence that such longer term rotations can also be economically viable (cf. Welsh, R. 1999. The Economics of Organic Grain and Soybean Production in the Midwestern United States. Henry A. Wallace Institute for Alternative Agriculture, Washington).

[114] See stories on this topic in numerous 2001 issues of the Manitoba Cooperator and Western Producer.

[115] See MacArthur, M. 2000. Triple-resistant canola weeds found in Alta. Western Producer. February 10, 2000.

[116] Ewin, A. 2001. Canola popping up where it's not wanted. The Western Producer July 12, 2001.

[117] Serecon Management Consulting Inc. and Koch Paul Associates. 2001. An Agronomic and Economic Assessment of Transgenic Canola. Prepared for the Canola Council of Canada. January.

[118] Furtan, H. and Holzman. J. 2001. Ch. 4. Agronomic costs and benefits of GMO crops: what do we know? In: Richard Gray et al. (ed). Transforming Agriculture: The Benefits and Costs of Genetically Modified Crops. Report Commissioned by the Canadian Biotechnology Advisory Council. http://www.cbac.gc.ca/documents/Richard_Gray_English.pdf

[119] They are a much bigger part of medical GE applications.

[120] Mepham, B. 2000. A framework for the ethical analysis of novel foods. J. Agricultural and Environmental Ethics 12:165-176.

[121] Silverman, 2000. International Approaches to Non-science Issues in Regulating the Products of Biotechnology. Prepared for the Canadian Biotechnology Advisory Committee, Ottawa.

[122] For example, Agriculture and Agrifood Canada scientists have played a large role in the development of GE canola and GE wheat. Natural Resources Canada scientists are playing a major role in the development of GE trees.

[123] Canadian Food Inspection Agency, http://www.inspection.gc.ca/english/ppc/biotech/gen/approvale.shtml

[124] *Canadian Environmental Protection Act* provisions have been changed in the latest revisions to the act, revisions that significantly reduce legislative capacity to examine risk. See, for elaboration, Bjorkquist, S. and Winfield, M. 1999. The Regulation of Agricultural Biotechnology in Canada. Canadian Institute for Environmental Law and Policy, Toronto. However, *CEPA* provisions are still sufficiently in force that a petition was filed May 9, 2000 by several environmental organizations with the Auditor General claiming that the federal government is violating *CEPA* (and other federal provisions) in the way in which it is regulating genetically engineered foods. The petition proposed a number of significant changes that must be made to the current system. Seven ministries responded without addressing any of the issues raised in a substantive way, and now the petitioners are examining ways to contest the adequacy of the responses. See http://www.cielap.org for details.

[125] The federal government is currently going through the formal process of listing exempted legislation (e.g., the *Feeds Act*, the *Fertilizers Act*, the *Health of Animals Act* and the *Seeds Act*) under schedule 4 of *CEPA* 1999 (where exempted legislation must be listed to prevent an environmental assessment of GE crops under *CEPA*).

[126] This is consistent with the Canadian history of GE development. Products have been commercialized since the early 1990s without the complete regulatory system in place. See, for an example, Abergel, E. 2000. Growing Uncertainty: the environmental risk assessment of genetically engineered herbicide tolerant canola in Canada. Ph.D. Dissertation. York University, Toronto.

[127] For more go the Health Canada web site on Assisted Human Reproduction, http://www.hc-sc.gc.ca/english/protection/biologics_genetics/reproduction/index.htm

[128] Draft amendments to Regulatory Directive 2000-07 Addressing Confined Research Trials of PNTs for Pharmaceutical Production have been proposed (http://www.inspection.gc.ca/english/plaveg/pbo/pbobbve.shtml). The finalized amendment is anticipated by March 2002. A new Regulatory Directive, incorporating these amendments and other general improvements will replace the existing Regulatory Directive 2000-07 by April 1, 2002.

[129] Environment Canada and Health Canada. 2001. Guidelines for the Notification and Testing of New Substances: Organisms. Pursuant to the New Substances Notification Regulations of the Canadian Environmental Protection Act, 1999. Government of Canada, December.

[130] Abergel, E. 2000. Growing Uncertainty: the environmental risk assessment of genetically engineered herbicide tolerant canola in Canada. Ph.D. Dissertation. York University, Toronto.

