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Canada

AGRICULTURAL BIOTECHNOLOGY ANNUAL

Agricultural Biotechnology Annual

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Report Highlights:

Canada is ranked as the fifth largest producer of biotech crops in the world, with 7.6 million hectares planted, following behind the United States, Argentina, Brazil and India, respectively. This is according to a report released by the International Service for the Acquisition of Agri-biotech Applications (ISAAA) in February 2009, The four major biotech crops produced in Canada are canola, corn, soybeans, and sugarbeets (in very small amounts). Crop data for 2008/2009 on crop average sown and crop size dedicated to biotech varieties was largely unavailable. Using data based on planting surveys, in 2009, it is estimated that about 62% of corn for grain seeded is biotech corn and that about 43% of soybeans seeded is biotech varieties. This represents a 9.6 % increase in share of biotech corn from 2008 levels. For soybeans, this represents a 7.4 % decrease in biotech soybean share from year 2008 levels. According to the survey results, Canadian grains and oilseeds producers seeded 6.5 and 6.4 million hectares to canola in 2008 and 2009, respectively. Almost all canola grown in Canada is biotech. Production of biotech sugar beets is expected to increase is Western Canada with the announcement that Canadian sugar company Lantic Inc., which owns the only sugar beet processing plant in Canada, has made the decision to allow biotech sugar beets in its sugar production. Areas of this report have been updated to include data on crops submitted for regulatory approval, field trial submissions, approved biotech crops. This report now includes an animal biotechnology section. Canada is a leader in the development of animal biotechnology with applications in the livestock and aquaculture industries. There are currently three biotech animal projects being pursued for purposes of (eventual) commercialization. These three projects include Guelph University's the Enviropig, (an "environmentally friendly" breed of pigs that utilizes plant phosphorus efficiently), Aqua Bounty's fast-growing salmon, and Nexia's transgenetic goats. Canadian regulators are currently working on the development of a more robust and predictable process for the regulation of these new technologies.

Section I. Executive Summary:

The United States is Canada's most important and largest trading partner, with Canada exporting roughly 60% of its agricultural

products to the United States on an annual basis. In addition, Canada is the number one export market for U.S. agriculture products. The U.S. exports roughly 14% of its agriculture products to Canada on annual basis. The signing of the Free Trade Agreement and the North American Free Trade Agreement has greatly increased the flow of products in both directions. In addition, Canada, the U.S. and Mexico are working cooperatively in the development of regulatory policy related to the biotechnology sectors in the three countries, through the North American Biotechnology Initiative (NABI).

Canada is a signatory to the Cartagena Protocol, but there has still been no movement by the Government of Canada to ratify it. Within the Canadian agriculture industry there has been strong arguments for and against the Protocol's ratification. For the medium term, the Canadian government will keep the decision on ratification under active review while continuing to participate in Protocol processes as a non-Party and acting voluntarily in a manner that is consistent with the objective of the protocol. Canada relies heavily on U.S. exports of major grains and oilseeds like corn and soybeans to meet the needs of its processing and livestock industries. The ratification of the Protocol by Canada could have an impact on future imports of biotech grains from the United States.

Canada's regulatory system is science-based. Canada's regulatory process is based upon the traits expressed and not on the basis of the method used to introduce the traits. Canada biotechnology is defined as "the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms." This broad definition encompasses products produced through various techniques including conventional breeding, mutagenesis, and genetic engineering.

In order to obtain regulatory approval for a plant with novel traits (PNTs) or novel foods, the products must go through the six-steps of Canada's regulatory process. The Canadian Food Inspection Agency (CFIA), Health Canada and Environment Canada are the primary agencies responsible for monitoring and regulating the approval of a new product. The CFIA is responsible for granting approval for commercial release and use of a new product in livestock feed. Health Canada is responsible for providing approval for the consumption of a new product in the human food market. Environment Canada is involved when there is potential impact on the environment by a new product. From the time of development to the approval of a PNT or novel food can take anywhere between seven to ten years, and in some instances even longer.

Canada's biotech industry continues to grow as more and more producers are relying on biotech crops to meet their needs. With institutions like Agriculture and Agri-Food Canada, Genome Canada, Plant Biotechnology Institute, the University of Guelph, the University of Saskatchewan, Laval University and all private companies investing time and money into the development of new crops in Canada, the biotech industry in the country will continue to flourish and grow.

Section II. Biotechnology Trade and Production:

Canada is ranked as the fifth largest producer of biotech crops in the world, with 7.6 million hectares planted, following behind the United States, Argentina, Brazil and India, respectively. This is according to a report released by the International Service for the Acquisition of Agri-biotech Applications (ISAAA) in February 2009. The four major biotech crops produced in Canada are canola, corn, soybeans, and sugarbeets.

As Statistics Canada does not keep detailed data sets on biotech plants grown in Canada, planting surveys conducted by Statistics Canada provide the best estimate of the level of biotechnology adoption by agricultural producers. The following estimates are based on the June farm surveys for year 2008 and 2009, which is Statistics Canada's largest area survey. According to the survey data, Canadian agricultural grains and oilseeds farmers planted 1,204.0 and 1,406.6 thousand hectares (THT) of corn (for grain) in 2008 and 2009, respectively, and seeded 1,202.4 and 1,230.6 THT of soybeans in 2008 and 2009, respectively. According to the survey results, Canadian grains and oilseeds producers seeded 6,539.6 and 6,404.0 THT to canola in 2008 and 2009, respectively. In 2009, it is estimated that 61.8% of corn for grain seeded is biotech corn and that 42.9% of soybeans seeded is biotech. This represents a 9.6 % increase in share of biotech corn from 2008 levels. For soybeans, this represents a 7.4 % decrease in biotech soybean share from year 2008 levels.

Quebec and Ontario are the primary corn growing regions in Canada, accounting for over 92% of the corn acreages in Canada. Acreages seeded to grain corn in 2009 are reported to be 395.0 THT and 738.6 THT for Quebec and Ontario, respectively. Quebec and Ontario are also the primary soybean growing regions in Canada, accounting for a little over 85% of soybean acreages in Canada in 2009. Acreages seeded to soybeans in 2009 in Quebec and Ontario are reported to be 242.0 THT and 971.2 THT, respectively.

In 2009, Quebec farmers report planting 275.0 THT of biotech corn (for grain). Biotech corn in 2009 as a percentage of the total provincial corn for grain acreage increased from 58.7% in 2008 to 69.6% in 2009. Quebec farmers also report planting 118.0 THT of biotech soybeans in 2009. Biotech soybeans in 2009, as a percentage of total provincial soybeans seeded increased only marginally, from 48.7% in 2008 to 48.8% in 2009.

In 2009, Ontario farmers report planting 485.6 THT of biotech corn (for grain). Biotech corn in 2009, as a percentage of the total provincial corn for grain, increased to 65.7% in 2009 from 55.7% in 2008. Ontario farmers also report planting 485.6 THT of biotech soybeans in 2009. In 2009, the total area of biotech soybean, as a percentage to the total provincial area seeded to soybeans, decreased from 57.8% in 2008 to 50% in 2009.

Western Canada, which is comprised of the provinces of Manitoba, Saskatchewan, Alberta and British Columbia, is the primary canola-growing region in Canada. In 2009, 30% of the grains and oilseed crop acreages were dedicated to canola, most of which were of the herbicide tolerant variety. In 2009, 6.373.8 million hectares (MHT) were seeded to canola, representing a 1.9% decrease from 2008 levels. This slight decrease, after years of steady growth in acreages, is likely due to rotational constraints and drought-like conditions in parts of western Canada. With the continual development of new biotech varieties, the expectation is that the area sown to biotech crops in Canada will continue to increase. This is especially true with the development of biotech crops that are considered a health benefit. For example, some varieties of canola and soybeans have been developed with modified fatty acid contents to cater to the populace concerned about trans fatty acids.

