

Regulating Genetic Engineering... for Profit

**A guide to corporate power
and Canada's regulation of
genetically engineered foods**

A Polaris Institute Report
Prepared by **Lucy Sharratt**

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Purpose of this booklet

This booklet describes the Canadian regulatory system for genetically engineered crops and argues that the system is designed to quickly approve new products for sale, not to assess risks, and that this is a direct result of a powerful partnership between the Canadian Government and the biotechnology industry.

- 1) The booklet is an overview of how the Canadian government approves genetically engineered foods.
- 2) It is also an introduction to the biotechnology corporations that have the most power in this system.

This booklet is designed as a resource for concerned and active citizens who are engaged in campaigns against genetic engineering or who want to take action. The booklet identifies problems with the regulatory system and points towards opportunities for action, potential corporate targets and strategies.

Outline

Part 1 introduces the genetically engineered crops that are approved by the Canadian government - and the corporations that own them. It introduces the politics of genetic engineering including the conflict over definitions and wording, as well as the government's financial investments in biotechnology and state support for the industry. It also discusses how the government is working with industry to promote a positive image of government regulation as a part of a public relations strategy to promote genetic engineering.

Part 2 goes inside the regulatory system to describe which departments are responsible for decision-making and how they make their decisions to approve genetically engineered crops and foods.

Part 3 outlines different ways that the system is undemocratic and suggests strategies for taking back public control over government decision-making.

At the end of the booklet there are lists of books, websites and action group contacts.

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Introduction

“The risks in biotechnology are undeniable, and they are from the unknowable in science and commerce. It is prudent to recognize and address those risks, not compound them by overly optimistic or foolhardy behaviour.”

- FROM THE EDITORS OF NATURE BIOTECHNOLOGY, OCTOBER 2000 QUOTED BY THE ROYAL SOCIETY OF CANADA’S EXPERT PANEL ON THE FUTURE OF FOOD BIOTECHNOLOGY, FEBRUARY 2001.

This is how the Royal Society of Canada’s Expert Panel on the Future of Food Biotechnology introduced their report that criticizes the regulation of genetic engineering in Canada. The reference to “overly optimistic or foolhardy behaviour” warns us about the reckless way that the Canadian government regulates genetically engineered foods.

The Royal Society Panel released their report in February 2001 and made 53 recommendations calling for an overhaul of our regulatory system (See www.rsc.ca)¹. By this time over 40 genetically engineered foods had been approved by Canadian regulatory agencies. Some of these are on our grocery store shelves now, and have been for a number of years.

The first genetically engineered crops (corn and canola) were approved for growing in 1995, introducing genetically engineered organisms into our environment, food system and society – without public knowledge or democratic discussion.

The major corporations that are developing genetically engineered crops have also had a heavy hand in creating regulations. They are determined to have their products approved for market and to have us buy them and this is the driving force behind government regulation.

“The biotech race can be won- and I’m confident it will be- because it must be...Biotechnology is the background upon which all future technology battles will be fought... This time we must succeed. We must not let our lead slip away because of bad public policy.”

- FORMER CEO OF MONSANTO COMPANY, RICHARD MAHONEY,
ADDRESSING AN ANNUAL AWARDS DINNER AT YORK UNIVERSITY, 1993.

Summary

The regulatory system is the system by which our government reviews products for safety and approves them for introduction into the marketplace. There are two main conflicting interests in this system:

- 1) the interest of corporations to have their products approved and approved quickly so they can sell them on the market for profit, to recoup research costs (though much research is actually publicly funded) and increase returns to company shareholders
- 2) the public interest to ensure that products are safe for human consumption, safe for the environment, meet social needs, are ethical and do not result in harmful social or economic upheaval.

There is little democracy in decision-making over science and the development and introduction of new technologies. In the case of genetic engineering this means that the corporate profit motive dictates the direction of innovation as well as the way the technology is regulated.

- The Canadian government regulates genetic engineering as if it were **nothing new**.
- The regulatory system is designed simply to approve products for commercial introduction if they are judged to be “safe” - there are no explicit questions asked about ethics, social and economic impacts, or social need.

In their **World Scientists’ Statement**, 136 scientists from 27 countries called for a moratorium on genetically engineered crops and a ban on patents. They argue: “Government advisory committees lack sufficient representation from independent scientists not linked to the industry. The result is that an untried, inadequately researched technology has been rushed prematurely to market, while existing scientific evidence of hazards are being downplayed, ignored, and even suppressed, and little independent research on risks are being carried out.”

(See the Third World Network at <http://www.twinside.org.sg/title/world-cn.htm>)

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PART 1 : INTRODUCING REGULATION AND CORPORATE POWER

The Current Reality: Few Crops, A Handful of Corporations

“The hope of the industry is that over time the market is so flooded [with genetic engineering] that there’s nothing you can do about it, you just sort of surrender.”

- DON WESTFALL, VICE PRESIDENT, PROMOR INTERNATIONAL, STRATEGIC AGRICULTURE AND MARKETING CONSULTANTS²

The industry and the Canadian government would like us to believe that genetically engineered foods are already all over the market, that the “genie is out of the bottle” — with no way of getting it back in. This is a corporate strategy to make us feel that genetic engineering is inevitable and that we are powerless to stop it. But the reality is that genetic engineering is not everywhere. In fact it is just a small number crops that are engineered in a few specific ways, owned by only a handful of corporations, that are on the market.

- Of the 46 genetically engineered crops/foods approved by July 2001, 12 were canola varieties and 15 were corn varieties.
- Though there are 46 varieties of crops approved, in total this represents only 8 types of food crops. Of these, only 3 genetically engineered crops are currently grown commercially in Canada: **canola, corn, and soy**. **Cotton** is the only other food ingredient on the market but it is not grown in Canada, it is imported as cottonseed oil and animal feed.
- **Canola, corn and soy** are the main genetically engineered crops on the market. Most of these end up as ingredients in processed food (like cookies and frozen dinners) or as grains for animal feed. This is where the information “up to 70% of all processed foods may contain genetically engineered ingredients” comes from.
- Some of the approved crops have never entered our food system. Some are not actually grown in Canada - cotton for example cannot grow in Canada’s climate but is approved for human consumption by Health Canada because cottonseed oil is imported for our food market.
- Many crops are approved for use as **animal feed**. (In the U.S. 90-95% of soybean harvests and 60% of traded corn are eaten by livestock, not humans.)³

Table 1: Crops Approved in Canada lists all the genetically engineered crops approved by the Canadian government as of July 2001, what traits they are engineered for, which companies own them and how many varieties they own, and where they are (or are not) in our food system. The table is taken from the Canadian Food Inspection Agency's list of crops they have approved – but with added information on what foods these are and where we might find them in our grocery stores. (<http://www.inspection.gc.ca/english/plaveg/pbo/pntvcne.shtml>)

- Note that some varieties are engineered for more than one trait (for example they may be engineered for both herbicide and virus resistance).
- 70% of all the approved crops are engineered to be resistant to brand name herbicides.

GENETIC ENGINEERING

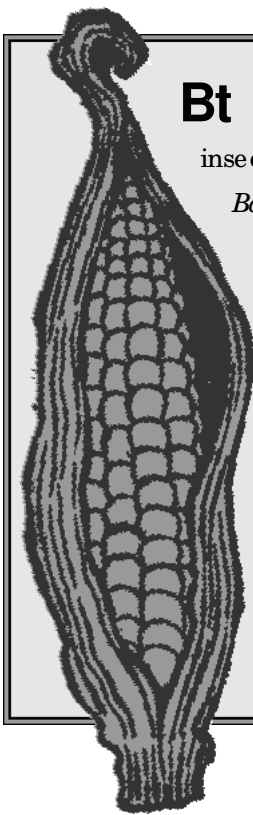
What?

Genetic engineering is recombinant DNA technology – meaning the recombination of genetic material. It is a new technology that enables scientists to isolate genes and move them from one organism directly into the DNA of another. This means that completely new (exotic) genes can be transferred from one species to another, entirely unrelated, species. For example, genes have been taken from a soil bacterium and put into the DNA of corn. This type of genetic transfer crosses what is called the “species barrier.” It has never been done before and cannot be achieved through traditional plant breeding. Genetic engineering can therefore introduce genes into food crops that have never before been a part of the human diet.

How ?

Foreign genes are inserted directly into host organisms with a “gene gun” which shoots DNA into the cells of another organism or they are transferred through the use of vectors, like a virus, to carry genes across. Genes that are transferred are tagged with one or more “marker” genes (often antibiotic resistant genes) to identify the location of the new genes, as well as “promoters” to make sure the genes becomes active.

(See *Genetic Engineering: Dream or Nightmare?* By Dr. Mae-Wan Ho)



Bt corn is the corn genetically engineered to be resistant to the insect the European corn borer. Bt refers to the genes from the soil bacterium *Bacillus thuringiensis* that are toxic to a certain class of insects. Bt genes are transferred into the DNA of corn to create a plant that kills the insects that try to eat it. 5 of the 15 genetically engineered corn varieties approved in Canada are Bt.

Bt is toxic to a whole class of insects (the class *Lepidoptera* to which monarch butterflies belong) and is therefore used to engineer insect resistance in a number of different crops. All of the 5 potato varieties commercialized by Monsanto are Bt potatoes (resistant to the Colorado Potato Beetle) and Monsanto has developed a Bt tomato that has been approved by Health Canada but is not yet on the market.

Table 1: Crops Approved in Canada

Corn		
Number of Varieties Approved: 15		
GENETICALLY ENGINEERED FOR WHAT TRAITS?	WHICH COMPANIES DEVELOPED AND OWN THESE VARIETIES?	IS IT IN CANADIAN STORES? WHERE?
14 herbicide resistant – 5 of these are combined with resistance to the insect the European Corn Borer, know as Bt corn – and 1 just Bt.	Monsanto (5) Deklab Genetics Corporation (2) Pioneer Hi-Bred International (2) CIBA Seeds/Mycogen (1) ICI/Zeneca Seeds (1) Northrup King Co. (1) BASF (1) AgrEvo (1) Plant Genetics Systems (1)	Yes Most of this corn is used for animal feed - for hogs, dairy cows and poultry. Other corn is processed and appears in stores as ingredients like corn syrup and cornstarch. Less than 2% of sweet corn in Canada is Bt (ask your farmer or store produce manager). Coca-Cola and PepsiCo both use high fructose corn syrup in their soft drinks.

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Canola

Number of Varieties Approved: 12 (one is not registered for use in Canada)

GENETICALLY ENGINEERED FOR WHAT TRAITS?	WHICH COMPANIES DEVELOPED AND OWN THESE VARIETIES?	IS IT IN CANADIAN STORES? WHERE?
10 herbicide resistance, 1 high oleic/ low linolenic acid, 1 higher quantities of laurate and myristate	Monsanto (3) AgrEvo (3) Pioneer Hi-Bred International (2) Plant Genetic Systems (2) Calgene (1) Rhône-Poulenc (1)	Yes Appears as canola oil – used as a cooking oil and as an ingredient in many processed foods. Is also used as a grain for animal feed.

Potato

Number of Varieties Approved: 5

GENETICALLY ENGINEERED FOR WHAT TRAITS?	WHICH COMPANIES DEVELOPED AND OWN THESE VARIETIES?	IS IT IN CANADIAN STORES? WHERE?
Insect resistance, 2 combined with virus resistance, 1 with virus resistance and herbicide resistance (All are NewLeaf™ varieties)	Monsanto	No These potatoes are no longer grown in Canada or the US. Monsanto says they stopped selling them because they captured less than 5% of the North American market - McCains and McDonalds asked farmers they buy from not to grow these potatoes – but there were also problems in Canada with Monsanto not following environmental guidelines for growing.

Cotton

Number of Varieties Approved: 4

GENETICALLY ENGINEERED FOR WHAT TRAITS?	WHICH COMPANIES DEVELOPED AND OWN THESE VARIETIES?	IS IT IN CANADIAN STORES? WHERE?
Insect resistance, herbicide resistance	Monsanto (3) Calgene (1)	Yes Cotton is not a crop that can be grown in Canada's climate but Health Canada has approved it for human consumption because cotton meal is imported from the U.S. for animal feed and cottonseed oil is imported for use as an ingredient in processed foods.