[131] The Canadian Regulatory Framework for Biotechnology (1993).

[132] Bjorkquist, S. and Winfield, M. 1999. The Regulation of Agricultural Biotechnology in Canada. Canadian Institute for Environmental Law and Policy, Toronto.

[133] Bjorkquist, S. and Winfield, M. 1999. The Regulation of Agricultural Biotechnology in Canada. Canadian Institute for Environmental Law and Policy, Toronto.

[134] The only exception to this was a private member's bill (C-287) sponsored by Liberal Charles Caccia on one aspect of regulation, mandatory labelling of GE foods. It was defeated on second reading in October 2001.

[135] Abergel, E. 2000. Growing Uncertainty: the environmental risk assessment of genetically engineered herbicide tolerant canola in Canada. Ph.D. Dissertation. York University, Toronto.

[136] Regulatory Directive Dir94-08: Assessment criteria for determining the environmental safety of plants with novel traits. December 16, 1994. http://www.cfia-acia.agr.ca/english/plaveg/pbo/dir9408e.shtml#A4

[137] Barrett, K. and Abergel, E. 2000. Breeding familiarity: environmental risk assessment for genetically engineered crops in Canada. Science and Public Policy 27:2-12.

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[139] Clark, E.A. 1999. The faulty assumptions of field crop genetic engineering. Presentation to "Is Your Food Safe?" sponsored by the Professional Institute of the Public Service of Canada. 7/8 May.

[140] See http://www.hc-sc.gc.ca/english/protection/royalsociety/index.htm

[141] Substantial equivalence is "the equivalence of a novel trait within a particular plant species, in terms of its specific use and safety to the environment and human health, to those in that same species, that are in use and generally considered as safe in Canada, based on valid scientific rationale." Regulatory Directive Dir94-08: Assessment criteria for determining the environmental safety of plants with novel traits. December 16, 1994. http://www.cfia-acia.agr.ca/english/plaveg/pbo/dir9408e.shtml#A4

[142] Millstone, E. et al. 1999. Beyond substantial equivalence. Nature 401:525-526.

[143] For a review, see Clark, E.A. and Lehman, H. 2001. Assessment of GM crops in commercial agriculture. J. Agricultural and Environmental Ethics 14:3-28.

[144] An Expert Panel Report on the Future of Food Biotechnology Prepared by the Royal Society of Canada at the request of Health Canada, Canadian Food Inspection Agency and Environment Canada. 2001. Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada. January.

[145] Barrett, K. and Abergel, E. 2000. Breeding familiarity: environmental risk assessment for genetically engineered crops in Canada. Science and Public Policy 27:2-12.

[146] The federal government's response to criticisms of substantial equivalence leveled by the a panel of the Royal Society of Canada has been to clarify its communications materials. For the government's response, see Action Plan of the Government of Canada in response to the Royal Society of Canada Expert Panel Report, Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada. Nov. 23, 2001. Available at: http://www.hc-sc.gc.ca/english/protection/royalsociety/index.htm

[147] Barrett, K. and Abergel, E. 2000. Breeding familiarity: environmental risk assessment for genetically engineered crops in Canada. Science and Public Policy 27:2-12.

[148] Industry Canada official, quoted in Abergel, E. 2000. Growing Uncertainty: the environmental risk assessment of genetically engineered herbicide tolerant canola in Canada. Ph.D. Dissertation. York University, Toronto.

[149] Rance, L. 2001. Farmers want protection from Roundup Ready® wheat. Manitoba Cooperator. March 1, 2001. P. 17.

[150] The basic reason why the market cannot determine societal value is that many societal values do not have a price and are not bought and sold in the market. So all these values are not part of the way markets behave.

[151] Agriculture and Agri-Food Canada (AAFC). 1993. Assessment of the Economic Benefits of Pesticides. Regulatory Directive 93-17. AAFC, Ottawa. Available on the website of the Pest Management Regulatory Agency. http://www.pmra-arla.gc.ca

[152] Barrett, K. 1999. Canadian Agricultural Biotechnology: risk assessment and the precautionary principle. Ph.D. Dissertation, Department of Botany, University of British Columbia; Abergel, E. 2000. Growing Uncertainty: the environmental risk assessment of genetically engineered herbicide tolerant canola in Canada. Ph.D. Dissertation. York University, Toronto.