Nearly 80% of Canadian sugar beet production takes place near Taber, Alberta, where Canada's only sugar beet processing plant is located. Smaller amounts of sugar beets are produced in Ontario and in Prince Edward Island (PEI) for bio-fuels production. According to industry sources, PEI farmers, in 2008, grew approximately 1,400 hectares of biotech sugar beets for biofuel production, and the expectation is that that number will double by 2009. Canadian sugar company Lantic Inc., which owns the only sugar beet processing plant in Canada has made the decision to allow biotech sugar beets in its sugar production. This is expected to lead to increased amounts of GM sugar beets being planted in Alberta (no official statistics exist at this time).

The Canadian Food Inspection Agency (CFIA) is one of the regulatory bodies responsible for determining whether plants with novel traits (PNTs) are safe for use in feed and release into the environment. The regulatory approval procedure is ongoing and the CFIA is continually receiving new PNTs to assess. Below is a list of PNTs that have been submitted for regulatory approval to the CFIA as of July 2009.

Table 1. Crops Submitted and Awaiting Regulatory Approval

Product for Submission	Developer
Soybean (CV 127) which has been genetically modified for imidazolinone herbicide tolerance	BASF Canada Inc.
Cotton (T304-40 x GHB119) which has been genetically engineered for lepidopteran insect resistance and glufosinate-ammonium herbicide tolerance	Bayer CropScience Inc.
Corn (MON 87460) which has been genetically modified for drought tolerance	Monsanto Canada Inc.
Helianthus annuus, which has been developed for herbicide tolerance using mutagenesis and conventional breeding	BASF Canada Inc.

Source: Canadian Food Inspection Agency
http://www.inspection.gc.ca/english/plaveg/bio/pbopnte.shtml; website last accessed July 6, 2009
Since Post's last annual biotechnology report, one biotech crop, a soybean with high oleic, low linoleic and linolenic acid traits developed by Pioneer Hi-Bred, has received approval. The Plant Biosafety Office of the Plant Health and Biosecurity Directorate and Animal Feed Division of the Animal Health Directorate authorized the unconfined release into the environment and use as livestock feed of soybean event 305423 as of April 30, 2009. The soybean event was developed to provide the food and industrial oil sectors with a highly stable vegetable oil suitable for frying applications without the need for hydrogenation, and for formulation of industrial fluids. Canadian Food Inspection Agency published its decision document, within which was included the conditions under which the soybean event 305423 can be used. The soybean event 305423 received food safety approval from Health Canada on May 6, 2009.
The time between when a PNT is granted regulatory approval by the CFIA and Health Canada for commercial release and when a PNT is introduced into the market is dependent upon the company producing the product.

Imports

Canada imports biotechnology crops and products. This includes grains and oilseeds, specifically corn and soybeans. Many of Canada's secondary industries like the ethanol industry in Ontario import U.S. corn that is available right across the border. In addition, Canada's hog industry and to a lesser extent the beef industry also import corn and soybean from the United States. As a majority of the corn and soybeans grown in U.S. are biotech, this is what Canada imports. In addition, Canada also imports biotech papaya from Hawaii.

Development of Biotech Crops

A majority of the biotech products that have received regulatory approval in Canada have also gone through the regulatory process in the United States. It is an unwritten rule, but a general understanding that when a company chooses to introduce a new biotech product, regulatory approval is sought in both Canada and the United States. Because of the quantity and free flow of goods moving across the border on a daily basis, many of the multinationals, which generally have offices on both sides of the border, apply for regulatory approval for a PNT in both the U.S. and Canada at or close to the same time. This ensures than anything that is approved in one country is not hindered in its movement to the other country by lack of regulatory approval. In addition, approval in both countries eliminates any issues that may arise due to accidental contamination. There are many instances were biotech crops not grown in Canada have obtained regulatory approval here because those crops are grown in the United States. For example, the Canadian climate does not permit the growing of cotton, but several varieties of biotech cotton have been approved in Canada. For the most part, developers of biotech products that have received regulatory approval in Canada will most likely apply for regulatory approval in the United States. For products like wheat and canola developed through mutagenesis, which by the definition of biotechnology in Canada falls under the PNT heading and require regulatory approval, do not require regulatory approval in the United States.

Section III. New Technologies:

I. Development and Use:

Currently, animal biotechnology research is permitted in Canada, including research on livestock animals; however the animals must be housed in contained facilities to prevent release from the facility of the animal, its genetic material in living cells, or any material which might be associated with toxicity. To date, no animals produced using biotechnology have been approved for release into the Canadian environment, or into the food or feed chain. Specific projects being conducted in Canada at the time of this report include The Enviropig™, Aqua Bounty, and Nexia Biotechnologies of Montreal's transgenic goats.

The Enviropig™ is an "*environmentally friendly"* breed of pigs that utilizes plant phosphorus efficiently. Researchers at the University of Guelph in Ontario have developed a new breed of Yorkshire pigs trademarked Enviropig™ that use plant phosphorus more efficiency. Today's commercial pigs (i.e., non-transgenic pigs) are unable to use an indigestible form of phosphorus called phytate present in cereal grain diets. Therefore commercial hog producers add supplemental phosphate or phytase enzyme to the diet in order to meet the phosphorus requirement for optimal growth and development. The novel trait of the Enviropig™ enables it to degrade the indigestible phytate and absorb the phosphate eliminating the need to supplement the diet with readily available phosphate, and as a consequence the phosphorus content of the manure is reduced by as much as 60% thereby reducing the environmental impact when the pig manure is spread on agricultural land. Digestion of the phytate also leads to improvements in digestion of minerals in the diet.

Aqua Bounty Technologies, Inc. was incorporated in December 1991 in the state of Delaware. Aqua Bounty Canada, Inc., the Canadian Subsidiary, was incorporated in January 1994. In 1996, the company obtained the exclusive licensing rights for a gene construct (transgene) used to create a breed of farm-raised salmon that are expected to exhibit growth rates substantially faster than natural growth rates. The Company maintains biotechnology laboratories at St. John's, Newfoundland and San Diego, California, and operates a modern fish hatchery on a 3.5 acre site on Prince Edward Island . Aqua Bounty is developing advanced-hybrid salmon, trout, and tilapia broodstock engineered to grow faster than traditional broodstock. According to the company, *AquAdvantage*™ fish reach market size twice as fast and convert feed into body mass 10% – 30% more efficiently than traditional broodstock. These improvements provide both a highly compelling economic benefit to farmers (reduced growing cycle, better feed efficiency) as well as benefits to the environment from reduced release of waste products, faster fallowing cycles and potential improvement of the economic viability of inland operations, thereby mitigating the need for more environmentally consequential ocean pens. The fish are also neutered so the threat of interbreeding with native populations, a major recent concern in salmon farming, is avoided.

Nexia Biotechnologies of Montreal uses transgenic biology to transfer specific genes of interest into mice (gene testing) or goats (protein production) through nuclear transfer or microinjection. According to the company, once a transgenic fertilized egg is transferred to the foster recipient, a normal pregnancy ensues. Gestation time for goats is approximately 5 months. The kids produced from such a pregnancy may carry the gene of interest and are considered founder animals. If the founder is female, she will produce the (desired) protein in her milk when she lactates. Male founders also carry the gene of interest, but are unable to express it. These males are used to produce a second generation of females able to express the gene of interest. To encourage the genetic diversity, male founder goats are mated to larger standard female goats, which also serves to increase the milk yield per day. Nexia is reportedly also breeding goats that have been genetically modified with spider genes with hopes that their milk will be a plentiful source of the proteins required for spider silk to make strong fibres for commercial application.

The creators of the Enviropig have submitted an application for regulatory approval from the Food and Drug Administration in the United States during the winter of 2007, and have applied for regulatory approval just recently from Health Canada. Information on the commercialization timeline for the transgenic goats and Aqua Bounty was not available at the time of this report.