Soybeans

Number of Varieties Approved: 3 (Only one is actually registered for growing)

GENETICALLY ENGINEERED FOR WHAT TRAITS?	WHICH COMPANIES DEVELOPED AND OWN THESE VARIETIES?	IS IT IN CANADIAN STORES? WHERE?
Herbicide resistance, high oleic acid	Monsanto, AgrEvo, Optimum Quality Grains L.L.C.	Yes Only Monsanto's one herbicide resistant soybean, Roundup Ready™, is registered for growing in Canada. It is used in animal feed and as processed ingredients like soy oil and soy lethicin (in chocolate bars for example).

Tomato

Number of Varieties Approved: 3

GENETICALLY ENGINEERED FOR WHAT TRAITS?	WHICH COMPANIES DEVELOPED AND OWN THESE VARIETIES?	IS IT IN CANADIAN STORES? WHERE?
Delayed ripening	Calgene (FlavrSavr™), DNA Plant Technology (Endless Summer™), Zeneca Seeds	No These tomatoes were never approved for growing in Canada and none of them are now in the food system. The Zeneca tomato was grown in the US and imported to the UK as tomato paste. Calgene's Flavr Savr™ tomato was "test marketed" in Canada at one grocery store in Toronto for a few weeks. (See box page 7-8) DNA Plant Technology's tomato was only briefly test marketed in the US.

Squash

Number of Varieties Approved: 2

GENETICALLY ENGINEERED FOR WHAT TRAITS?	WHICH COMPANIES DEVELOPED AND OWN THESE VARIETIES?	IS IT IN CANADIAN STORES? WHERE?
Virus resistance	Seminis Vegetable Inc.	No These are varieties of Crookneck squash. It is grown in the U.S. but not in Canada. If it is imported into Canada, it will likely appear in a processed form rather than as fresh squash.

Flax		
Number of Varieties Approved: 1		
GENETICALLY ENGINEERED FOR WHAT TRAITS?	WHICH COMPANIES DEVELOPED AND OWN THESE VARIETIES?	IS IT IN CANADIAN STORES? WHERE?
Herbicide resistance	University of Saskatchewan	No This flax has been deregistered on request from its developers, the University of Saskatchewan, because of pressure from flax growers, largely represented by the Flax Council of Canada. It is therefore now illegal to grow this flax in Canada. (see page 11-12)
Sugar Beet		
Number of Varieties Approved: 1		
GENETICALLY ENGINEERED FOR WHAT TRAITS?	WHICH COMPANIES DEVELOPED AND OWN THESE VARIETIES?	IS IT IN CANADIAN STORES? WHERE?
Herbicide resistance	Aventis CropScience	No This sugar beet is not grown in Canada or in the U.S. Aventis has not applied for variety registration in Canada and sugar companies are not presently interested in using sugars and byproducts from genetically engineered sugar beet.
Wheat*		
Number of Varieties Approved: 1		
GENETICALLY ENGINEERED FOR WHAT TRAITS?	WHICH COMPANIES DEVELOPED AND OWN THESE VARIETIES?	IS IT IN CANADIAN STORES? WHERE?
Herbicide resistance	Cyanamid Crop Protection	No <u>* This wheat is not a product of genetic engineering</u> but is still regulated as a “novel food” (See page 12) so it appears on the government’s list. It cannot be grown in Canada until Cyanamid’s application for variety registration is accepted (the decision is pending). The crop is produced using chemically induced seed mutagenesis – the application of chemicals to cause mutations.

Though there are only a few genetically engineered crops currently on the market the table below shows that many more are being tested for research and commercialization.

The government keeps the exact location of these trials secret. (See page 21 of this booklet for more information on field trials)

Table II: Field Trials 2001

Crop	Objective	Provinces where Field Trials took place
63 alfalfa	122 Herbicide Tolerance	96 Ontario
59 wheat	76 Stress Tolerance	96 Saskatchewan
44 canola/napus	26 Fungal Resistance	35 Manitoba
2 barley	23 Other (like altered	44 Alberta
25 brown mustard	metabolism for example)	11 Quebec
16 lentils	21 Insect Resistance	
10 flax	17 Modified Oil Composition	
10 soybean	11 Genetic Research	
10 potato	9 Male Sterility/Restoration	
5 tobacco	3 Pharmaceutical	
3 white clover	1 Nutritional Change	
2 sugarbeet		
2 monoccum		
2 safflower		
3 spruce		
1 canola/rapa		
1 creeping bentgrass		
1 perennial ryegrass		
1 poplar		

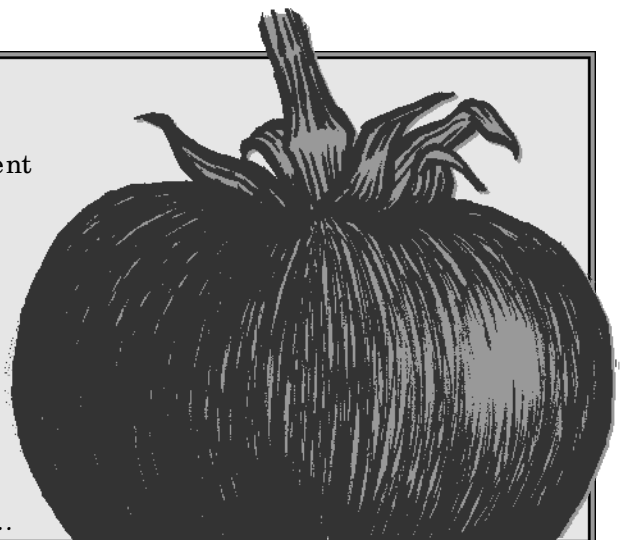
From the Plant Health and Production Division, Plant Biosafety Office <http://www.inspection.gc.ca/english/plaveg/pbo/triesse.shtml>

The Flavr Savr™ tomato

is a tomato approved by the Canadian government for human consumption but is not currently on the market.

It was the much-celebrated tomato developed by **Calgene Inc.**, with sponsorship from **Campbell Soup Company**, that turned into a huge market flop. It was genetically engineered for delayed ripening so that it could be transported long distances and

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stay on grocery store shelves longer without rotting. Calgene scientists isolated and copied the gene they identified as causing the tomato to soften and inserted it backwards into the tomato DNA.

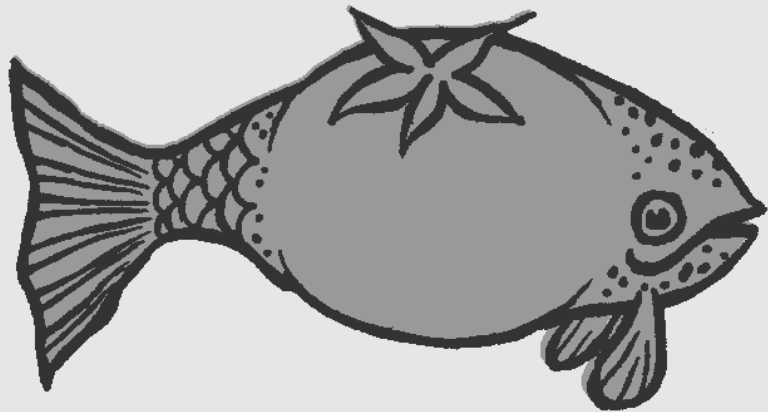
The product did not succeed for various reasons including problems with taste and texture. Campbell Soup Company also decided in 1993 not to use the tomatoes because of consumer pressure. By the summer of 1995 Calgene was close to bankruptcy and was bought out by Monsanto in 1996.

Health Canada still uses the Flavr Savr™ as one of four examples of genetically engineered crops it has approved. This maintains the illusion that there is a diversity of crops on the market and that they are genetically engineered for more traits than just herbicide and insect resistance.

The famous **fish-tomato**

is an experiment where flounder genes were inserted into the DNA of tomatoes to produce fruits that could be frozen and thawed without getting mushy. Developed by

DNA Plant Technology Corporation, this tomato has a patent number but was never submitted for regulatory approval and never entered the market.



CORPORATE OWNERS

The following table is a list of the companies, mostly transnational agrochemical corporations, that own these technologies and the total number of products approved in Canada that they own. The table makes it clear that there is a high level of concentration in ownership and control over genetically engineered foods, especially as many of the companies that submitted products for approval have since been bought by other corporations, and some products were created in joint ventures between corporations.

Monsanto owns 16 of the 46 genetically engineered crop varieties approved in Canada (35%).

Chemical companies like Monsanto and Dupont started buying seed companies in the late 1980s, they kept growing larger and diversified their investments, recreating themselves as 'life sciences' corporations. Now 10 companies control over 30% of the world's commercial seed market and 100% of the commercial GE seed market. Many of these corporations have extensive investments in biotechnology to produce pharmaceutical drugs as well as seeds for agriculture. (See *Gallop ing Gene Giants*, Polaris Institute)

Table III: Corporate Concentration: Who Really Owns What

Current Parent Company	CFIA Registered Crop Owner	Number of Varieties Approved in Canada	Comments
Monsanto Company (U.S.)	Monsanto Canada Calgene Dekalb Genetics Corp.	16 3 2	Monsanto bought Calgene and Dekalb (Dekalb controls 11% of the U.S. corn seed market). Monsanto is the second largest seed company in the world.
Aventis (France)	AgrEvo Canada Plant Genetic Systems Rhône-Poulenc Aventis CropScience	5 3 1 1	Rhône-Poulenc and Schering merged some of their operations to form AgrEvo. Rhône -Poulenc then merged (taking AgrEvo with it) with Hoechst in 1999 to form Aventis, now the world's third largest agribusiness corporation.
Dupont (U.S.)	Pioneer Hi-Bred International Optimum Quality Grains LLC.	4 1	When Dupont bought Pioneer Hi-Bred in 1999 they became the world's largest seed company.
Grupo Pulsar (Mexico)	Seminis Vegetable Incorporated (U.S.) DNA Plant Technology	2 1	Seminis is the world's largest vegetable seeds company and the fifth largest seed company.
Syngenta (Switzerland)	ICI/Zeneca Seeds Northrup King Company Zeneca Seeds	1 1 1	In 1999 Zeneca merged with Astra to form AstraZeneca which then merged its agribusiness units with Novartis' to form Syngenta in 2000, now the world's largest agribusiness corporation and the world's third largest seed company.
BASF (Germany)	BASF Cyanamid Crop Protection	1 1	In 2000, BASF bought Cyanamid from American Home Products, making BASF the third largest agrochemical producer in the world.
Dow AgroSciences (U.S.)	CIBA Seeds/Mycogen	1	In a joint venture, CIBA Seeds and Mycogen developed the first Bt corn. Mycogen is an affiliate of Dow AgroSciences.
University of Saskatchewan (Canada)	University of Saskatchewan	1	This product was developed with research money from the Saskatchewan government.

The following is just a sample of information about three owners of genetically engineered foods approved by the Canadian government. This type of information can expose the interests these corporations have in developing specific types of genetically engineered foods and the degree of power that they can have over regulatory agencies and Canadian policy.

- **MONSANTO**

The majority of genetically engineered crops approved in Canada are produced by Monsanto. Monsanto has great economic and political power as the second largest seed company in the world. However, they have also hit on hard times thanks to worldwide resistance to genetic engineering. (See *Galloping Gene Giants*, Polaris Institute)

Monsanto started out as a chemical company and as such has a long history of polluting the environment and endangering human health. Herbicide resistant crops account for most of Monsanto's profits in genetic engineering — 67% of total sales in 2000. These crops are engineered to be resistant to its brand name herbicide Roundup™, the biggest selling herbicide in the world. They are called Roundup Ready™ crops and are the exclusive property of Monsanto Company.

To protect its property Monsanto makes farmers sign contracts when they buy Roundup Ready™ seed. Monsanto's "Grower Agreement" makes it illegal for farmers to save the seed for growing the next year and gives Monsanto the right to inspect farms for up to three years after planting. Monsanto has already successfully sued Saskatchewan farmer Percy Schmeiser for growing Roundup Ready™ canola without the company's permission and is pursuing cases against other Canadian farmers. (See Percy Schmeiser's website at <http://www.percyschmeiser.com/>)

To protect its patents even further, Monsanto attempted to buy Terminator Technology – a technology that makes seeds sterile after the first planting. Many companies are now developing crops that either become sterile after the first harvest or only become fertile when sprayed with particular brand-name chemicals. (See ETC group, www.etcgroup.org)

In February 2000 Monsanto merged with pharmaceutical giant Pharmacia & Upjohn to become a subsidiary of the newly formed **Pharmacia**. More recently, Pharmacia has decided to divest itself of Monsanto in 2002.