[153] Barrett, K. 1999. Canadian Agricultural Biotechnology: risk assessment and the precautionary principle. Ph.D. Dissertation, Department of Botany, University of British Columbia.

[154] Hilbeck, A. et al. 2001. Bt Proteins in Soil: is enough known to assess the impacts of Bt plants on soil ecosystems? Report to Greenpeace International. EcoStrat, Zurich, Switzerland.

[155] Hilbeck, A. et al. 2000. Review of Non-Target Organisms and Bt Plants. Report to Greenpeace International, Amsterdam. EcoStrat GmbH (available at http://www.greenpeaceusa.org); National Research Council. 2000. Genetically Modified Pest-Protected Plants: science and regulation. National Academy Press, Washington, DC; Benbrook, C. 2000. Comments submitted to Docket Number OPP-30487a: registration application for Cry3Bb transgenic corn modifed to control the corn rootworm. Submitted to the Environmental Protection Agency March 20, 2000; Purrington, C.B. and Bergelson, J. 1995. Assessing weediness of transgenic crops: industry plays plant ecologist. Trends in Ecology and Evolution 10(8):340-342; Wrubel, R.P. et al. 1992. Field testing trangenic plants. BioScience 42:280-289.

[156] Not as much of the data used for food-safety assessments is currently publicly available, so criticisms are based more on international literature and decision documents posted on Health Canada's website.

[157] Clark, E.A. 2000. Food Safety of GM Crops in Canada: toxicity and allergenicity. Genetic Engineering Alert Canada. Available at: http://www.canadians.org. See also, Clark, E.A. and Lehman, H. 2001. Assessment of GM crops in commercial agriculture. J. Agricultural and Environmental Ethics 14:3-28.

[158] An Expert Panel Report on the Future of Food Biotechnology Prepared by the Royal Society of Canada at the request of Health Canada, Canadian Food Inspection Agency and Environment Canada. 2001. Elements of Precaution: recommendations for the regulation of food biotechnology in Canada. January 2001.

[159] Domingo, J.L. 2000. Health risks of GM foods: many opinions but few data. Science 288(June):1748-1749.

[160] An Expert Panel Report on the Future of Food Biotechnology Prepared by the Royal Society of Canada at the request of Health Canada, Canadian Food Inspection Agency and Environment Canada. 2001. Elements of Precaution: recommendations for the regulation of food biotechnology in Canada. January 2001.

[161] Clark, E.A. 2000. Food Safety of GM Crops in Canada: toxicity and allergenicity. Genetic Engineering Alert Canada. Available at: http://www.canadians.org

[162] CFIA. 2000. Investing in Our Most Important Resource: managing our people at CFIA ... a strategy 2000-2003.

[163] Doern, G.B. 2000. Inside the Canadian Biotechnology Regulatory System: a closer look. Prepared for the Canadian Biotechnology Advisory Council. Ottawa.

[164] Action Plan of the Government of Canada in response to the Royal Society of Canada Expert Panel Report Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada. Nov. 23, 2001. Available at: http://www.hc-sc.gc.ca/english/protection/royalsociety/index.htm

[165] This assessment is based on the written response to Dr. Ann Clark's critique of novel food assessment discussed above, departmental responses to an NGO petition to the Auditor General's Office (see http://www.cfia-acia.agr.ca/english/ppc/biotech/enviro/sierrae.shtml), AAFC official statements to the Standing Committee on Environment and Development in 1996, and public events at which NGOs and government officials have participated.

[166] The best example of this is the report commissioned to Dr. Mark Sears and colleagues of the University of Guelph for an assessment of the impacts of Bt corn on monarch butterflies. In drawing conclusions vindicating Bt corn, Sears et al. do not adequately account for the sub-acute negative effects present in their own data. See Sears, M.K. et al. 2001. Final Report of the Ecological Impact of Bt Corn Pollen on Monarch Butterflies in Ontario. http://www.inspection.gc.ca/english/plaveg/pbo/bt/btmone.shtml

[167] Prince, M. 2000. Regulators and Promoters of Genetically Modified Food in the Government of Canada: an organizational and policy analysis. Prepared for the Canadian Biotechnology Advisory Committee, Ottawa.