II. Regulation

In Canada, the animal biotechnology sector, which includes research and development activities and the resultant animals and their products, is subject to the same rigorous health and safety regulations that apply to conventional animals and their derived products. As with conventional animals and their derived products, these regulatory controls include the *Health of Animals Act* and *Regulations*, the *Food and Drugs Act* and *Regulations*, the *Meat Inspection Act* and *Regulations* and the *Feeds Act* and *Regulations* which are administered by the Canadian Food Inspection Agency (CFIA) and Health Canada. Animals and their derived products

produced through biotechnology, due to the fact that they are considered "novel" or "new", are subject to additional regulatory controls. Three departments have the principle responsibilities for regulating and assessing animals produced through biotechnologies: Health Canada, the Canadian Food Inspection Agency (CFIA) and Environment Canada.

Health Canada requires that novel foods, which includes animals produced through biotechnology and their by-products, undergo a pre-market safety assessment before they can receive regulatory approval for importation, sale, or manufacturing in Canada. The Canadian Food Inspection Agency requires that novels feeds, which includes by-products of animals produced through biotechnology, be subject to assessment before they can be released into the feed chain. Environment Canada requires that animals produced through biotechnology and their progeny meet the Environment Canada notification requirements which, depending on the intended use of the product, include a safety assessment for potential impacts to the environment.

Table 8. Regulating Agencies and Relevant Legislation

Department/Agency: Environment		
Responsibilities (as it relates to biotech animals)	***Relevant Legislation***	***Regulations***
◦ conducts safety assessments for potential impacts to the environment ◦ this is a pre-market requirement for GE animals sold, imported, or manufactured in Canada ◦ evaluates safety of GE animal-derived products for industrial use (like bio-silk for bullet-proof vest) in conjunction with Health Canada	*Canadian Environmental Protection Act, 1999* (CEPA, 1999)	*New Substances Notification Regulations*

Department/Agency : Health Canada		
Responsibilities (as it relates to biotech animals)	***Relevant Legislation***	***Regulations***
◦ co-administers CEPA, 1999 in regard to human health aspects; ◦ evaluates the human health aspects, including the safety of the people working with the animals. ◦ evaluates safety of biotech animal-derived products for industrial use (like bio-silk for bullet-proof vest) in conjunction with Environment Canada	*Canadian Environmental Protection Act, 1999* (CEPA, 1999)	*New Substances Notification Regulations* conducted through its Healthy Environments and Consumer Safety Branch

◦ conducts food safety assessments for novel foods, including products or by-products of biotech animals or their prodigy that are destined to enter the human food supply in Canada; ◦ controls the sale of novel foods in Canada through a mandatory premarket notification procedure; ◦ currently preparing guidelines for assessing novel foods that are of animal and fish origin; products or by-products of these biotech animals or their progeny into the human food supply in Canada, unless they have been subject to a pre-market safety assessment which is required for novel foods	Food and Drugs Act	Novel Food Regulations; also known as Division 28 of the Food and Drug Regulations

Department/Agency: Canadian Food Inspection Agency		
***Responsibilities** (as it relates to biotech animals)*	***Relevant Legislation***	***Regulations***
◦ analyzes and evaluates the technical documentation related to the GE animal's health (in conjunction with Environment Canada ◦ this supporting documentation is required for the manufacturing, importation, or sale to Canada of any animal derived through biotechnology ◦ responsible for assuring that diseases do not spread between animals	*Health of Animals Act*	Health of Animals Regulations
◦ should food products or by-products of biotech animals or their prodigy be approved by Health Canada, products still subject to CFIA meat regulations	**Meat Inspection Act**	Meat Inspection Regulations, 1990
◦ should fish products and fish by-products of biotech fish be approved by Health Canada for use as food, those products will	Fish Inspection Act	Fish Inspection Regulations

still have to meet the requirements of the CFIA's Fish Inspection Program		
◦ CFIA's Feed Section assists in consultation when end-use (by-product of biotech animal) is for animal feed	*Feeds Act*	*Feeds Regulations*, 1983
◦ CFIA's Veterinary Biologics Section assists in consultation process when end-product is a veterinary biologic	Health of Animals Act	Health of Animals Regulations

Department/Agency: Fisheries and Ocean Canada		
Responsibilities	***Relevant Legislation***	***Regulations***
◦ role is to protect fish health, habitat and environment	*Fisheries Act*	◦ currently developing regulations for aquatic organisms that are derived through biotechnology
◦ assessment currently done in conjunction with Environment Canada	*Canadian Environmental Protection Act, 1999* (CEPA, 1999)	*New Substances Notification Regulations*

The Canadian Food Inspection Agency provides additional guidance documentation which is available at the following web-links:

- Livestock and Animal Products Derived Through Modern Biotechnology: Roles and Responsibilities of the Government of Canada
- Fish Products Derived Through Modern Biotechnology: Roles and Responsibilities of the Government of Canada
- Government of Canada's comments on the USFDA's document "Animal Cloning: a Draft Risk Assessment"
- Animal Health Risk Analysis Framework for Biotechnology-Derived Animals
- Notification Guidelines for the Environmental Assessment of the Use of Animal Biotechnology in Livestock

III. Stakeholder/Public Opinions

As with crops developed through biotechnology, Canadian regulators will leave the ethical, social and religious issues of genetically engineered animals to the marketplace. As there are currently no animals produced from biotechnology that have entered commercial channels in Canada, it is difficult at this time to accurately gauge what market acceptance may be. The general feeling from industry stakeholders involved in animal biotechnology is that given the generally strong market acceptance in Canada of biotechnology in crops and crops by-products, the same may hold true for animals produced with biotechnology. There will be those who embrace the benefits that are offered by biotechnology and those who will reject it. While definitive guidelines with regards to animals and fish produced through biotechnology have not been released yet, it is unlikely that Canada will require meats, or other products produced by genetically engineered animals to be labels as such. As a result, Canadian consumers may not be in a position to make value judgments. Of note, the developers of the Enviropig hold the position that they would like the meat produced from their more environmentally friendly pig to be identified as having come from an Enviropig.

IV. International Organizations

While Canada does attend international forums where agricultural biotechnology may be discussed (CODEX, OIE), Canada refrains

from taking an official position as there is currently no definitive, comprehensive Canadian position with regards to the regulation of animal biotechnology.

V. Outreach, Needs and Strategies

Not applicable to the Canadian situation.

Section IV. Biotechnology Policy:

Canada's Regulatory System

Canada has an extensive science-based regulatory framework used in the approval process of agricultural products produced through biotechnology. Plants or products that are created with different or new traits from their conventional counterparts are referred to in the Canadian regulatory guidelines and legislation as plants with novel traits (PNTs) or novel foods. Plants with novel traits are defined as:

- A plant variety/genotype possessing characteristics that demonstrate neither familiarity nor substantial equivalence to those present in a distinct, stable population of a cultivated seed in Canada and that have been intentionally selected, created or introduced into a population of that species through a specific genetic change. Plants included under this definition are plants that are produced using recombinant DNA (rDNA) techniques, chemical mutagenesis, cell fusion and conventional cross breeding.

A novel food is defined as:

- A substance, including a microorganism that does not have a history of safe use as a food.
- A food that has been manufactured, prepared, preserved or packaged by a process that has not been previously applied to that food, and causes the food to undergo a major change.
- A food that is derived from a plant, animal or microorganism that has been genetically modified such that the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism; the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism; or one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism.

The Canadian Food Inspection Agency (CFIA), Health Canada (HC) and Environment Canada (EC) are the three agencies are responsible for the regulation and approval of products derived from biotechnology. The three agencies work together to monitor development of plants with novel traits, novel foods and all plants or products with new characteristics not previously used in agriculture and food production.

The CFIA is responsible for regulating the importation, environmental release, variety registration, and the use in livestock feeds of PNTs. Health Canada is responsible for assessing the human health safety of foods, including novel foods, and approving their use in commerce. Environment Canada is responsible for administering the New Substances Notification Regulations and for performing environmental risk assessments of *Canadian Environmental Protection Act* (CEPA) toxic substance, including organisms and microorganisms that may have been derived through biotechnology**.** A new player in the regulatory landscape, Fisheries and

Oceans Canada, is developing regulations for aquatic organisms that are derived through biotechnology. No timeline as to when these regulations will be published has been given and in the meantime any request to develop fish using modern biotechnology for commercial purposes would be subject to the *New Substances Notification Regulations* under CEPA, 1999.