- **AVENTIS CROPSCIENCE**

Aventis CropScience owns the second largest number of genetically engineered crops approved in Canada, after Monsanto. Aventis CropScience Canada Co. has its head offices in Regina, Saskatchewan. In 2002 Aventis CropScience is expected to be acquired by **Bayer CropScience** to create the second largest agribusiness corporation in the world after **Syngenta**, with annual sales projected at approximately \$6.5 billion.

The decision by Aventis to get rid of its agribusiness operations came only three days after the corporation admitted that its genetically engineered corn StarLink™ – a product approved for animal consumption but not for humans – had in fact contaminated the human food chain.

A number of Aventis CropScience's research and development centres are also located in Saskatchewan, including its Biotechnology Development and Breeding Centre, Biotech Research and Plant Breeding Facility, and Research and Development Main Farm and Sub-Farms. With strong ties to the government in Saskatchewan, mainly through the government funded industry organization Ag-West Biotech, Aventis CropScience is well positioned to advance its operations in Canada. (Ag-West Biotech was established in 1989 and is funded by the Saskatchewan Department of Agriculture and Food. The mandate of Ag-West Biotech is to “initiate, promote and support the growth of Saskatchewan's agricultural biotechnology industries.”) One of Ag-West Biotech's board members is Dr. Malcolm Devine, Global Head of Technology Identification, Assessment and Acquisition at Aventis CropScience.

Aventis and Monsanto are both being sued by Saskatchewan organic farmers for contaminating their canola crops with genetically engineered canola. The farmers are also seeking an injunction to prevent the introduction of genetically engineered wheat. (See www.saskorganic.com for more information.)

• UNIVERSITY OF SASKATCHEWAN

It may be surprising to see that one of the approved crops was developed and is owned by the University of Saskatchewan. The story of this product provides some important lessons about the need to develop products with democratic input from farmers and consumers since international resistance to genetic engineering has rendered this crop useless.

Alan McHughen, a professor and senior research scientist at the Crop Development Centre (CDC), University of Saskatchewan, developed a genetically engineered flax seed to be herbicide resistant. He named his creation “the triffid,” in reference to John Wyndham's 1953 novel, *The Day of the Triffids*. In the book, the triffid was a terrifying flesh eating plant that was almost impossible to kill. The flax was developed with public money through provincial government funding of the CDC. (McHughen is author of the book *Pandora's Picnic Basket: The Potential Hazards of Genetically Modified Foods* that concludes genetic engineering is safe. The book is distributed free to schools in Canada by the industry group the **Council for Biotechnology Information**⁴, created by Aventis CropScience, Monsanto, Syngenta, Dow AgroSciences, BASF and Bayer.)

The “CDC Triffid” was approved and registered in Canada in 1996 but was never grown commercially and was de-listed in April 2001. It was de-registered (meaning that it is now illegal to grow) because Canadian flax growers were concerned that Europe, their largest market for flax, would not import Canadian flax seed if genetically engineered flax was also on the market, because of fears it would be contaminated. The Canadian flax industry agreed not to grow the flax in order to protect this export market.

Recently, the Saskatchewan Government actually cut funding for CDC genetic research. The Centre director stated, “Certainly we know that the market is not prepared to accept GMO [genetically modified] varieties of the crops that we have plant-breeding programs in right now, and that covers wheat, barley, oats, flax, and the pulse crops.”⁵

“Genetic Engineering is Nothing New” : Naming the Technology to Define Away Risk

Genetic engineering, genetic modification, genetically altered, biotechnology, life sciences, plants with novel traits, novel foods ... are all names given to the same technology.

Definitions are important and are central in regulation. The industry and our government try to define genetic engineering as nothing new so that they do not have to develop new regulations and so that the public does not view genetic engineering as a new technology with new risks. This is a deliberately false representation that contradicts what many people think and know about genetic engineering.

Paul Mayers (then Acting Chief of the Evaluation Division, Bureau of Microbial Hazards and now the Director of Food Policy Integration) of Health Canada argues, “we recognize that the application of biotechnology as just a technology doesn’t bring with it any unique risks.”⁶

NOVEL FOOD

The government has created the new term and category called **novel foods** or **plants with novel traits** in order to hide genetic engineering amongst a range of other technologies. As the CFIA states:

“This term covers products that have not been previously available for sale in Canada, have been substantially modified, or are produced by a new process.”

By categorizing genetically engineered foods as “novel” the government tries to regulate them without bringing attention to the particular process of genetic engineering. Through this regulation the Canadian Government treats genetic engineering as if it is simply an extension of traditional plant breeding.

TRADITIONAL PLANT BREEDING

The industry often defines genetic engineering as just a speeding up or extension of traditional plant breeding. This definition is also designed to reassure the public. It invites familiarity and comfort through an association with traditional plant breeding techniques that are the basis of our diverse food system. But genetic engineering is dramatically different from traditional plant breeding and creates different organisms, with new risks.

Traditional plant breeding relies on the reproductive systems of plants and animals, making use of existing genes and alleles present in related organisms.

BIOTECHNOLOGY (BEER, CHEESE AND FISH TOMATOES)

The Canadian Environmental Protection Act defines biotechnology broadly as, “the applied use of living organisms, or their parts, to produce new products.”

Genetic engineering is most often referred to by industry as biotechnology. Much like the category of novel foods and the industry’s use of the term modification (“we’ve been modifying food for centuries”), the advantage of using this term is that genetic engineering can be lumped together with older, different techniques: the Canadian Food Inspection Agency says that, “the term covers all organisms, whether developed traditionally or through the newer molecular techniques such as genetic engineering.” By using the term biotechnology the industry can create timelines that place genetic engineering, activities like splicing genes from a fish into a tomato and cloning animals, on a continuum from using yeast to brew beer and enzymes and bacteria to make cheese.

A Powerful New Technology : More than Food

Genetic engineering is a technology that can be used to create products in many economic sectors, including pharmaceuticals, agriculture, chemicals (like plastics and textiles), environmental clean-up and the military. For this reason Industry Canada argued that, “many people see biotechnology as the next important ‘change maker’ after the convergence of information, computer and telecommunications technologies, which have transformed our lives.” (Canadian Biotechnology Strategy, Industry Canada, 1998:2)

Almost 60% of all Canadian biotech companies are actually in the healthcare/ pharmaceutical sector while only 20% are in agriculture and food processing.

“Simply put, biotechnology is the use of living organisms, or their parts, to produce new products. If you’ve ever eaten bread or cheese, or used antibiotics, then you’ve ingested something that was produced through biotechnology.”

– FROM THE PAMPHLET “FOOD SAFETY AND YOU” DEVELOPED BY THE CANADIAN FOOD INSPECTION AGENCY AND SENT TO EVERY HOUSEHOLD IN CANADA TO REASSURE US THAT THE FOOD WE ARE EATING IS SAFE – EVEN IF ITS GENETICALLY ENGINEERED.

The biotech industry and our government are interested in having us believe that genetic engineering is nothing new, so that we accept it into our food and environment without stricter safety regulations or mandatory labelling.

Efficient Regulation for Economic Growth

The primary objective of Canadian government policy on genetic engineering is “to make Canada a leader in biotechnology.” The regulatory system is shaped by this goal of promoting genetic engineering and therefore sidelines safety questions and ethical concerns as much as possible.

The Canadian Government believes that taking a lead in promoting high technology innovation like genetic engineering is key to economic growth. In 2001 Prime Minister Jean Chretien stated, “In the new economy, the race goes to the quick - those who are first with new discoveries, first to market, first with better ways of doing things...Canada must have one of the most innovative economies in the world.” To this end, the Canadian government has spent millions to support the biotechnology industry.

Because the primary policy concern is to promote the industry, corporate representatives have had a strong voice in Canadian Government decision-making on genetic engineering from the very beginning.

SEEKING APPROVAL

Approving products for sale on the market is one main way that our government protects corporate investments in genetic engineering.

The Canadian regulatory system is designed to approve genetically engineered foods and crops quickly, without controversy. Hence, the Canadian government sometimes refers to the product review system as the “approval process.”

The speedy commercialization of new products is important to manufacturers because it means that they can sell their products on the market sooner and begin to get returns for company shareholders. Genetically engineered products take a long time and a lot of money to develop and, therefore, the stakes in getting a product to market quickly are extremely high.

For example: the genetically engineered drug recombinant Bovine Growth Hormone (rBGH) cost companies an estimated \$15 billion to develop and was expected to bring in a profit of \$300 - \$500 million each year in the U.S. alone⁷. Monsanto lost projected revenue for every year that rBGH was denied approval. In 1995 Monsanto threatened to pull its investments out of Canada if our government legislated a moratorium on approving rBGH. (Though it was approved in the U.S. in 1994, approval was delayed in Canada and eventually denied in 1999 because of popular protest.)

The regulatory system relies on the predictability of science to get products approved because democratic debate and public participation in risk assessment would take more time and create an unpredictable environment for industry. The biotech industry argues that the system should be “efficient” —meaning speedy — and therefore “**science-based**” rather than open to non-scientific considerations and debate; “the licensing and approval process is absolutely critical to the future development and

growth of the industry, and should focus on a science-based approach rather than one that is weighted by social and political concerns.”⁸ Our government advertises abroad that, “international companies investing in Canada’s ag-biotech sector will find...a predictable and effective regulatory environment.”⁹

The priority of supporting the biotech industry has been central in designing the regulatory system and has therefore emphasized speed and predictability over rigorous safety testing and democratic debate.

The **regulatory system**

in Canada was founded on the following principles outlined in the 1993 *Federal Regulatory Framework for Biotechnology*:

1. Maintain Canada’s high standards for the protection of human health and the environment;
2. Use existing legislation and regulatory institutions to clarify responsibilities and avoid duplication;
3. Continue to develop clear guidelines for evaluating products which are in harmony with national priorities and international standards;
4. Provide for a sound scientific database on which to assess risk and evaluate products;
5. Contribute to the prosperity and well-being of Canadians by fostering a favourable climate for investment, development, innovation and adoption of sustainable Canadian biotechnology products and processes.

Deregulation

In the name of reducing the debt and deficit and now in the name of promoting innovation, the Government has been minimizing the costs and trouble of regulation to corporations. The 1994 *Federal Regulatory Plan* asked all government departments “to reduce the regulatory burden on Canadian business and individuals.” This was one of the principles used to formulate the regulatory system for genetic engineering. Biotechnology was chosen as one of six target areas because, “The industry has pinpointed regulatory uncertainty and lengthy approval processes as the key impediments to investment and jobs.” (*Agenda for Jobs and Growth, 1994*)

State Supported Biotech Industry: History in Genetically Engineered Time

The Canadian government decided to give public money to the industry and approve genetically engineered foods without consulting the public and before most Canadians had ever even heard of genetic engineering. Important first decisions to support the biotech industry and push ahead with genetic engineering were made in the early 1980's with corporate players. (The federal and provincial governments spend public money on the biotech industry through infrastructure investments, tax incentives, research grants, and partnering projects.) The lead government departments in this decision-making were Industry Canada and Agriculture Canada.

The following table outlines some significant points in the history of federal government investments in genetic engineering (with a few landmark product approvals added for context).

Table IV: Significant Federal Government Investments in Genetic Engineering

1983	The federal government made its first financial commitment to genetic engineering by making Saskatoon one of five government biotechnology research "Centres of Excellence" that link industry and academic researchers.
1983	Industry Canada set up the National Biotechnology Strategy with a National Biotechnology Advisory Committee (NBAC) to be a "consultative body in partnership with industry and academia to advise and direct the government regarding the direction of biotech development."
1988	The National Biotechnology Strategy was granted over \$10 million for each year.
1988	First confined field trials of herbicide resistant canola.
1995	The first genetically engineered product, an herbicide resistant corn, was approved.
1995	Agriculture Canada created the Matching Investment Initiative where the government matches research money coming from corporations for projects.
1997	Jean Chretien identified biotechnology as an important sector for jobs and growth. According to Statistics Canada, the federal government spent \$314 million on biotech in 1997-98. ¹⁰
1998	Industry Canada set up the Canadian Biotechnology Strategy to ensure the future of biotechnology in Canada. The Canadian Biotechnology Advisory Committee was formed out of this project, replacing NBAC but still housed in Industry Canada. It later began a series of "consultations." (See page 46)
1998	The Canadian International Development Agency began a three-year project to spend \$280,000 convincing farmers in China to grow Monsanto's genetically engineered cotton and corn.
1999	Health Canada denied Monsanto's submission for approval of recombinant Bovine Growth Hormone (rBGH), after ten years of widespread public resistance.