[168] As of the time of writing, there were 101 signatories to the Biosafety Protocol. Only three, however, have ratified and 50 signatories must ratify the protocol for it to come into effect. Canada has not yet ratified the protocol and is not likely to do so in the short term since, according to a federal government official, there are significant matters to be resolved regarding liability, the body that will ensure compliance, how to document transboundary movement, and mechanisms to help developing countries (personal communication, Desmond Mahon, Environment Canada, June, 2001).

[169] These pieces of legislation include the *Food and Drugs Act*, the *Feeds Act*, the *Fertilizers Act*, the *Seeds Act*, the *Plant Protection Act*, and the *Health of Animals Act*.

[170] Government of Canada. 2001. A Canadian Perspective on the Precautionary Approach/Principle: Discussion Document. Sept. 2001.

[171] The Guidelines are available on Health Canada's website, http://www.hc-sc.gc.ca/food-aliment/english/subjects/novel_foods_and_ingredient/novel_foods_and_ingredient. html. Novel foods are defined, by an October 1999 amendment to the Food and Drug Regulations (Schedule 948) that formalized health-safety assessments of GE foods, as:

"(a) a substance, including a microorganism, that does not have a history of safe use as a food;

(b) a food that has been manufactured, prepared, preserved or packaged by a process that
(i) has not been previously applied to that food, and
(ii) causes the food to undergo a major change; and

(c) a food that is derived from a plant, animal or microorganism that has been genetically modified such that
(i) the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism,
(ii) the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or
(iii) one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism."

The amendment can be accessed at the same URL.

[172] For a general overview of Canada's approach to GE feeds, see http://www.cfia-acia.agr.ca/english/anima/feebet/bfeebete.shtml

[173] Instead it has established the Canadian Biotechnology Advisory Committee to "engage the Canadian public in a conversation" on biotechnology. What CBAC produces, however, does not substitute for a fuller public discussion and so will not provide advice to the Canadian government that satisfies the requirement for citizen participation in policy development.

[174] Tickner, J. 1997. Precautionary principle. The Networker: the newsletter of the Science and Environmental Health Network 2(4).

[175] MacRae, R.J. et al., 1989. Agricultural science and sustainable agriculture: a review of the main scientific barriers to sustainable food production and potential solutions. Biological Agriculture and Horticulture 6:173-219; Barrett, K. and Raffensperger, C. 1999. Precautionary science. In: C. Raffensperger and J. Tickner (eds.). Protecting Public Health and the Environment: implementing the precautionary principle. Island Press, Washington. Pp. 106-122.

[176] A pertinent GE example is the comparison of rBGH and rotational pasture management as different approaches to improving milk yields. See Liebhardt, W.C. (ed.). 1993. The Dairy Debate: consequences of Bovine Growth Hormone and rotational grazing technologies. University of California SAREP, Davis, Ca.

[177] Hilbeck, A. et al. 2000. Review of Non-Target Organisms and Bt Plants. Report to Greenpeace International, Amsterdam. EcoStrat GmbH (available at http://www.greenpeaceusa.org).

[178] Clark, E.A. 2000. Comments to the Senate Committee on Energy, The Enyironment and Natural Resources Regarding the Canadian Food Inspection Agency (CFIA). May 9, 2000. Available at: http://www.plant.uoguelph.ca/faculty/eclark/Cfia.htm

[179] An Expert Panel Report on the Future of Food Biotechnology Prepared by the Royal Society of Canada at the request of Health Canada, Canadian Food Inspection Agency and Environment Canada. 2001. Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada. January 2001.

[180] The Edmonds Institute. 1999. Manual for Assessing Ecological and Human Health Effects of Genetically Engineered Organisms: Volumes I and II. The Edmonds Institute, Edmonds, Washington.

[181] Report of the Canadian Veterinary Association Expert Panel on rbST. Submitted to Health Canada. November, 1998. http://www.hc-sc.gc.ca/english/diseases/rbst/animals/index.htm

[182] MacKenzie, D.J. 2000. Analysis of relevant Canadian legislation. Prepared for the Canadian Biotechnology Advisory Committee, Ottawa.

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