Table 2. Regulating Agencies and Relevant Legislation

Department/Agency	Products Regulated	Relevant Legislation	Regulations
Canadian Food Inspection Agency	Plants and seeds, including those with novel traits, Animals, Animals vaccines and biologics, Fertilizers, Livestock feeds	*Consumer Packaging and Labeling Act,* *Feeds Act,* *Fertilizer Act,* *Food and Drugs Act,* *Health of Animals Act,* *Seeds Act,* *Plant Protection Act*	*Feeds Regulations,* *Fertilizer Regulations,* *Health of Animals Regulations,* *Food and Drug Regulations*
Environment Canada	Biotechnology products under CEPA, such as microorganisms used in bioremediation, Waste disposal, mineral leaching or enhanced oil recovery	*Canadian Environmental Protection Act* (CEPA)	*New Substances Notification Regulations* (These regulations apply to products not regulated under other federal legislation)
Health Canada	Foods, Drugs, Cosmetics, Medical devices, Pest control products	*Food and Drugs Act,* *Canadian Environmental Protection Act,* *Pest Control Products Act*	*Cosmetics Regulations,* *Food and Drug Regulations,* *Novel Foods Regulations,* *Medical Devices Regulations,* *New Substances Notification Regulations,* *Pest Control Products Regulation*
Fisheries and Oceans Canada	Potential environmental release of transgenic aquatic organisms	*Fisheries Act*	Under development

Table 3. Agencies' Responsibilities

Category	CFIA	Health Canada	Environment Canada
Human Health & Food Safety			
• Approval of novel foods		X	
• Allergens		X	
• Nutritional content		X	
• Potential presence of toxins		X	
Food Labeling Policies			
• Nutritional content		X	
• Allergens		X	
• Special dietary needs		X	
• Fraud and consumer protection	X		
Safety Assessments			
• Fertilizers	X		
• Seeds	X		
• Plants	X		
• Animals	X		

• Animal vaccines • Animal feeds	X X		
Testing Standards • Guidelines for Testing Effects on Environment			X

Plants with novels traits are subjected to examination under Canada's six-step regulatory process. The six steps are:

- Scientists working with genetically modified organisms, including the development of PNTs, adhere to Canadian Institute for Health Research directives, as well as the codes of practice of their own institutional biosafety committees. These guidelines protect the health and safety of laboratory staff and ensure environmental containment.

- The CFIA monitors all PNT field trials to comply with guidelines for environmental safety and to ensure confinement, so that the transfer of pollen to neighboring fields does not occur.

- The CFIA scrutinizes the transportation of seed to and from trial sites as well as the movement of all harvested plant material. The CFIA also strictly controls the importation of all seeds, living plants and plant parts, which includes plants containing novel traits.

In 2008, Canada had 124 submissions and 420 field trials of various crops from numerous companies. Of the 420 field trials conducted in 2008, 365 (87%) of them involved plants with "stacked" traits.

Table 4. Field Trials in 2008 (excluding canola)

Crop	Alfalfa	Brown Mustard					Camelina			Corn										Cuphea	Ethiopian Mustard	Poplar	Safflower	Soybean							Sweetroot Worm
Number of Traits	2	2	2	3	4	4	1	2	2	1	1	2	2	2	2	3	3	3	3	3	1	2	1	2	1	2	2	2	2	3	3	1
Number of Field Trials	1	8	8	8	8	8	6	2	8	2	12	3	3	10	66	2	2	3	3	4	3	1	1	2	10	3	7	18	30	2	12	1
Traits																																
Genetic Research	X																						X									
Selectable Marker	X															X		X	X			X							X			
Fertility Restoration		X		X		XX																										
Male Sterility			X		XX											XX																
Herbicide Tolerance / Resistance		X	X	XX	XX	XX			X	X		X	XX	X			X	X		XXX			X	X	X		XX			X		
Insect Resistance																	XX		XX													
Yield Increase							X	XX	X			X																X		X	XX		
Modified Oil Composition																						X									XX	
Stress Tolerance											X			X	X			X														
New Species To Canada																				X												
Modified Composition																										X						X
Antibiotic Resistance															X												X			X		
Precursor Of A Pharmaceutical Compound																							X									

Source: Canadian Food Inspection Agency

Table 5. Canola Field Trials in 2008

Number of Traits	1		2											3		4		
Number of Field Trials	6	14	1	1	3	5	6	8	10	12	14	24	36	1	8	2	4	8
Traits																		
Selection Marker			X						X					XX			XX	
Yeild Increase	X				X								X					
Herbicide Tolerance		X						X		X	X				XX	X		XX
herbicide tolerance as a selectable marker							X					X	X					
Nitrogen Use Efficiency							X			X								
Anitbiotic Resistance				X	X	X												
Fertility Restoration															X			XX
Male Sterility								X										
Stress Tolerance						X			X								XX	
Improved Agronomics											X							
Water Use Efficiency												X						
Modified Oil Composition			X	X										X		XXX		

Source: Canadian Food Inspection Agency

- Before any PNT is permitted to be grown outside of confined trials, CFIA must complete an environmental safety assessment focusing on:
    - Potential for movement of the novel trait to related plant species
    - Impact on non-target organisms (including insects, birds and mammals)
    - Impact on biodiversity
    - Potential for weed infestations arising from the introduced trait(s)
    - Potential for the novel plant to become a plant pest

- The CFIA evaluates all livestock feeds for safety and efficacy, including nutritional value, toxicity and stability. Data submitted for novel feeds include a description of the organism and genetic modification, intended use, environmental fate and potential for the gene (or metabolic) products to reach the human food chain. Safety aspects cover the animal eating the feed, consumption of the animal product by humans, worker safety and any environmental impacts related to use of the feed.

- Health Canada is responsible for assessing food with no previous history of safe use or food that is manufactured by a new process that causes a significant change in composition or is derived from an organism genetically modified to possess novel trait(s). Health Canada developed the *Guidelines for the Safety Assessment of Novel Foods, Volumes I and II*, in consultation with experts from the international community, including the Food and Agriculture Organization (FAO), the

World Health Organization (WHO) and the Organization for Economic Co-operation and Development (OECD). Using the *Guidelines for the Safety Assessment of Novel Foods*, Health Canada examines:

- How the food crop was developed, including molecular biological data
- Composition of the novel food, compared to non-modified counterparts
- Nutritional data for the novel food, compared to non-modified counterparts
- Potential for new toxins
- Potential for causing any allergic reaction
- Dietary exposure by the average consumer and population sub-groups (such as children)

- Canada's system of registration for newly developed crop varieties ensures that only varieties with proven benefits to producers and consumers are sold. Once approved for use in field trials, varieties are evaluated in regional field trials. Plant varieties produced through biotechnology cannot be registered and sold in Canada until authorized for environmental, livestock feed and food safety.

Developers of plants with stacked traits, which were created from previously authorized PNTs, are required to notify the CFIA's Plant Biosafety Office (PBO) at least 60 days prior to the anticipated date of the environmental release of these plants. Following notification, the PBO may issue a letter (within 60 days of notification) informing the developer of any concerns it may have regarding the proposed unconfined environmental release. The PBO may also request and review data to support the safe use of the modified plant in the environment. Stacking of traits with potential incompatible management requirements, possible negative synergistic effects, or where production of the plant may be extended to a new area of the country, may require an environmental safety assessment. Until all environmental safety concerns have been resolved, the modified plant should not be released in the environment.

- Once environmental, feed and food safety authorizations are granted, the PNT and feed and food products derived from it can enter the marketplace, but are still subject to the same regulatory scrutiny that applies to all conventional products in Canada. In addition, any new information arising about the safety of a PNT or its food products must be reported to government regulators who, upon further investigation, may amend or revoke authorization and/or immediately remove the product(s) from the marketplace.

From development to the time the product has been approved for human consumption can take anywhere between seven to ten years. In some instances the process takes longer than 10 years.