1999	The federal budget included \$55 million pledged over three years to the Canadian Biotechnology Strategy, “to make Canada a leader in biotechnology.”
2000	The federal budget allocated \$90 million “specifically to enhance the government’s capacity for regulating products of biotechnology.”
2000	The Minister of Health announced \$20 million in federal funds for national genome health research (mapping human genes) with “the potential to unlock the mystery of cancer and other human diseases.”

Industry Canada is a dues paying member of the industry lobby group **BIOTECCanada** which states that it “provides a unified industry voice and focuses resources to: promote a supportive policy and regulatory environment.” Industry Canada has given a total of \$5.7 million to BIOTECCanada through various grants.¹¹ On top of this, the group has also received grants from the Canadian International Development Agency and International Development Research Centre.

BIOTECH RESEARCH

Research is another way that the Government supports the industry since much public research ends up being turned over to the private sector. Agriculture and Agri-Food Canada has its own research laboratories as well as numerous research funds for corporations and universities (public funding for university research usually requires corporate partnerships and matching funds). Agriculture Canada is, for example, working with Monsanto to design a wheat resistant to Monsanto’s herbicide Roundup™.

Agriculture Canada promotes the “life sciences revolution” as the future for Canadian farmers:

*The new millennium has finally arrived. And along with this calendric event is the germ of a revolution that, when full-grown, will stand shoulder to shoulder with the colossal upheavals that have shaped our world – the agrarian revolution, the industrial revolution, the high-technology revolution. We are on the threshold of the life sciences revolution. As we begin to unravel the mysteries of life itself, we will increase our knowledge and understanding of the world around us and within us. And that will lead to a better quality of life for all of us. This meshes well with the goal of Agriculture and Agri-Food Canada, whose raison d’etre is to improve the quality of life for all Canadians. And achieving this objective relies heavily upon research.*¹²

Government Regulation as Public Relations Strategy

“There are many alarming articles coming out of Europe demonstrating a concern that there are dangers associated with this technology. The adoption of new products on the market depends greatly on consumer confidence in the effectiveness of the regulatory regime.”

– HEALTH CANADA, INTERNAL MEMO, “MEMORANDUM TO JOHN DOSSETOR,”
FROM ACCESS TO INFORMATION DOCUMENTS OBTAINED BY KEN RUBIN

Promoting Canada’s current system of regulation as “one of the best food safety systems in the world” is a central public relations strategy used by both our government and the biotech industry. Our government is spending public money, not to change the system to make it safe and democratic, but to assure Canadians that the system is already “rigorous” and that the products it approves are therefore safe.

The biotech industry depends on this positive promotion of regulation to sell their products. As a former CEO of Monsanto argued, “Regulation is very appropriate, in our view, and it’s needed not only to make prudent regulatory judgements but at least as important to assure the public that the products of this new technology are indeed safe.”¹³

This also means that other corporate players, including food processing companies (like Unilever and General Mills) and grocery retailers (like Loblaws and Sobeys), can answer public concerns about labelling and safety by simply stating, “we trust government regulation.”

The CFIA directly promotes its role in regulating genetic engineering for safety through its own publications like the pamphlet “Food Safety and You,” which it sent to every household in Canada at a cost of over \$2 million, as well as through advertisements such as a \$150,000 pro-biotechnology insert in *Canadian Living Magazine*.

The biotech industry argues that it is the responsibility of regulators to communicate the role they play in ensuring food safety. Industry sees regulators as trusted spokespeople who can represent genetic engineering to the public and they are now working to promote that trust in government. In 1997 Europe’s most powerful biotechnology industry lobby group, EuropaBIO, hired the public relations company Burston Marsteller to study the problem of public concern about genetic engineering. (Burston Marsteller was hired by Union Carbide after their pesticide factory leak in Bhopal India killed thousands of people and by Exxon after their massive oil tanker spill.) The company concluded that, “where safety is concerned there is no substitute for credible public regulators. It thus must become a strategic objective of this [public relations] campaign to help build that credibility.”¹⁴

In Canada, the biotech industry has recently become even more worried about public skepticism of regulation and has taken out full-page advertisements in the *Globe and Mail* to market their products as having been approved through “stringent regulatory guidelines.”

PART 2 : INSIDE THE REGULATORY SYSTEM

Federal Departments Involved in Regulating Genetic Engineering and Their Responsibilities

Several agencies of the federal government, under various legislation, evaluate genetically engineered products for human and animal health, and for environmental safety. The two main agencies involved are the Canadian Food Inspection Agency (CFIA) which works under the authority of Agriculture and Agri-Food Canada, and Health Canada.

Table V: Main Roles of CFIA and Health Canada in Regulating Genetically Engineered Foods

<p>CFIA</p> <ul style="list-style-type: none"> • Assesses the impact on the environment. • Enforces food safety standards. • Assesses livestock feed safety. 	<p>Health Canada</p> <ul style="list-style-type: none"> • Assesses food safety for human consumption.
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Table VI: Genetically Engineered Agricultural Products, Legislation and Departments Responsible

Genetically Engineered Agricultural Products	Legislation	Departments
FOODS	<i>Food and Drug Act and Novel Foods Regulations</i>	HEALTH CANADA Health Products and Food Branch (formerly the Health Protection Branch)
PLANT SEEDS INCLUDING TREES	<i>Seeds Act</i>	CANADIAN FOOD INSPECTION AGENCY Plant Biotech Office
PLANTS FOR IMPORT	<i>Plant Protection Act</i>	Plant Products Division
LIVESTOCK FEEDS AND ADDITIVES	<i>Feeds Act</i>	CANADIAN FOOD INSPECTION AGENCY Feeds Section Plant Products Division
FERTILIZERS/ SUPPLEMENTS (GENETICALLY ENGINEERED MICRO ORGANISMS FOR EXAMPLE)	<i>Fertilizers Act</i>	CANADIAN FOOD INSPECTION AGENCY Fertilizer Section Plant Products Division

continued...

ANIMALS	<i>Health of Animals Act and Regulations</i>	CANADIAN FOOD INSPECTION AGENCY Veterinary Biologics and Biotechnology Section Animal Health and Production Division
VETERINARY DRUGS LIKE RBGH, HORMONES OR VACCINES	<i>Food & Drugs Act and Novel Foods Regulations</i>	HEALTH CANADA Veterinary Drugs Directorate Health Products and Food Branch
OTHER PRODUCTS NOT COVERED UNDER EXISTING LEGISLATION	<i>Canadian Environmental Protection Act</i>	ENVIRONMENT CANADA
Source: www.inspection.gc.ca/english/ppc/biotech/reg/bare.shtml		

CANADIAN FOOD INSPECTION AGENCY (CFIA)

The CFIA is the lead agency responsible for regulating genetically engineered plants or “plants with novel traits” for environmental safety under the Seeds Act. It grants approval for field trials and for commercial growing (unconfined release). The CFIA also approves crops for use as animal feed under the Feeds Act and Regulations. The CFIA enforces food safety standards through inspection and monitoring activities and is also involved in consumer “education.”

The CFIA was established in 1997. It was created to consolidate all federal food inspection services as well as plant protection and animal health programs, services that were previously provided by four departments: Agriculture and Agri-Food Canada; Fisheries and Oceans Canada; Health Canada; and Environment Canada. The CFIA took over Health Canada’s responsibility for food safety inspections and Agriculture Canada’s enforcement duties. The CFIA reports to the Minister of Agriculture and provides “a single window” for biotechnology regulation. Well-known author and critic of genetic engineering Brewster Kneen argues that the new agency deflects attention away from the departments and Ministries where the real decisions are in fact made — Health Canada and Agriculture and Agri-Food Canada.

The CFIA has a serious conflict of interest because it regulates genetic engineering at the same time that it promotes it. The CFIA’s mandate is to promote trade and commerce as well as to regulate for food safety, and the agency has taken a prominent lead role in promoting genetic engineering.

For example, the CFIA has given grants to the Food Biotechnology Communications Network (FBCN) — created by industry and government in 1995 to be a “neutral” source of public information but which has long been promoting genetic engineering. The CFIA contracted the FBCN to produce bibliographies for public reference and gave \$12,000 to the FBCN to install and promote their toll free information line.¹⁵ In this way our government is redirecting citizens away from its own departments and public institutions that are accountable to all Canadians, and referring us instead to the FBCN which is a private unaccountable organization, with industry funding.

Secret Field Trials

Before a crop is grown commercially it must be approved for release into the environment. The Canadian Food Inspection Agency is responsible for these environmental assessments. For assessments, the CFIA requests information from companies about the “novel trait,” the method used to introduce it, and potential risks to biodiversity.

The CFIA sanctions and inspects field trials of genetically engineered plants and trees. The trials are conducted by the product developers, under government guidelines. However, small-scale field trials can only offer limited information about what might really happen when a plant is released into the environment.

The location of all field trials is kept secret from the public. Monsanto is currently conducting secret trials of genetically engineered wheat in Canada and the CFIA refuses to tell anyone where the trials are located. When asked about this policy, CFIA official Stephen Yarrow stated, “We are on the side of the protection of proprietary information. That’s how it looks because that’s how it is.”¹⁶ When the Agriculture Minister of Prince Edward Island asked the CFIA where field trials in his province were, they referred him to the company (Novartis in this case) which refused to give him the information.



AGRICULTURE AND AGRI-FOOD CANADA

Agriculture and Agri-Food Canada is the main department, aside from Industry Canada, that promotes genetic engineering. It is the department with primary responsibility for the CFIA.

HEALTH CANADA

Health Canada is responsible for assessing the human health safety of genetically engineered foods (including meat from genetically engineered animals) as well as the safety of veterinary drugs, pharmaceuticals, pesticides and cosmetics.

Health Canada regulates under the *Food and Drugs Act and Regulations*, in particular the “*Novel Food Regulations*” and “*Guidelines for the Safety Assessment of Novel Foods*”. Health Canada has a Pest Management Regulatory Agency that regulates pesticides under the *Pest Control Products Act*.

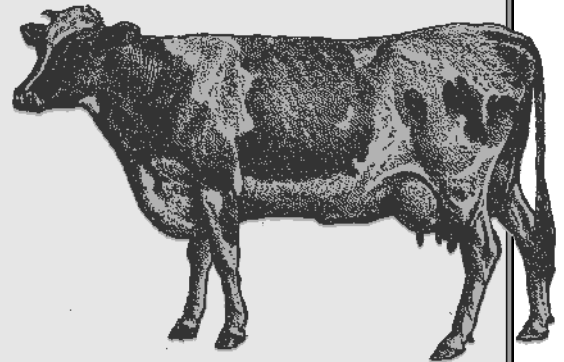
Health Canada regulates drugs and medical devices (products like blood, organs, diagnostic machines and equipment like heart valves) under the *Food and Drugs Act and Regulations* and *Medical Devices Regulations*. Health Canada therefore also regulates **xenotransplantation**, the use of animal or human-animal organs, cells and tissues for human transplantation.

Monsanto's Influence Inside Health Canada

rBGH In the case of government review of recombinant Bovine Growth Hormone (rBGH), six scientists in the Bureau of Veterinary Drugs at Health Canada say that they were threatened and harassed by their managers to approve the genetically engineered drug. The scientists had continuing questions about the product's safety for both animals and humans (it is injected into dairy cows to make them produce more milk) and allege that their safety concerns were suppressed and ignored in favour of product approval because of industry pressure.

One of the six scientists, Dr Margaret Haydon, as well as the then Director General Dr Bill Drennen, say that, in a meeting they attended in 1994, a Monsanto official offered a bribe of \$1-2 million for approval of rBGH without further delay.