In order to maintain the integrity of Canada's regulatory system, several advisory committees have been established to monitor and advise the government of current and future regulatory needs. The Canadian Biotechnology Advisory Committee (CBAC) was established in 1999 to advise the government on ethical, social, scientific, economic, regulatory, environmental and health aspects. The mandate of the Canadian Biotechnology Advisory Committee (CBAC) ended on May 17, 2007. The government replaced the CBAC with the Science, Technology and Innovation Council, as part of a broader effort to consolidate external advisory committees and strengthen the role of independent export advisors. The Council is an advisory body that provides the Government of Canada with external policy advice on science and technology issues, and it produces regular national reports that measure Canada's science and technology performance against international standards of excellence. In May, 2009, the Science, Technology and Innovation Council released its first public report, entitled *State of The Nation 2008 - Canada's Science, Technology and Innovation System*, which benchmarks Canada's science, technology and innovation system against the world's innovating countries.
CFIA, in the fall of 2006, began consultations regarding a proposal to facilitate the modernization of the seed regulatory framework,

specifically addressing the Variety Registration System with the possible creation of a lower cost variety registration option. In late June 2008, CFIA published its proposed regulatory amendments in the Canada Gazette (Part 1). The 75-day consultation period on these proposed amendments is now closed and the feedback is being reviewed. A copy of these proposed amendments are available on the following website: Proposed Regulatory Amendments to increase the flexibility of the Variety Registration System. While CFIA has made it clear that the proposed change in no way changes the safety assessment of novel genetically modified crops, it does have potential to allow for a quicker registration. In short, what the CFIA is proposing is a system that would divide the list of all crops that require variety registration into three parts with three levels of variety registration requirements. For all parts, basic variety registration information would continue to be required, including information demonstrating conformity with minimum health and safety standards, information confirming the identity of new varieties, information supporting the verification of claims, and information required for seed certification purposes. However, the three parts would each have different pre-registration testing (field trials and laboratory testing) and merit assessment requirements. At this time, all crops that require variety registration follow the same pathway.

Updates on consultations taking place are available at the following web address: Seed Consultations.

In early 2008, Canadian Agriculture Minister, Gerry Ritz, ordered the removal of the kernel visual distinguishability (KVD) requirements as of August 1, 2008. In August of 2008, the CFIA announced amendments of the Seed Regulations to accomplish this. The KVD requirement was initially part of the quality assurance system for western wheat but limited the ability to develop and use new high-yielding varieties of wheat suitable for industrial purposes (such as biofuels) if they looked too similar to milling varieties of wheat. With new niche markets developing, Minister Ritz felt that these requirements were hindering Canada's ability to progress towards a bio-based economy. Some industry players were hoping that the amendments would go further bring about amendments to the variety registration system and thereby allow the importation of seed of *unregistered* wheat varieties for seeding by the importer. CFIA has made the decision to hold additional consultations on this issue and so the importation of seed of unregistered wheat varieties for seeding by the importer remains prohibited (allowed only for research purposes). While the KVD requirements have been removed, the *Seeds Regulations* continue to require that only seed of registered varieties may be sold in Canada. For more information on the amendments to the *Seeds Regulations* as published in *Canada Gazette*, Part II, visit the CFIA Web site at www.inspection.gc.ca or call 1-800-442-2342.

Table 6. Recently Approved Plants with Novel Traits in Canada

Crop	Designation / Event	Applicant(s)	Trait	Reviewed and Approved Uses Within Canada	Approval and link to decision document	
Soybean	High Oleic Soybean Event 305423	Pioneer Hi-Bred Production Ltd.	Increased levels of oleic acid and decreased levels of linoleic and linolenic acids in seeds, Tolerance to ALS-inhibiting herbicides.	Environment, feed, food	6-May-09	DD2009-76
Soybean	Enhanced Stearate Soybean; non-LMO	Monsanto Canada Inc	Enhanced stearic acid content	Environment, feed, food	7-August-08	DD2008-75
Corn	Corn Event	Monsanto	Lepidopteran	Environment,	19-June-08	DD2008-74

	MON 89034	Canada Inc.	resistance	feed, food		

Source: Canadian Food Inspection Agency, web-based data base last accessed July 6, 2009

Table 7. Plants with Novel Traits Approved in Canada

Crop	Designation/Event(s)	Applicant(s)	Trait	Reviewed Uses Within Canada
Canola	(B. rapa) HCR-1	AgrEvo Canada Inc. (currently Bayer CropScience)	Glufosinate ammonium tolerance	Environment, feed
Canola	(B. rapa) ZSR500, ZSR502, ZSR503	Monsanto Canada Inc.	Glyphosate tolerance	Environment, feed
Canola	Canol B. juncea	BASF Canada	Imidazolinone tolerance; ***non-LMO***	Environment, feed, food
Canola	23-198, 23-18-17	Calgene Inc. (currently Monsanto Canada Inc.)	Higher quantities of laurate and myristate	Environment, feed, food
Canola	45A37, 46A40	Pioneer Hi-Bred International Inc.	High oleic / low linolenic acid	Food
Canola	GT200 (RT200)	Monsanto Canada Inc.	Glyphosate tolerance	Environment, feed, food
Canola	GT73 (RT73)	Monsanto Canada Inc.	Glyphosate tolerance	Environment, feed, food
Canola	HCN28 (T45)	AgrEvo Canada Inc. (currently Bayer CropScience)	Glufosinate ammonium tolerance	Environment, feed, food
Canola	HCN92	AgrEvo Canada Inc. (currently Bayer CropScience)	Glufosinate ammonium tolerance	Environment, feed, food
Canola	MS1, RF1, RF2 (MS1xRF1, MS1xRF2)	Plant Genetic Systems (currently Bayer CropScience)	Male sterility / fertility restoration / glufosinate ammonium tolerance	Environment, feed, food
Canola	MS8, RF3 (MS8xRF3)	Plant Genetic Systems (currently Bayer CropScience)	Male sterility / fertility restoration / glufosinate ammonium tolerance	Environment, feed, food
Canola	NS738, NS1471, NS1473	Pioneer Hi-Bred International Inc.	Imidazolinone tolerance	Environment, feed, food
Canola	Oxy235 (Westar Oxy-235)	Rhône Poulenc Inc. (currently Bayer CropScience)	Oxynil (bromoxynil and loxynil) tolerance	Environment, feed, food

Corn	375IR	Pioneer Hi-Bred International Inc.	Imidazolinone tolerance	Environment, feed, food
Corn	Cornline 1507	Dow AgroSciences Canada Inc. and Pioneer Hi-Bred International Inc.	Lepidopteran resistance / glufosinate - ammonium tolerance	Environment, feed, food
Corn	Cornline 603	Monsanto Canada Inc.	Glyphosate tolerance	Environment, feed, food
Corn	DBT418	Dekalb Genetics Corporation (currently Monsanto Canada Inc.)	European Corn Borer resistance/ glufosinate ammonium tolerance	Environment, feed, food
Corn	DK404SR	BASF Canada Inc.	Sethoxydim tolerance	Environment, feed, food
Corn	DLL25	Dekalb Genetics Corporation (currently Monsanto Canada Inc.)	Glufosinate ammonium tolerance	Environment, feed, food
Corn	Event 176	Ciba-Geigy Corporation, Ciba Seeds (currently Syngenta Seeds) and Mycogen Corporation	European Corn Borer resistance	Environment, feed, food
Corn	Event 3272	Syngenta Seeds Canada Inc.	Expression of a thermostable alpha amylase enzyme	Environment, feed, food
Corn	Event Bt11 (4334 CBR 4374 CBR)	Northrup King Ltd. (currently Syngenta Seeds)	European Corn Borer resistance	Environment, feed, food
Corn	Event DAS-06275-8	Dow AgroSciences Canada Inc.	Lepidopteran resistance / glufosinate - ammonium tolerance	Environment, feed, food
Corn	Event LY038	Monsanto Canada Inc.	Increased level of free lysine	Environment, feed, food
Corn	Event MIR604	Syngenta Seeds Canada Inc.	Western and Northern Corn Rootworms resistance	Environment, feed, food
Corn	EXP1910IT	ICI / Zeneca Seeds (currently Advanta Seeds)	Imidazolinone tolerance	Environment, feed, food
Corn	GA21	Monsanto Canada Inc.	Glyphosate tolerance	Environment, feed, food
Corn	Liberty Link™ lines: T14, T25	AgrEvo Canada Inc. (currently	Glufosinate ammonium	Environment, feed, food