Dr Haydon and her colleague Dr Shiv Chopra were threatened by Health Canada for speaking publicly about their concerns. They took their case to a labour board hearing where they charged that they were being taken off files and moved around the department as punishment. The Supreme Court of Canada later ruled that they were entitled to speak out as they had tried every other reasonable means to have their concerns heard inside Health Canada. (For more information see <http://www.sierraclub.ca/national/genetic/bgh.html>)

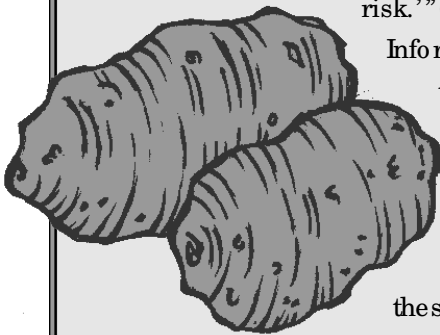


Bt potatoes In 1999 Health Canada and the CFIA struck a private deal with Monsanto to approve two types of their Bt potatoes. Monsanto was refusing to give Health Canada information they were asking for in order to finish their safety review. Health Canada stated that, "Monsanto objected to these requests; believing that their data adequately supports their conclusions that these products present 'no significant environmental, feed or food safety risk.'" (Memorandum to John Doessetor, obtained through Access to

Information by Ken Rubin for the Canadian Health Coalition) To obtain the data they wanted from Monsanto, the departments negotiated a deal with the company where they pledged to decide on approval within 30 days of receiving the information.

Internal memos also show that John Doessetor, then senior policy advisor to Health Minister Allan Rock, was kept up to date about these negotiations – an unusual situation since the Minister's office is not supposed to be directly involved in product reviews. Less than two years later Doessetor was hired by Monsanto to be their top lobbyist in Ottawa, "responsible for the development and implementation of Monsanto's government affairs strategies in Canada."

(For documents from this story see <http://www.healthcoalition.ca/factsheets/john-dossetor.PDF>)



ENVIRONMENT CANADA

Environment Canada plays a surprisingly small role in regulating genetically engineered organisms. The *Canadian Environmental Protection Act (CEPA)* is the only piece of federal legislation that specifically regulates genetic engineering. But CEPA is just used as a “catch-all” to regulate products that fall outside the responsibilities of other departments. For example, CEPA would cover the environmental assessment of genetically engineered animals at the moment since there are no specific regulations yet that cover this.

CEPA could have been used to regulate crops for environmental safety but the responsibility was given over to Agriculture and Agri-Food Canada, now the CFIA.¹⁷ The CFIA argues that, “Since agricultural products of biotechnology are regulated under agricultural acts that clearly provide for environmental safety assessments, additional reviews are not required under the *Canadian Environmental Protection Act*, administered by Environment Canada.”

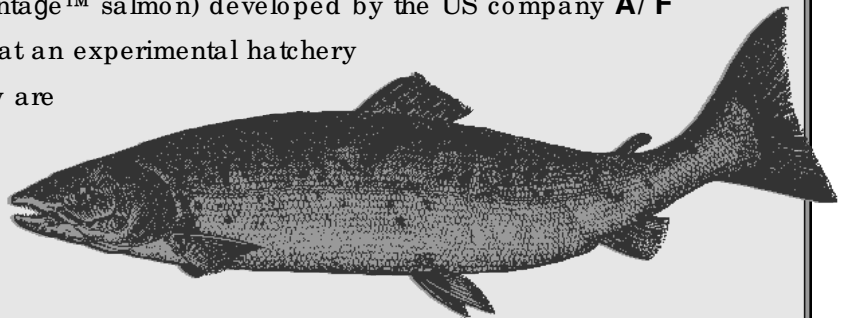
Overall, the health of our environment is not a Government priority and the general capacity of Environment Canada has been reduced in recent years. The Auditor General observed that over the three years ending in 1997-98, Environment Canada’s budget was reduced from \$737 million to \$503 million and the department lost about 1,400 of 5,100 employees.

DEPARTMENT OF FISHERIES AND OCEANS

The Department of Fisheries and Oceans is still developing regulations under the Fisheries Act to govern the introduction of genetically engineered fish.

The Royal Society Panel recommended that all genetically engineered fish be raised in land-based facilities rather than in ocean net-pens in order to avoid fish escaping into the wild. (Escaped farmed fish are already competing with wild fish in waters across the world, resulting in dramatic decreases in the size of some wild fish populations.)

Genetically engineered **fish** are not yet on the food market. But over 100,000 genetically engineered Atlantic salmon (AquAdvantage™ salmon) developed by the US company **A/ F Protein/ AquaBounty** are growing at an experimental hatchery in Fortune, Prince Edward Island. They are engineered to grow 4 to 6 times faster than usual. (See Greenpeace www.greenpeace.ca for campaign materials on this issue)



Trees

The CFIA is the agency with responsibility to regulate genetically engineered trees for environmental safety. Although they are only currently at the stage of drafting guidelines for field trials of “novel trees” there have already been some trials conducted. The CFIA has developed the terms and conditions for these experiments on a case-by-case basis with advice from the **Canadian Forest Service (CFS)**. These trials have been for research purposes and there are yet to be any submissions for the approval of genetically engineered trees. It may be 5 years before there are any requests from corporations for market approval of GE trees.

The CFS is field-testing some trees to examine specific questions around genetic engineering like the potential impacts of Bt trees on soil and of using antibiotic-resistant market genes. In 2001 there were four tree field trials in Canada, all CFS research trials conducted by their Laurentian Forestry Centre.

The CFS, under Natural Resources Canada, is not a regulatory agency but conducts research; “In its pioneering work to develop hardier, faster-growing trees that give better wood and resist insects and disease, the CFS is among a handful of organizations worldwide that is actively working to genetically engineer conifer species.” (“Building a Better Tree” CFS printed Aug 2, 2001 <http://www.nrcan.gc.ca/cfs/solutions/winter98/build.html>)

CFS research scientists have genetically engineered a virus to kill the spruce budworm. The virus was created with financial backing from **Rohm and Haas**, one of the world’s largest manufacturers of specialty chemicals, which now owns the patent for the virus.

The Canadian Regulatory System: Don’t Look, Don’t Find

Canadian policy on genetic engineering was not made openly through democratic debate in Parliament. Instead, policy was decided inside bureaucracies at Agriculture and Agri-Food Canada and Health Canada, as well as in the international body the Organization for Economic Cooperation and Development (OECD) (See page 27) - all in collaboration with industry representatives and without public participation.

The policy approach of the Canadian Government towards genetic engineering supports the technology and the industry. This policy is most clearly expressed through the regulatory system or product review process that approves products one by one, gradually putting them onto the market without public debate over genetic engineering and without extensive risk assessment.

The regulatory system is designed to sideline risk questions, and thus support the introduction of genetic engineering, in three central ways that will be explored in this section:

A. Reviewing the product, not the process:

This approach introduces the new technology into our society gradually, product by product, by stealth with no public scrutiny or parliamentary oversight. The risks of genetic engineering are not fully evaluated because it is the product, rather than the process, that is evaluated.

B. Safety reviews depend on comparisons, using the concepts called “familiarity” and “substantial equivalence.”

These concepts are poorly defined and can allow corporations to bypass risk assessment. The use of these comparisons is a part of how the system depends on defining genetic engineering as just an extension of traditional plant breeding (“novel foods” and “plants with novel traits”). This also means that the system can depend largely on existing legislation.

C. Testing: there is no long term testing or monitoring and there is no independent testing; instead the government relies on data from corporations.

The system is said to be “science-based” (largely excluding ethical and social considerations) but this “science” is not publicly available to be scrutinized. Testing is done by the corporations that want to sell their products and this data is privately owned. The system also fails to ask broad enough questions or use techniques that can investigate long-term ecological and health impacts - what has been called a “Don’t Look, Don’t Find” approach.¹⁹

A. REVIEWING THE PRODUCT NOT THE PROCESS

Our government refuses to acknowledge that genetic engineering is distinct from other processes used to produce food. Regulation therefore ignores the production process as an issue and subject of risk assessment and focuses instead on examining the end product. Products are reviewed on a case-by-case basis where the product of genetic engineering, not the process, is evaluated.

Each product approval can form a precedent to be used as the basis for the next product review. In this way genetic engineering actually becomes the standard for new approvals.

The government’s definition of genetically engineered plants as “plants with novel traits” (PNTs) defines away the importance of genetic engineering since a plant with a novel trait is defined by the novelty of its characteristics, rather than by the process that created it. **“Plants in Canada are regulated on the basis of the traits expressed and not on the basis of the method used to introduce the traits.” - CFIA**

The biotech industry prefers not to place a spotlight on the process of genetic engineering because many people have ethical problems with the technology itself and also because scrutinizing the process would lead to new questions about risk, highlight problems with the science itself, and take

a longer time to review for safety. This is why, in 1994, corporate consultants argued that, “Industry believes this emphasis on process as well as product places the industry at a commercial disadvantage.”²⁰

If our government were to review the process of genetic engineering it would have to acknowledge that this technology is very different from others, and it would have to create new regulations to deal with this. Instead our government wants to introduce genetic engineering into our lives, one product at a time, as quickly as possible – for the benefit of the biotech industry.

B. REVIEWS DEPEND ON COMPARISONS, USING THE CONCEPTS “FAMILIARITY” AND “SUBSTANTIAL EQUIVALENCE”

The regulatory system is based on the widely criticized and highly controversial concepts of “familiarity” and “substantial equivalence.” These two concepts, as suggested by their names, are about compar-

Problems with the Process

Scientists who critique genetic engineering argue that the science itself is flawed. Many scientists across the world, including Drs Mae-Wan Ho (prominent UK scientist and writer for the Third World Network) and David Suzuki, argue that genetic engineering is based on a falsely simple and reductionist way of viewing the world. They argue that organisms are not simply a sum of their parts and that we cannot separate out the functions of genes into individual traits since genes work together in complex environments inside organisms that are also influenced by external factors. Because of this complexity and because genes evolve within the unique context of a particular organism, moving genes from one organism to another can create new and unpredictable consequences.

(See the Third World Network for more explanations of risk www.twinside.com)

isons. Through these concepts, products of genetic engineering are compared to non-genetically engineered products or products of “conventional technology” that are already on the market.

The two concepts presume that we have enough information already to judge the safety of genetically engineered organisms. Regulators can decide that they know enough about potatoes and the soil bacterium known as Bt to compare Bt potatoes to non-genetically engineered potatoes already on the market – without conducting long-term safety tests. If a genetically engineered product is judged to be “substantially equivalent” to an existing product, then corporations can avoid extensive safety testing. They can be required instead to simply describe their new products, compare them to what we know about existing products, and infer that they are safe.

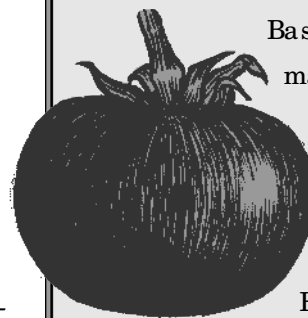
Comparisons through familiarity and substantial equivalence can allow corporations to bypass extensive risk assessment.

Familiarity is defined by the government as “our knowledge of the characteristics of a plant species and experience with the use of that species in Canada.” A crop or food must first be judged to be “familiar” to then undergo evaluation to judge if it is “substantially equivalent.”

Substantial equivalence is defined as “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.”

The Organization for Economic Cooperation and Development (OECD) states that: “The concept of substantial equivalence embodies the idea that existing organisms used as food, 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...If the new or modified food or food component is determined to be substantially equivalent to an existing food, then further safety or nutritional concerns are expected to be insignificant.”

“Health Canada compared the Flavr Savr™ to other commercial varieties and found no difference in composition or nutritional characteristics.



Based on Calgene’s information, the Department found the Flavr Savr™ to be as safe and nutritious as other tomato varieties.” –

Health Canada, Safety Assessment of the Flavr Savr™ Tomato, April 1997

Organization for Economic Cooperation and Development (OECD)

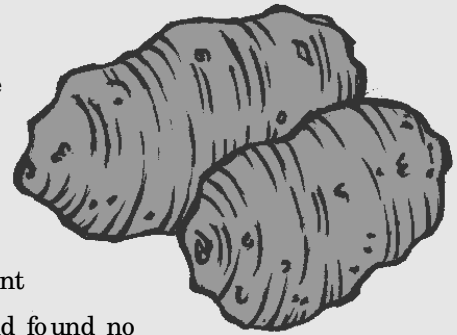
The Canadian government defends its use of substantial equivalence by arguing that because these concepts were developed by the OECD they are “internationally accepted principles” and therefore legitimate. The OECD, comprised of 30, mostly wealthy, countries, works to promote trade and economic development. The remaining 160 plus countries of the world are not members.