		Bayer CropScience)	tolerance	
Corn	Line 59122	Dow AgroSciences Canada Inc. and Pioneer Hi-Bred Production Inc.	Western and Northern Corn Rootworms resistance/ Glufosinate-ammonium tolerance	Environment, feed, food
Corn	MON 88017	Monsanto Canada Inc.	Western and Northern Corn Rootworms resistance/ Glyphosate tolerance	Environment, feed, food
Corn	MON-89034-3	Monsanto Canada Inc.	Lepidopteran resistance	Environment, feed, food
Corn	MON802	Monsanto Canada Inc.	European Corn Borer resistance / glyphosate tolerance	Environment, feed, food
Corn	MON809	Pioneer Hi-Bred International Inc.	European Corn Borer resistance / glyphosate tolerance	Environment, feed, food
Corn	MON810	Monsanto Canada Inc.	European Corn Borer resistance	Environment, feed, food
Corn	MON832	Monsanto Canada Inc.	Glyphosate tolerance	Food
Corn	MON863	Monsanto Canada Inc.	Resistance to Western and Northern corn rootworms	Environment, feed, food
Corn	MS3	Plant Genetic Systems (currently Bayer CropScience)	Male sterility / glufosinate ammonium tolerance	Environment, feed, food
Corn	TUSC1	Pioneer Hi-Bred International Inc.	Reduced zein expression	Environment, feed
Cotton	Not assigned	Monsanto Canada Inc.	Bromoxynil tolerance / lepidopteran resistance	Food
Cotton	MON-15985-7	Monsanto Canada Inc.	Lepidopteran resistance	Feed, food
Cotton	531: MON-00531-6; 757: MON-00757-7; 1076: MON-89924-2	Monsanto Canada Inc.	Lepidopteran resistance	Feed, food
Cotton	Not assigned	Calgene Inc. (currently Monsanto Canada Inc.)	Bromoxynil tolerance	Feed, food
Cotton	DAS-24236-5	Dow	Lepidopteran	Feed, food

		AgroSciences Canada Inc.	resistance	
Cotton	DAS-21023-5	Dow AgroSciences Canada Inc.	Lepidopteran resistance	Feed, food
Cotton	BCS-GH002-5	Bayer CropScience	Glyphosate tolerance	Feed, food
Cotton	ACS-GH001-3	Bayer CropScience	Glufosinate ammonium tolerance	Feed, food
Cotton	MON-88913-8	Monsanto Canada Inc.	Glyphosate tolerance	Feed, food
Cotton	1445: MON-01445-2; 1698: MON-89383-1	Monsanto Canada Inc.	Glyphosate tolerance	Feed, food
Flax	FP967 (CDC Triffid)	University of Saskatchewan	Sulfonylurea tolerance	Environment, feed, food
Lentils	RH44	BASF Canada Inc.	Imidazolinone tolerance	Environment, feed, food
Potato	New Leaf™ Atlantic lines: ATBT04-6, ATBT04-27, ATBT04-30, ATBT04-31, ATBT04-36	Monsanto Canada Inc.	Colorado Potato Beetle resistance	Environment, feed, food
Potato	New Leaf™ Plus line: RBMT22-082	Monsanto Canada Inc.	Colorado Potato Beetle resistance / Potato Leafroll virus resistance	Environment, feed, food
Potato	RBMT21-350: NMK-89185-6; RBMT21-129: NMK-89684-1	Monsanto Canada Inc.	Colorado Potato Beetle resistance / Potato Leafroll virus resistance	Environment, feed, food
Potato	New Leaf™ Russet Burbank lines: BT06, BT10, BT12, BT16, BT17, BT18, BT23; Superior lines: SPBT02-5, SPBT02-7	Monsanto Canada Inc.	Colorado Potato Beetle resistance	Environment, feed, food
Potato	New Leaf™ Y lines: RBMT15-101, SEMT15-02, SEMT15-15	Monsanto Canada Inc.	Colorado Potato Beetle resistance / Potato virus Y resistance	Environment, feed, food
Rice	CL121, CL141, CFX51 (derived from 93A33510)	BASF Canada Inc.	Imazethapyr tolerance	Feed, food
Rice	Event LLrice62	Bayer CropScience	Glufosinate ammonium tolerance	Feed, food
Rice	IMINTA 1 and IMINTA 4	BASF Canada Inc.	Imidazolinone tolerance	Feed, food
Rice	PWC16	BASF Canada Inc.	Imazethapyr tolerance	Feed, food
Soybeans	Event 305423	Pioneer Hi-Bred ProductionLtd.	High oleic / low linoleic and	Environment, feed, food

			linolenic acids	
Soybeans	A2704-12, A5547-127	AgrEvo Canada Inc. (currently Bayer CropScience)	Glufosinate ammonium tolerance	Environment, feed, food
Soybeans	Delicious Soybean	Monsanto Canada Inc.	Reduced glycinin content	Environment, feed, food
Soybeans	G94-1, G94-19 and G168	Optimum Quality Grains (currently Dupont Canada)	High oleic acid	Environment, feed, food
Soybeans	GTS 40-3-2	Monsanto Canada Inc.	Glyphosate tolerance	Environment, feed, food
Soybeans	MON 89788	Monsanto Canada Inc.	Glyphosate tolerance	Environment, feed, food
Squash	CZW3	Seminis Vegetable Seeds Inc.	Virus resistance	Food
Squash	ZW20	Seminis Vegetable Seeds Inc.	Virus resistance	Food
Sugar Beet	1022S, 1026S, 1031S (derived from Event T120-7)	AgrEvo Canada Inc. (currently Bayer CropScience)	Glufosinate tolerance	Environment, feed, food
Sugar Beet	Line H7-1	Monsanto Canada Inc. and KWS SAAT AG	Glyphosate tolerance	Environment, feed, food
Sunflower	Clearfield™ Oilseed Sunflower Hybrid X81359	BASF Canada Inc.	Imidazolinone tolerance	Environment, feed, food
Sunflower	ExpressSun™ SU7	Pioneer Hi-Bred ProductionLtd.	Sulfonylurea tolerance	Environment, feed, food
Tomato	1345-4	DNA Plant Technology	Delayed ripening	Food
Tomato	1401F, h382F, 11013F, 7913F	Zeneca Seeds (currently Advanta Seeds Inc.)	Delayed ripening	Food
Tomato	5345	Monsanto Canada Inc.	Lepidopteran insect resistance	Food
Tomato	Flavr Savr™	Calgene Inc. (currently Monsanto Canada Inc.)	Delayed ripening	Food
Wheat	AP205CL	BASF Canada Inc.	Imidazolinone tolerance	Environment, feed, food
Wheat	AP602CL	BASF Canada Inc.	Imazamox tolerance	Environment, feed, food
Wheat	BW255-2 and BW238-3	BASF Canada Inc.	Imidazolinone tolerance	Environment, feed, food
Wheat	BW7	BASF Canada Inc.	Imidazolinone tolerance	Environment, feed, food
Wheat	Durum (Triticum turgidum L.) event DW1	BASF Canada Inc.	Imidazolinone tolerance	Environment, feed, food
Wheat	Durum (Triticum	BASF Canada	Imidazolinone	Environment,

	turgidum L.) events DW2, DW6, and DW12	Inc.	tolerance	feed, food
Wheat	SWP 965001	Cyanamid Crop Protection (currently BASF Canada Inc.)	Imidazolinone tolerance	Environment, feed, food
Wheat	Teal 11A	BASF Canada Inc.	Imidazolinone tolerance	Environment, feed, food

Source: Canadian Food Inspection Agency, web-based data base last accessed July 6, 2009

Coexistence Between Biotech and Non-Biotech Crops

In Canada, the coexistence between biotechnology and non-biotechnology crops is not regulated by the government, but rather the onus is on the producers. For example, if producers of organic crops wish to avoid GM events in their production systems the onus for implementing measures to facilitate this falls on them. In return, those producers are able to charge a premium price for their product, for incurring costs associated with meeting the requirements of their customers and certification bodies.