If it Looks and Smells Like a Potato, It must be a Potato

The following is an excerpt from Health Canada's explanation of their approval for Bt potatoes:

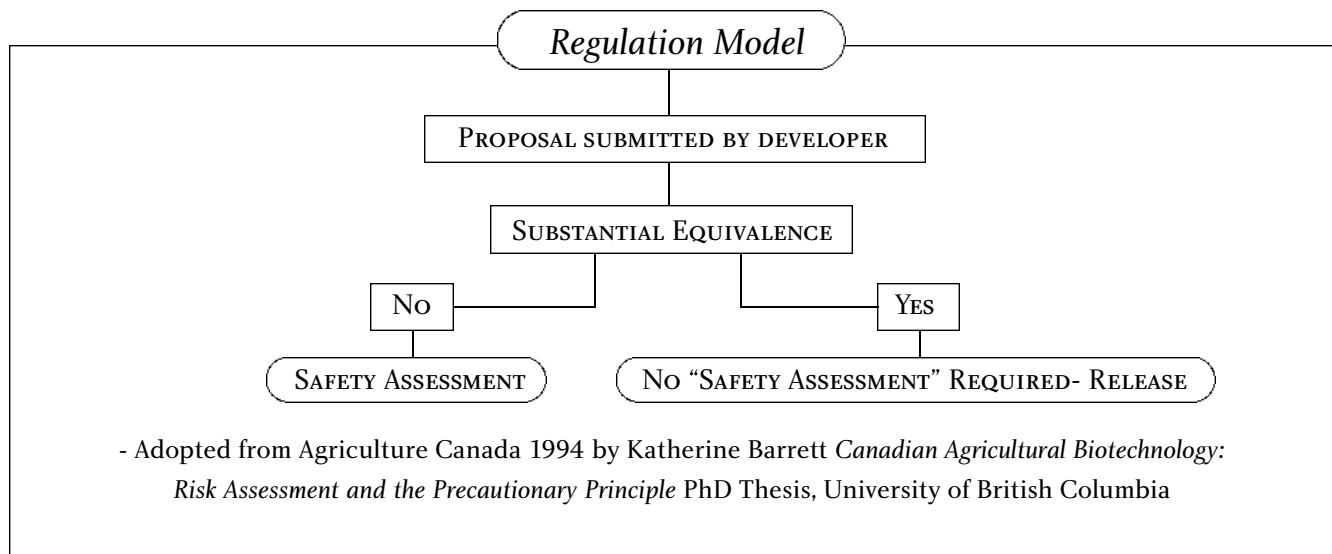
Four elements present in the CPB [Colorado Potato Beetle]-resistant potatoes distinguish them from other potato varieties. These are two new genes... isolated from bacteria, and the two proteins these new genes produce.

One gene produces a protein derived from *Bacillus thuringiensis* (Bt) subspecies *tenebrionis* which provides the protection ... A second gene produces an enzyme, a biological marker, that allows researchers to identify the modified plants.



Health Canada reviewed the comparison of the CPB-resistant potatoes to other commercial potatoes (Russet Burbank) and found no difference in composition except for the two introduced proteins. These results and a thorough review of the development and production of the CPB-resistant potatoes demonstrate that the introduction of genetic information (DNA) into these potatoes to make them resistant to CPB does not result in any differences in the composition or nutritional quality of the potatoes. Health Canada has concluded that these potatoes are as safe and nutritious as other commercially available potato varieties.

(Health Canada, Safety Assessment of Potatoes Resistant to the Colorado Potato Beetle, April 1997)



Eric Millstone, Eric Brunner and Sue Mayer²¹ argued in the magazine *Nature*, (a top scientific journal that was the first to publish Crick and Watson's 1953 pioneering proposal that DNA is structured as a double helix) that substantial equivalence is a vague concept used to the advantage of the industry. They argue that:

Companies did not want to have to conduct toxicological experiments, which would delay access to the marketplace by at least five years and would add approximately US\$25 million per product to the cost of research and development... The adoption of the concept of substantial equivalence by the governments of the industrialized countries signalled to the GM (genetically modified) food industry that, as long as companies did not try to market GM foods that had a grossly different chemical composition from those of foods already on the market, their new GM products would be permitted without any safety or toxicological tests.

In addition they argue that:

The substantial-equivalence concept was also intended to reassure consumers... The biotechnology companies wanted government regulators to help persuade consumers that their products were safe, yet they also wanted the regulatory hurdles to be set as low as possible.

The Royal Society Panel also criticized the Canadian government's use of substantial equivalence:

The Panel finds the use of "substantial equivalence" as a decision threshold tool to exempt GM agricultural products from rigorous scientific assessment to be scientifically unjustifiable and inconsistent with the precautionary regulation of the technology. (p. ix) (See page 33 in this booklet on the precautionary principle)

The Panel also wrote that they were concerned that approvals may be based upon "unsubstantiated assumptions about the equivalence of the organisms, by analogy with conventional breeding." (p. 182)

The government argues in their defence that they don't use substantial equivalence in this way, but there is no evidence to confirm this since corporate data is protected, product review is different in each case and the review process is therefore not transparent.

C. TESTING

Because the government defines genetic engineering as nothing new, departments argue that safety testing is not necessarily needed. As discussed earlier, if a product is judged to be substantially equivalent it does not have to be tested and undergo extensive risk assessment. Substantial equivalence asks companies to evaluate their own products through comparisons and present these arguments to government scientific evaluators.

There is no long term testing.

There is no long term testing done to examine the health effects of eating genetically engineered food. For example, Health Canada argues that:

Given that the application of genetic modification does not introduce unique risk, the potential for long term effects of these foods are no different than that for conventional foods which have been safely part of the Canadian diet for a long time. Therefore there is no current evidence to indicate that long term studies are needed to ensure the safety of foods produced using this technology.

Professor Anne Clark of the University of Guelph has studied the government's summaries of their decisions (Decision Documents that are available for some but not all products and don't include test data) and argues that, "No effort was reported to test risk of chronic exposure, reflecting the risk to

humans routinely consuming GM crops over time, as through long term feeding trials."²²

Surveillance?

In February 2002 it was discovered that Health Canada, through their Centre for Surveillance Coordination at the Population and Public Health Branch, has in fact started the "Biotechnology Surveillance Project" to monitor any long-term health effects of eating genetically engineered foods (and using genetically engineered vaccines and therapeutics). This project is only at the stage of investigating how the department can survey for possible health problems and has yet to come up with a system – a task that might be difficult if they can't locate unlabelled genetically engineered foods in the food system.

The stated reason for beginning this project is not because of public health concerns but because the public is worried; "while many biotechnology developments will have a positive impact on human health, they also evoke a certain level of public concern and scepticism."

There is not even any long term monitoring of human health safety once food products are on grocery store shelves, though we have recently found out that Health Canada has started the new "Biotech Surveillance Project."

(See box) The British Medical Association argues that, if genetically engineered foods are on the market, mandatory labelling is necessary to trace possible health effects. Currently in Canada it is the responsibility of corporations to report any new evidence they find of negative health or environmental problems to the government.

There is no independent testing; instead the government relies on corporate data.

The government uses the term "assessment," rather than "testing," to describe their review process.

- The government does not do its own testing and there is no other independent testing done. All genetically engineered foods are approved through the government's "scientific evaluation"

of data developed and owned by corporations. Data is submitted by the product manufacturer and is then reviewed by scientists inside government departments. The data is corporate property and is not publicly available.

- The government does not outline standards for safety testing. Test methodologies are designed by the company that is presenting the data and wants to have their product approved, not by the government. After extensive study, the Royal Society Panel concluded that, “it appears to the Panel that no formal criteria or decision-making framework exists for food safety approvals of GM [genetically modified] products by Health Canada. Decisions are largely made on a case-by-case, ad-hoc basis.” (p. 37)
- The private ownership of data means that the public has no access to this information. The data owned by corporations is protected as a trade secret where companies themselves decide what is “Confidential Business Information.” The government publishes “Decision Documents” that describe their decisions to approve products but these do not include details of the design or results of any experiments.
- Lack of transparency compromises the scientific method and essentially renders data non-scientific. The Royal Society Panel observed that there are, “no means of determining the extent to which information requirements are actually met during the approval process or of assessing the degree to which the approvals are founded on scientifically rigorous information.” They argue that, “there is no means for independent evaluation of either the quality of the data or the statistical validity of the experimental design used to collect those data. Furthermore it appears that a significant part of the decision making process can be based on literature reviews alone.” The Panel concludes therefore that, “lack of transparency in the process raises questions concerning scientific rigor of the approval process.” (p. 214).

Peer Review is the process where independent scientists assess the work of others – it is a fundamental and defining practice of science. The science used to approve genetically engineered products is not peer reviewed and cannot even be accessed publically for review by other scientists. As the Royal Society Panel states, “peer review and independent corroboration of research findings are axioms of the scientific method, and part of the very meaning of the objectivity and neutrality of science.” (p. 214) Without peer review, the data used to approve products cannot be assumed to be good science, or indeed “science” at all.

“In the judgement of the Expert Panel, the more regulatory agencies limit free access to the data upon which their decisions are based, the more compromised becomes the claim that the regulatory process is “science based.” This is due to a simple but well-understood requirement of the scientific method itself – that it be an open, completely transparent enterprise in which any and all aspects of scientific research are open to full review by scientific peers.” (p. 214)

SUMMARY OF REGULATION :

From the CFIA website, "Frequently asked questions on genetically modified foods":

Question: What is the government doing to address the long-term impacts of genetically modified foods?

Answer: The foods that have been approved to date represent examples of relatively simple genetic engineering, involving the transfer of one or two genes that introduce a limited number of new traits, including resistance to an insect or a plant virus. A scientific comparison of their traits with those of conventional foods indicates that they are no less safe than conventional foods that have been safely part of the Canadian diet for a long time. The comparative approach permits linking the composition of the new food to existing products with a history of safe use, permitting prediction of the impact of the new food in the diet. Differences identified in the comparison are the focus of further detailed assessment.

However, as the science advances, should developments in the technology result in modifications that provide significantly different nutrient combinations or other novel food characteristics not previously encountered in the food supply, such foods may require additional considerations to permit comprehensive assessment. The guidelines for the safety assessment of novel foods provide this flexibility of approach. If Health Canada and CFIA scientists' assessments indicate that longer term studies are required, the food will not be approved and the organization applying for approval will be required to undertake the longer term studies and submit further detail before their application is considered further. At this time no products representing such true novelty to the food supply have been proposed for commercialization."

(<http://www.inspection.gc.ca/english/ppc/biotech/gen/faqe.shtml>, last accessed October 2001)

Keeping Corporate Data Private: Protecting Monsanto and Pushing rBGH

The excuse of protecting corporate trade secrets has been used to keep critical data away from Health Canada scientists, independent scientists, parliamentarians and the public.

In the case of rBGH, managers in Health Canada locked files away from government scientists.

They also censored an internal departmental report before handing it over to the Senate Committee on Agriculture. A leaked memo from the Minister of Health's office revealed that department officials were concerned about what Monsanto lawyers in the U.S. would think if some of their "confidential business information" came out in Senate hearings on rBGH. Health Canada managers were consequently planning to "engineer" the testimony of their scientists

in order to protect Monsanto.

Protecting Monsanto's secrets in this case was an attempt to

make sure rBGH was approved - it was eventually denied because of damaging scientific evidence that finally came to light after 10 years of public pressure.

CONFIDENTIAL

PART 3 : SEARCHING FOR DEMOCRACY

Adopting the Precautionary Principle: “Better Safe Than Sorry”

“When it comes to human and environmental safety there should be clear evidence of the absence of risks; the mere absence of evidence is not enough.”

- CONRAD BRUNK, CO-CHAIR OF THE ROYAL SOCIETY PANEL²³

This is an expression of the precautionary principle that focuses on reducing or eliminating hazard. The precautionary principle is promoted internationally as a way to prioritize health and environmental safety when regulating genetic engineering or other potentially harmful technologies. It advises us to take action to anticipate and prevent harm even when we don't have conclusive evidence about causes. This is because it is extraordinarily difficult to establish cause and effect when we introduce new technologies (like PCBs and CFCs for example) into our complex ecosystem.

The precautionary principle is invoked when there is recognition of potential harm and of scientific uncertainty - both of which are denied by the Canadian government in the case of genetic engineering.

The precautionary principle states:

“When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause-and-effect relationships are not fully established scientifically.”

- FROM THE 1998 WINGSPREAD STATEMENT ON THE PRECAUTIONARY PRINCIPLE

or

Lack of scientific certainty due to insufficient relevant scientific information and knowledge shall not prevent parties from taking decisions aimed to avoid adverse or minimize effects.

Contrary to this, the Canadian government concludes that because they see no scientific evidence that proves genetically engineered foods are dangerous, they must be safe:

“Health Canada has been reviewing the safety of foods derived from genetic modification for the last seven years, and is not aware of any scientific evidence which demonstrates that genetically modified foods are less safe than traditional foods.”

“FREQUENTLY ASKED QUESTIONS ON GENETICALLY MODIFIED FOODS”

([HTTP://WWW.CFIA-ACIA.AGR.CA/ENGLISH/PPC/BIOTECH/GEN/FAQE.SHTML](http://www.cfia-acia.agr.ca/english/ppc/biotech/gen/faqe.shtml))

(As discussed earlier, Health Canada does not actively seek out this scientific evidence.)

The precautionary principle has its origin in 1970s German environmental law and is recognized as customary international law. The precautionary principle is a part, in various forms, of international statements and agreements including the 1992 Rio Declaration on Environment and Development and the Cartagena Protocol on Biosafety which regulates trading in genetically engineered organisms. The principle appears in the Canadian Environmental Protection Act (CEPA) but with the qualifier that any precautionary action must be “cost effective.”

The precautionary principle challenges the power that corporations have over safety regulations because it challenges decision making to become more democratic.

The precautionary principle raises the following questions and considerations:

- Are there alternative technologies or products that we could use that are less risky? Do we really need this technology?
- Scientific study is important but science also has limitations. Science cannot be isolated from political and ethical issues - decisions to act or not act are political.
- The burden of proof and responsibility for precaution must be placed on the proponents of the activity or those who have resources, in this case the corporations that are developing and selling genetically engineered products.
- People who will be affected by a new technology must have a say in decisions about risk.
- Preventative action must be taken at the very first stages in technology design.

The precautionary principle requires democracy in the development and approval of genetically engineered products. It opens up the option that any new technology can and should be rejected if necessary. It also demands that corporations take responsibility for proving their products are safe.

“A total ban may not be a proportional response to a potential risk in all cases. However, in certain cases, it is the sole possible response to a given risk.”

– EUROPEAN COMMISSION²⁴

(For more information on the precautionary principle see the Science and Environmental Health Network, www.sehn.org)

What About Parliament?

The role of Parliament in decision-making is decreasing as the influence of the biotech industry over government increases. More decisions are being made inside department bureaucracies like Health Canada and Agriculture and Agri-Food Canada, without the involvement of elected representatives.

Thanks to some Members of Parliament, however, various House of Commons and Senate committees have contributed to a public debate by examining aspects of genetic engineering. Through parliamentary committees our representatives can study issues and seek out divergent perspectives. Committee hearings offer a unique opportunity to hear from many voices in a debate and the testimony and evidence is recorded and made publicly available. Parliamentary committees can also demand information from government departments that no one else can get.

In 1994 the House of Commons Committee on Agriculture and Agri-Food studied rBGH, as did the Senate Committee on Agriculture and Forestry in 1998. Both of these hearings were instrumental in providing places for democratic debate on the issue and in uncovering new and vital information. In 1996 the House of Commons Standing Committee on the Environment and Sustainable Development also made many recommendations for improving the regulation of genetic engineering .

Mandatory Labelling

The issue of labelling illustrates how far our Government will go to protect corporate profits. The Canadian government opposes mandatory labelling of genetically engineered foods despite 8 polls between 1994 and 2001 confirming that over 90% of Canadians want labelling.

Health Canada and the CFIA share responsibilities for food labelling under the *Food and Drugs Act*. Health Canada is responsible for labelling with respect to health and safety matters and the CFIA is responsible for the development of non-health-and-safety labelling – for example, labelling foods to meet the needs of religious communities.

Instead of legislating mandatory labelling our Government says it wants to give consumers more information: “The Canadian Food Inspection Agency strongly supports providing consumers with information to help them better understand the nature of their food choices.”²⁵ So our Government is spending public money to “educate” Canadian consumers while blocking attempts to get mandatory labelling. This way the Government and corporations hope to convince us to accept genetically engineered foods, long before they are labelled on grocery stores shelves and we have the chance to reject them. (The industry

is fighting labelling because, as a 2001 ABC News poll found, over half of all people in the U.S. are less likely to eat genetically engineered foods if they were labelled.)

The government's only response to the overwhelming public call for mandatory labelling, aside from its consumer "education" initiatives, has been to strike a committee to create a national standard for **voluntary labelling**. In September 1999 the Canadian General Standards Board formed a *Committee on Voluntary Labelling of Foods Obtained Through Biotechnology* (which promptly changed its name to the *Committee on Voluntary Labelling for Foods Obtained or Not Obtained through Genetic Engineering* and then to switched terminology again to *Genetic Modification*).

Voluntary labelling means that a company can label its products as free from genetic engineering, or as containing genetically engineered ingredients, if it wants to. Voluntary labelling has always been an option in Canada though there has been no national standard for what wording the label should use.

Mandatory labelling means that **all** genetically engineered ingredients must be labelled by law.

The committee was an initiative of the Canadian Council of Grocery Distributors (CCGD)- a national organization representing about 80% of grocery and supermarket companies in Canada. Agriculture and Agri-Food Canada is actually funding the process through grants to the CCGD, an association that promotes genetic engineering.²⁶

The Canadian General Standards Board states that it is acting to "manage the development of a voluntary consensus standard by using a balanced committee

of experts providing broad-based input to the standard." The committee however is not balanced since most of the public groups that were invited (over 25) declined to participate in the process (with the notable exception of the Consumer's Association of Canada (CAC) which is against mandatory labelling) and demanded that the committee develop a standard for mandatory, not voluntary, labelling. (There was a conflict of interest with the CAC representative Lee Anne Murphy who was elected committee chairperson at the first meeting but resigned a year later to take a job with Monsanto.)

At the same time, the Government is using the phrase "mandatory labelling" in a misleading way by saying we have "mandatory labelling of foods where significant nutritional or compositional changes have been made in comparison to foods already on the marketplace." This only means that when we know a food causes allergies or is less nutritious this will be stated on the package. This is not the mandatory labelling of all genetically engineered foods that is being called for.

Close to 40 countries have or are developing mandatory labelling legislation including Australia and China as well as the European Union.

The Consumer's Association of Canada working for Corporate Interests

The Consumer's Association of Canada (CAC) has been actively working against mandatory labelling for years. The CAC takes the view that labels would be too confusing, not useful, and that consumers need more information about genetic engineering first, from other sources. This is why the CAC is a part of the Food Biotechnology Communications Network (FBCN) (see page 20) and develops education materials with the biotech industry.

The CAC does not believe in the consumer right to know or in labelling for ethical or religious reasons:

No one has denied that consumers have a right to know about a product when it relates to health and safety; however, when products are derived from a genetic engineering process, such as transferring genes across species or addressing non-health or safety concerns, the responsibility of government and industry to inform the consumer is much less clear. CAC believes that labelling is a problematic and impractical way to meet a consumer's need to know.

(Chris Mitchler, Consumer's Association of Canada, House of Commons Committee on Environment and Sustainable Development, June 5, 1996)

The CAC have been a part of government consultations and meetings since the early 1990s and their participation is regularly used by the government to say that they have consulted with consumers and public interest groups.

International Trade Regimes and Rules that Protect Corporations: "Trade made me do it"

International trade regimes are having an important impact on national regulation of genetic engineering. As Canada's Auditor General observed, "The regulation and inspection of food is increasingly a part of international trade agreements and economic competitiveness."²⁷ The Department of Foreign Affairs and International Trade is therefore playing an a greater role in making decisions about genetic engineering.

International trade regimes establish rules to ensure the free flow of goods and services across national borders and subordinate regulations for human health, the environment, ethics and social considerations to this supreme economic objective. Thus, the Canadian Government is passing over its responsibilities

for regulating food and environmental safety onto international trade bodies like the World Trade Organization (WTO), organizations that are not democratically run and are not accountable to local peoples.

Our Government is now using Canada's commitments in international trade agreements as an excuse not to regulate nationally on genetic engineering. The Canadian Biotechnology Advisory Committee (in a report that did not call for mandatory labelling) argued that, "A mandatory labelling system might...be considered to be contrary to international trade obligations. This could draw retaliation from trading partners and harm the international competitiveness of Canadian GM food products."²⁸ Similarly, there is evidence that national bans on genetically engineered food could be challenged

Codex

The WTO uses the voluntary guidelines created by the United Nation's Codex Alimentarius Commission as standards for its rulings on food safety and labelling. At the Codex, delegates from national governments negotiate standards. In these negotiations, Canada has obstructed all efforts to agree on a standard label for genetically engineered foods. In the past, Canadian government delegates also tried to have rBGH approved through Codex while it was still being reviewed by Health Canada.

as barriers to trade under WTO rules. For example, in order to continue their ban on importing hormone-produced beef, the WTO ruled that the European Union had to pay compensation to Canada and the U.S. for lost export revenue.²⁹

Trade regimes thus enforce the harmonization of regulatory approaches. This means that national regulations cannot be stricter than internationally

established levels of protection and that the WTO can rule any stricter regulations as barriers to trade. As the Canadian Codex office argues, "countries which establish requirements that are more stringent than the standards, guidelines and recommendations developed by Codex could be required to provide justification for their higher standards if a trade dispute arises."³⁰ Only scientific justification is allowed, however, because harmonizing regulation is only possible if rules are based on "scientific evidence". These trade regimes therefore also reinforce the move away from considering social and ethical issues in decision-making.

In addition, trade challenges brought to the WTO are decided by dispute panels of appointed trade experts (not food safety or environmental experts) who can second guess the evidence used to form food safety standards.

The WTO contains several bodies of rules that serve, in effect, to protect the interests of the biotech industry: the SPS Agreement (Agreement on Sanitary and Phytosanitary Measures), TRIPS (Trade Related Aspects of Intellectual Property Rights) and the TBT Agreement (Agreement on Technical Barriers to Trade). The SPS Agreement, for example, strives to eliminate differences in food regulations,

it covers food safety and livestock, fisheries and plant health and relies on Codex standards and the industry funded ISO (International Organization for Standardization). The SPS rules were used to defeat the EU's ban on hormone-treated beef. Under the TBT, the U.S. government argues that mandatory food labelling is an illegal barrier to trade. This is while the TRIPS Agreement provides corporations with the tools to claim and protect intellectual property, appropriating traditional knowledge and then denying countries access to seeds and medicines that they cannot afford. (See *Galloping Gene Giants*, Polaris Institute)

Even in the face of these agreements, however, peoples and governments across the world are challenging the influence of trade rules over regulation. People are demanding that their governments establish regulations to protect social values, human health, and the environment, as in the case of countries that are labelling genetically engineered foods for example, even at the risk of provoking a trade challenge. Protest of trade regimes as vehicles for corporate control over national policy making has become widespread across the world and across sectors of society.

“Science-Based” Regulation: Excluding the Public, and Social and Ethical Concerns

In order for corporations to control the introduction of genetic engineering, the public is excluded from the process of product review. The public receives no notice of foods or crops that have been submitted for market approval and has no input into these decisions.

Canadian regulation defines the question of risk as a scientific one and therefore not an issue for ordinary citizens. By defining risk as a **technical question**, the government tells us to trust the experts instead. We are asked to accept genetically engineered products if they are judged safe by the Canadian government, regardless of our possible objections on other (non-scientific) grounds such as ethical, social or economic concerns.

The industry benefits greatly from this so-called “science-based” review and corporations lobbied hard for this government reliance on what they refer to as “sound science”:

“Science must continue to be the basis of regulations. Other issues, such as socio-economic and ethical issues, are too variable and could be used by industry opponents to hold up the approval of new products indefinitely.”