Biotech stewardship conditions applies to biotech crops in Canada, with some companies providing biotech crop farmers with coexistence type recommendations for minimizing the chances of adventitious presence of biotech crop material being found in non-biotech crops of the same species. In addition, producers of biotech crops are provided with weed management practice guides. These changes in management practices may help to improve the coexistence between biotech and non-biotech crops, without the need to introduce government regulations. For example, Croplife Canada has developed the Stewardshipfirst™ initiatives in order to manage the health, safety and environmental sustainability of the industry's products throughout their life cycle. Stewardshipfirst™ includes Best Management Practices Guide for growers of GM crops.

Despite the fact that the government does not regulate the coexistence between biotech and non-biotech crops, the presence and increasing trend toward biotech crops has not hindered the organic industry. The growth or lack thereof in the organic industry is based on demand by consumers, rather than the presence or absence of biotech crops. There have been disputes between the biotech community and the organic community due to adventitious presence of biotech crops (for example canola) in organic crops, but the lack of complete information indicating the actual levels of the biotech crops in organic crops, the frequency of testing of organic crops, location of crops relative to biotech crops, the origin of seed, measures taken to minimize adventitious presence occurring, means that it is not possible to fully assess whether there have been or may be coexistence problems between organic and biotech crops in Canada.

Labeling of Genetically Modified Products

In 2004, the Standards Council of Canada adopted the *Standard for Voluntary Labeling and Advertising of Foods that Are and Are Not Products of Genetic Engineering*, as a National Standard of Canada. The development of the voluntary standards was carried out by multi-stakeholder committee, facilitated by the Canadian General Standards Board (CGSB), at the request of the Canadian Council of Grocery Distributors, and began in November 1999. The committee was made up of 53 voting members and 75 non-voting members from producers, manufacturers, distributors, consumers, general interest groups and six federal government departments, including Agriculture and Agri-Food, Health Canada and the CFIA.

Health Canada and the CFIA are responsible for all federal food labeling policies under the *Food and Drugs Act*. Health Canada is responsible for setting food labeling policies with regards to health and safety matters, while the CFIA is responsible for development of non-health and safety food labeling regulations and policies. It is the CFIA's responsibility to protect consumers from misrepresentation and fraud with respect to food labeling, packaging and advertising, and for prescribing basic food labeling

and advertising requirements applicable to all foods.

The *Standard for Voluntary Labeling and Advertising of Foods that Are and Are Not Products of Genetic Engineering*, was developed to provide customers with consistent information for making informed food choices while providing labeling and advertising guidance for food companies, manufacturers and importers. The definition of genetically engineered food provided by the Standard are those foods obtained through the use of specific techniques that allow the moving of genes from one species to another. The regulations outlined in the Standard are:

- The labeling of food and advertising claims pertaining to the use or non-use of genetic engineering are permissible as long as the claims are truthful, not misleading, not deceptive, not likely to create an erroneous impression of a food's character, value, composition, merit or safety, and in compliance with all other regulatory requirements set out in the *Food and Drugs Act*, the *Food and Drugs Regulations*, the *Consumer Packaging and Labeling Act* and *Consumer Packaging and Labeling Regulations*, *the Competition Act* and any other relevant legislation, as well as the *Guide to Food Labeling and Advertising*.
- The Standard does not imply the existence of health or safety concerns for products within its scope.
- When a labeling claim is made, the level of accidental co-mingling of genetically engineered and non-genetically engineered food is less than 5 percent.
- The Standard applies to the voluntary labeling and advertising of food in order to distinguish whether or not such foods are products of genetic engineering or contain or do not contain ingredients that are products of genetic engineering, irrespective of whether the food or ingredient contains DNA or protein.
- The standard defines terms, and sets out criteria for claims and for their evaluation and verification.
- The standard applies to food sold to consumers in Canada, regardless of whether it is produced domestically or imported.
- The standard applies to the labeling and advertising of food sold prepackaged or in bulk, as well as to food prepared at the point of sale.
- The standard does not preclude, override, or in any way change legally required information, claims or labeling, or any other applicable legal requirements.
- The standard does not apply to processing aids, enzymes used in small quantities, substrates for microorganisms, veterinary biologics and animal feeds.

The push from some groups in Canada for mandatory labeling of genetically engineered food continues despite the creation and implementation of the Standard. Over the past few years several private members' bills have been introduced into the House of Commons seeking to require the mandatory labeling of foods containing biotech components, although none have made it past second reading. At this time, there are two biotech-related private members bills that technically, although unlikely, could be called forward should they receive enough support. The first is bill C-205 which would require the Minister of Health to make regulation that would require the labeling of any meat or poultry product that has been produced using hormones, antibiotics, pesticides or genetically modified organisms. The second is a bill that has been introduced into Parliament during previous Parliamentary sessions. Bill C-370 would require the mandatory labeling of foods containing biotech components.

The Cartagena Protocol on Biosafety

In 2001, Canada signed onto the Cartagena Protocal, but has yet to ratify it. There is tremendous opposition from many farm groups, like the Canadian Canola Council, the Grain Growers of Canada, Viterra and many others, to the ratification of the Protocol. There are also those groups like the National Farmers Union and Greenpeace, which are pushing the government to ratify it. To determine the best course of action in regards to the Protocol, the Government of Canada has been consulting with stakeholders. The

consultations have resulted in three options on how the government should proceed being put forward:

a. Proceed to immediate ratification of the Protocol with the intent to participate as a Party in the first meeting of the Parties;
b. Keep the decision on ratification under active review while continuing to participate in Protocol processes as a non-Party and acting voluntarily in a manner that is consistent with the objective of the Protocol;
c. Decide not to ratify the Protocol.

The position the Government of Canada has taken follows along the line of option b and industry sources indicate that this is likely to remain the course for at least the medium term. The three Ministers responsible for deciding on whether or not to ratify the Protocol are split in their positions. The Minister of Agriculture and Agri-Food and the Minister of International Trade have both indicated that they are opposed to ratification of the Protocol, but the Minister of the Environment has indicated that he is leaning towards ratification. With two major ministers opposing ratification, the likelihood of ratification is very small.

In the event that the government does choose to ratify the Protocol, Environment Canada has published a copy of the regulation pursuant to the *Canadian Environmental Protection Act, 1999* (CEPA, 1999) that the department proposes to put in place to implement the Protocol if the government chooses to ratify it. A copy of these regulations can be found at: http://www.ec.gc.ca/substances/nsb/eng/reg_e.htm.

The CFIA has also published its proposed regulation to implement the Cartagena Protocol on Biosafety, if the government chooses to ratify the agreement, pursuant to the *Canada Agricultural Products Act*. The regulations would specifically cover agricultural products, including plants, plant products, fertilizers, feeds and veterinary biologics. The consultation document on the CFIA proposed regulations can be found at: http://www.inspection.gc.ca/english/sci/biotech/consult/consulte.shtml.

Canada and Canadian industries rely heavily on imports of U.S. crops to meet their requirements. Therefore, the ratification of the Cartagena Protocol could become a barrier to trade with the United States.

Intellectual Property Rights

The *Patent Act* and the *Plant Breeders' Rights Act* both afford breeders or owners of new varieties the ability to collect technology fees or royalties on their products. The *Patent Act* grants patents that cover the gene in the plant or the process used to incorporate the gene, but does not provide a patent on the plant itself. The protection of the plant would be covered by the *Plant Breeders' Rights* (PBR) *Act*. The *Patent Act* enables breeders to sell their product commercially to producers. The cost of the patented product will most likely include technology fees. This enables the breeders to recover the financial investment they have made in developing their product.