-PRESIDENT OF AG-WEST BIOTECH, MURRAY McLAUGHLIN (AGBIOTECH BULLETIN, JUNE 1995)

THE ROLE OF SCIENCE IN SOCIETY

- We all rely on science. Governments depend on scientific advice and a degree of certainty in order to make decisions about new technologies. But there is increasing scientific uncertainty as we create more and more complex technologies. How can government's make decisions when there is scientific uncertainty?
- We may have unrealistic expectations about the certainty that science can deliver. Science cannot necessarily find all the answers we need and there may not be a technological answer or "technological fix" to every problem that we create. We may need to recognize the limitations of science as well as the values embedded in science.
- Science cannot answer the question "how do we want to live?" And appealing exclusively to science in decision-making can close down democratic debate and public participation. People who live in communities affected by the introduction of new technologies, like farmers for example, have

If it's Science it's got to be good: Trust us, we're the experts

In a 1999 CBC Radio interview the Minister of Agriculture and Agri-Food, Lyle Vanclief, was asked about the CFIA's conflicting roles in both promoting and regulating genetic engineering. Vanclief replied, "I am not a promoter of biotechnology. I'm a promoter of anything we can do that is based on sound science."

knowledge to contribute about the risks of new technologies, knowledge which is usually ignored.

As the Royal Society Panel concluded, "It is now generally recognized in scholarly literature on the nature of risk analysis that many aspects of the

task of assessing the magnitude of technological risks and managing them within the limits of safety involve judgments and decisions that are not themselves strictly scientific." (p. 8)

In answer to the question

"Who decides whether or not we need these products?"

the government states:

*The Canadian Food Inspection Agency and Health Canada regulate for safety and efficacy of these products, but are not responsible for evaluating need. The issue of whether or not these products are "necessary" is left to the market place to determine.*³¹

In the case of Bovine Growth Hormone (rBGH) our government was ready to approve the drug and "let the market decide" even though there was wide-spread public opposition to its introduction (much like there is for GE wheat). Many sectors of society agreed that using the drug would create

animal welfare problems and result in harmful social and economic upheaval - but these objections were not judged as relevant to product review, instead only scientific questions of safety were considered. Farming communities believed introducing rBGH would hurt small farmers, dairy farmers did not want to inject their cows and were afraid of effects on animal health and welfare, people did not want to drink milk produced with a hormone that forced cows to produce more milk, and the product was generally seen as unnecessary since Canada actually has a milk surplus.

Because of public protest Health Canada finally rejected rBGH. However, Health Canada cited scientific reasons (related to animal health concerns) to justify its ban because, under international trade rules, Canada can only refuse a product based on scientific rationale and scientific evidence, not on the expressed will of the public.

Public participation, in the form of considering the ethics of a new technology for example, would slow down product approval and therefore be costly for corporations. As seen in the case of rBGH, public engagement can threaten product approval. Because the regulatory system is designed to approve genetically engineered products quickly, it therefore excludes the public and tries to avoid democratic debate.

Deliberately Undemocratic “Consultations”

The Canadian government wants to protect the biotech industry and because democratic debate threatens the future of genetic engineering, the government is keeping the issue far away from a full debate.

To avoid starting a democratic debate in Parliament and allowing any real public participation in decision-making, the Government has formed advisory committees and set up limited “consultation” processes instead. These consultations are designed to control public input and legitimate government decisions.

The CFIA insists that it consulted with Canadians before it developed its regulatory approach (its use of “substantial equivalence”) but Brewster Kneen was at these consultations and says that those who attended were “a small group, essentially self-selected with government and industry well represented along with the Consumers Association of Canada.” Kneen says that, contrary to the consultation reports and all subsequent government actions, the meetings did not reach consensus. (See www.ramshorn.org April 2000 “A Common Script” for the full story on how Brewster sees the government using his participation to justify its decisions.)

CANADIAN BIOTECHNOLOGY ADVISORY COMMITTEE

The one thing that the government has done in the name of public participation is to set up advisory committees. In 1988, the National Biotechnology Advisory Committee (NBAC) argued that, “The system should remain “open” [quotation marks are theirs] to allow the public and members of special interest groups to participate in the process through, for instance, advisory committees.” NBAC was replaced ten years later by the Canadian Biotechnology Advisory Committee (CBAC). CBAC was established to advise the government on issues like ethics and social impacts but still with the primary goal of ensuring a future for biotechnology and assuming its benefits. CBAC is described as “an expert, arm’s length committee to advise Ministers on biotechnology issues, raise public awareness and engage Canadians in discussions on biotechnology matters.” CBAC refers to their role not in terms of democratic debate but as promoting a “national conversation” on biotechnology issues.

CBAC is housed in Industry Canada and its committee members were chosen to the exclusion of many renowned and respected critical voices, while a number of well-known and vocal industry supporters were appointed.

In CBAC’s 2001 interim report the committee accepts the government’s category of novel foods and uses the phrase “GM and other novel foods.” The CBAC report talks of “improving” Canada’s regulation while refusing to recommend mandatory labelling. (See www.cbac.gc.ca)

Critics are calling for debate in Parliament and extensive public hearings rather than scattered advisory committees and “consultations”.

Conclusion

The Canadian Government has invested heavily in supporting the growth of a Canadian biotech industry and in promoting genetic engineering to the Canadian public. This has created a serious conflict of interest in the government’s role regulating the new technology. Some of the world’s most powerful transnational corporations now rely on the Canadian government to approve their products for sale. These corporations have a great deal of influence over the regulatory system – a system that is not democratic and is being used instead to subvert the democratic process.

In a democracy:

- The precautionary principle should guide technology development and regulation.
- Communities affected by the introduction of new technologies, like farmers and consumers, should have a say in the future of that technology.

- Science should be publicly run, in the service of the public. The development of new technologies should be democratically determined through a public research agenda.
- Rejecting any new technology should always be a policy option.
- Social and ethical concerns - not just economic and scientific ones - should be central in making decisions about new technologies.

In order for the government to make fundamental changes to the regulatory system and start an open public debate it needs to put a hold on all new approvals and to label or remove all foods presently on grocery store shelves.

The use of genetic engineering in agriculture has met with widespread opposition in Canada. United opposition successfully stopped the Canadian government from approving rBGH. Today, across the country, people in various communities are resisting the introduction of genetic engineering and increasing corporate control over our food system and our government by demanding accountability from our representatives.

Recommended Books

Altered Harvest: Agriculture, Genetics and the Fate of the World's Food Supply Jack Doyle, Penguin Books, New York, 1986.

Farmageddon: Food and the Culture of Biotechnology Brewster Kneen, New Society Publishers, Gabriola Island, British Columbia, 1999.

Galloping Gene Giants: How big corporations are re-organizing their push for a biotech future and what can be done to challenge this agenda Tony Clarke with Brenda Inouye, Polaris Institute, February 2002.

Genetic Engineering: Dream or Nightmare? Dr. Mae-Wan Ho, Continuum Publishing Company, New York, 1998.

Genetic Engineering, Food, and Our Environment Luke Anderson, Chelsea Green Publishing Company, White River Junction, Vermont, 2000.

The Ram's Horn Newsletter Brewster Kneen, S6, C27, RR#1 Sorrento BC V0E 2W0 phone/fax: 250-675-4866
<http://www.ramshorn.bc.ca/> ramshorn@ramshorn.bc.ca

Redesigning Life? The Worldwide Challenge of Genetic Engineering Edited by Brian Tokar McGill-Queen's University Press, Montreal & Kingston, 2001.

Silent Coup Confronting the Big Business Takeover of Canada Tony Clarke, Canadian Centre for Policy Alternatives, 1997.

Websites of Interest

Action Group on Erosion, Technology and Concentration
(ETC group) (formerly Rural Advancement Foundation International)www.etcgroup.org

Ag-West Biotech Inc.www.agwest.sk.ca

BIOTECCanadawww.biotech.ca

Canadian Food Inspection Agencywww.inspection.gc.ca

Canadian Institute for Environmental Law and Policywww.cielap.org

Corporate Watch UKwww.corporatewatch.org.uk

Corporate Watch USwww.corporatewatch.org

Food Biotechnology Communications Network (FBCN)www.foodbiotech.org

The Royal Society of Canadawww.rsc.ca

Third World Networkwww.twinside.org.sg

Action Group Contacts

The Council of Canadians

502-151 Slater Street,
Ottawa, Ontario, K1P 5H3
Tel: 613-233-2773, 1-800-387-7177
Fax: 613-233-6776
www.canadians.org
inquiries@canadians.org

The Canadian Health Coalition

2841 Riverside Drive
Ottawa, ON K1V 8X7
Tel: (613) 521-3400 (Ext. 219 #)
Fax: (613) 521-9638
www.healthcoalition.ca
chc@clc-ctc.ca

The National Farmers Union

2717 Wentz Avenue,
Saskatoon, SK S7K - 4B6
Tel: (306) 652 - 9465
Fax: (306) 664 - 6226
www.nfu.ca
nfu@sk.sympatico.ca

Greenpeace Canada

250 Dundas St. W, Suite 605,
Toronto, Ontario M5T 2Z5
Phone: 416-597-8408
Fax: 416-597-842
www.greenpeacecanada.org
greenpeace.toronto@dialb.green-
peace.org

The Sierra Club of Canada

National Office 412-1 Nicholas St.,
Ottawa, Ontario, K1N 7B7
Tel: (613) 241-4611 Fax: (613) 241-2292
www.sierraclub.ca
sierra@web.ca

This booklet was produced by the Polaris Institute

312 Cooper Street, Ottawa,
Ontario, K2P 0G7,
Tel: (616) 237 1717
Fax: (613) 237 3359
www.polarisinstitute.org
polarisinstitute@on.aibn.org

For more information or to provide feedback on this publication please contact Lucy Sharratt at the Polaris Institute lucy_sharratt@on.aibn.org See the Polaris Institute website for corporate profiles and further information on the biotechnology industry including the publication *Galloping Gene Giants*. The Polaris Institute also offers various workshops on genetic engineering and corporate power.

ENDNOTES

1. Health Canada, the Canadian Food Inspection Agency and Environment Canada requested the Royal Society of Canada undertake this study. The Royal Society is a senior national body of distinguished Canadian scientists and scholars. The government responded with an "Action Plan" <http://www.hc-sc.gc.ca/english/protection/royalsociety/index.htm>.
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5. Lori Coolican *Star Phoenix* 11 July 2001.
6. House of Commons Committee on the Environment and Sustainable Development, testimony, 5 June 1996.
7. Canadian Institute for Environmental Law and Policy *The Citizen's Guide to Biotechnology* 1995, p.26.
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9. Government of Canada *Investing in Canada's Dynamic Agricultural Biotechnology Sector* 1998.
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12. Agriculture and Agri-Food Canada *Spotlight on Research* 1999-20001.
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14. Burston Marsteller, *Government and Public Affairs Communications Programme for EUROPABIO* January 1997.
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16. CBC Radio, "Secrecy surrounds GM wheat trials in P.E.I." 27 July 2001.
17. Elizabeth Abergel *Growing Uncertainty: The Environmental Risk Assessment of Genetically Engineered Herbicide Tolerant Canola in Canada* PhD. Thesis, November 2000, p. 188.
18. Canadian Food Inspection Agency, Office of Biotechnology *Regulating Agricultural Biotechnology in Canada: An Overview*.
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20. KPMG *Biotechnology in Canada: Poised for Growth* May 1994, p.9.
21. Erik Millstone is a professor in Science and Technology Policy Research, University of Sussex; Eric Brunner is in the Department of Epidemiology and Public Health, University College London and Sue Mayer is at GeneWatch UK. Their article is "Beyond 'substantial equivalence'" *Nature*, 401, 1999, pp. 525-526.
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24. Commission of the European Communities *Communication from the Commission on the precautionary principle* 20 February 2000, p.4.
25. Canadian Food Inspection Agency *Building Biotechnology Capacity at the Canadian Food Inspection Agency*.
26. From Access to Information documents obtained by Bradford Duplisea of the Canadian Health Coalition.
27. Report of the Auditor General of Canada - December 2000 Chapter 24, p.13.
28. Canadian Biotechnology Advisory Committee *Improving the Regulation of Genetically Modified Food and Other Novel Foods in Canada: Interim Report* August 2001 p.40.
29. Instead of accepting compensation from the European Union the US chose to impose punitive duties on selected imports including Rochfort cheese - the cheese that French farmer Jose Bove makes. Jose Bove now works internationally against the WTO.
30. Office of the Codex Contact, Canada, 1998.
31. Canadian Food Inspection Agency, Office of Biotechnology, *Regulating Agricultural Biotechnology in Canada: An Overview* <http://www.inspection.gc.ca/english/ppc/biotech/reg/bioage.shtml>