The *Plant Breeders' Rights* (PBR*) Act* grants plant breeders of new varieties the exclusive rights to produce and sell propagating material of the variety in Canada. The PBR Act outlines that the holder of the plant breeders' rights is able to collect royalties on the product. The PBR Act became law in 1990 and adhered to the terms of the 1978 Union for the Protection of New Varieties of Plants (UPOV) Convention. In 1992, Canada was a signatory to 1991 UPOV Convention. In order to bring the PBR Act into compliance with the new convention, Canada must make amendments to the PBR Act. Consultations involving the Plant Breeders' Rights Office, the Canadian seed industry, representatives from the horticulture and agriculture industries and the Minister's Plant Breeders' Rights Advisory Committee have resulted in the development of amendments which would bring the PBR Act into conformity with 1991 UPOV Convention.

Section V. Marketing:

Overall market acceptance of biotechnology crops and products is strong in Canada. Many producers have taken advantage of the

benefits of growing biotech crops, including reduced herbicide use, and a reduction in losses due to insect resistant and disease resistant traits. Despite the opposition in some countries to importation of biotech crops, Canadian producers have been able to secure markets for their biotech crops. For example, Japan is one of the largest importers of Canadian canola, of which a majority is biotech. The Canadian Canola Council is a very proactive industry group, developing and securing markets for Canadian canola, as well as ensuring Canadian consumers are aware of the benefits of consuming canola. With the development of biotech canola that is high in oleic acids and low linonlenic acids, the Canola Council has been promoting the health benefits of consuming this particular variety of biotech canola. Acreage seeded to biotech canola continues to increase each year, which is a testament to the success and acceptance of biotech canola in Canada and in international markets.

Canadian flax producers have not met the same success in regards to the marketing of GM flax. The issue facing Canadian flax producers was not opposition to biotech flax at home, but in exports of flax to Canada's largest market, the European Union. In the late 1990's Triffid flax seed, an herbicide tolerant variety, was registered and approved by the CFIA and Health Canada for commercial production and consumption. But EU consumers indicated that they would not purchase biotech flax. Canadian flax producers were concerned that they would be unable to keep biotech and non-biotech flax segregated and rather than risking their largest market, Canadian flax producers pushed to have Triffid deregistered and pulled from the market. The concern over the loss of the EU market continues to plague the Canadian flax industry and may interfere with several companies' plans to introduce new biotech varieties of flax into the Canadian market. But the health benefits of the biotech flax created to be high in omega-3 fatty acids may supersede concerns of the Canadian flax producers, as more and more consumers in Canada are demanding additional sources of omega-3 fatty acids.

In 2002, the time when Monsanto was seeking regulatory approval for its Round-up Ready (RR) wheat, the issue of biotech wheat in Canada became very decisive with some producers strongly believing in the benefits of growing RR wheat and supporting its regulatory approval, while other producers feared the approval and commercialization of RR wheat would cost Canadian wheat farmers their international markets. The fear that lack of consumer acceptance of biotech wheat could result in loss of markets for Canadian wheat growers remains the main barrier to Canadian wheat farmers' willingness to embrace biotech wheat. The debate on biotech wheat seems to have been revived briefly after a May 14, 2009 statement by pro-biotech wheat groups from the United States, Canada, and Australia. The groups declared that they will be working towards the goal of synchronized commercialization of biotech traits in the wheat crops. Their statement highlighted the importance of wheat to the food supply and the declining wheat acres in the United States, Canada, and Australia which they attribute in part to competition from crops that have the advantages of biotech crops. The statement also stressed the importance of introducing biotech wheat in a coordinated fashion to minimize market disruption.

On June 1, 2009, farm and environment groups opposed to biotech wheat released a joint statement of opposition to biotech wheat. This most recent statement stated that due to the "global consumer rejection of genetically engineered wheat" the groups remain definitive in the opposition to biotech wheat and committed to stopping the commercialization of biotech wheat. Canadian wheat groups who were signatories to this statement included National Farmers Union (Canada), the Canadian Biotechnology Action Network, Union Paysanne (Canada) and Union Biologique Paysanne (Canada).

The Canadian Wheat Board was not one of the signatories and did not outright reject biotech wheat. The CWB's support for biotech wheat is predicated on a number of key conditions being met first. These conditions are: market acceptance, segregation systems, agronomic information and cost-benefit analysis. The CWB is a member of the Canada Grain Industry Working Group (CGIWG), and was involved in the drafting of conditions they deemed necessary in order to permit the commercial introduction of biotech wheat in Canada. The group defined market acceptance as:

Identified markets for the GM product, as well as the ability to meet the needs of key non-biotech markets so that farmers are not negatively impacted by lost markets.

The first condition for market acceptance was that biotech products had to receive regulatory feed, food and environmental approval, whichever is applicable, in the country of destination. In markets where regulatory approval has not been received, an achievable tolerance level for unapproved events must exist.

The second condition under market acceptance was that there were identified markets for biotech wheat.

The third condition for market acceptance was the ability to meet non-biotech market requirements, including the establishment of achievable tolerance levels for the presence of biotech material in non-biotech shipments. The tolerance levels must be physically possible and economically feasible to meet. In addition, tolerance levels must be established for each step of the supply chain.

The final condition for market acceptance was market harm. Market harm exists when major customers indicate that they will not purchase biotech wheat and require certification stating shipments do not contain biotech wheat. In addition, market harm exists when set tolerance levels are not achievable or the cost to achieve the set tolerance levels results in an uncompetitive product. The extent of market harm must be established and evaluated against any possible market, agronomic or other benefit expected.

A segregation system was the second condition required by the CGIWG. The CGIWP wanted the establishment of a segregation system to prevent the co-mingling of biotech and non-biotech wheat prior to the release of biotech wheat. The segregation system envisioned by the CGIWG would be closed-loop.

The third condition of the CGIWG was agronomic information. The working group wanted a clear understanding of the impact commercial release of biotech wheat would have on management practices and profitability with respect to each type of farming operation across a multi-year rotation. This condition also called for additional research to be reviewed by a panel of agronomists.

The final condition of cost-benefit analysis would include an analysis of the market and agronomic benefits, and the market and agronomic risks and costs for all production and marketing systems and for technology adaptors and non-adaptors. This would include investigating yield impacts, cost of production, interaction between biotech wheat and other crops in farmers' rotations, market benefit, lost market revenue, segregation costs, real option value, expected net return, irreversible market costs and irreversible environmental costs.

In addition to wanting these conditions met prior to the release of any biotech wheat, was the push by several farm groups including the CWB, to have the regulatory process amended to include a cost-benefit analysis before regulatory approval should be granted. Despite the pressure by the CWB and other groups to amend the regulatory process, the Government of Canada has resisted making changes to the regulatory system to include market acceptance as a mandatory condition for the approval of a PNT. The Government continues to base Canadian regulations on science.

The push by CWB to implement its conditions for the commercial release of biotech wheat and for changes to the regulatory approval process will make Canada a less attractive place for the commercial introduction of biotech wheat and possibly other biotech crops.

To summarize, the current state of play for biotech wheat is static at the moment, but there is hope for some movement towards acceptance of GM wheat in Canada in the long run. The removal of the KVD varietal control requirements on Western wheat in Canada is a step forward. In the United States, the regulations are less formal and the market dictates the success or failure of a variety. Up until now, this difference in varietal regulations between countries added an additional dimension to biotech wheat requirements. When approval for biotech wheat was first sought, both the U.S. and Canadian grain industries advocated for the release of biotech wheat in all of North America or not at all. As a result, Canada's stricter licensing system for new crop varieties became, de facto, the U.S. regulatory mechanism. A strict adherence to this licensing system, and the value that this system is believed to add to Canadian wheat has made the Canadian grains industry slow to adopt new varieties. However, the increasing numbers of niche markets and the growth of the Canadian bio-fuel industry have put a great deal of pressure on the system to change and may lead to openness for biotech wheat for industrial purposes.

Section VI. Capacity Building and Outreach:

Not applicable to Canada.

Section VII. Author Defined:

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