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Report Highlights:
This report updates CA7053. 2007/2008 data on crop average sown and crop size dedicated to genetically modified varieties was largely unavailable. Data based on planting surveys suggest that the amount of acreage planted to GM corn and soybeans in Quebec and Ontario in 2008 increased from 2007 levels. In addition, the provincial acreage dedicated to GM crops has also increased in those provinces. In Western Canada, acreage seeded to canola in 2008 also increased from 2007 levels. Areas of this report have been updated to include data on crops submitted for regulatory approval, field trial submissions, and approved biotech crops.

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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 16% 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 strong arguments 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 genetically modified grains from the United States.

Canada's regulatory system is science-based. Canada is the only country in world whose regulatory process is based upon the traits expressed and not on the basis of the method used to introduce the traits. This is why in 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

According to a report released by the International Service for the Acquisition of Agri-biotech Applications (ISAAA) in February 2008, Canada was ranked as the fourth largest producer of biotech crops in the world, with 7.0 million hectares planted, following behind the United States, Argentina and Brazil, respectively. The three major biotech crops produced in Canada are corn, canola and soybeans.

As Statistics Canada does not keep detailed data sets on genetically modified 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 2007 and 2008, which is Statistics Canada's largest area survey. According to the survey data, Canadian agricultural grains and oilseeds farmers planted 2,818 and 2,660.2 thousand hectares (THT) of corn, and soybeans in 2007 and 2008, respectively. Of total area seeded in 2008, 43.7% and 59.9%

was seeded with genetically modified corn and soybeans, respectively. This represents a 12% increase in GM corn share and a 11% increase in GM soybean share.

In 2008, Quebec farmers reported planting 232 THT of GM corn, a slight 1% decrease from 2007 levels of 234 THT. GM corn in 2008 as a percentage of the total provincial corn acreage (fodder corn and grain corn) increased from 47.1% in 2007 to 52.4% in 2008. Quebec farmers also report planting 113.0 THT of GM soybeans in 2008, an increase of 33.7% from year 2007 when Quebec farmers reported planting 84.5 THT of GM soybeans. The total area of GM soybean area as a percentage to the total provincial area increased in 2008 from 48.0% in 2007 to 48.7%.

According to the planting surveys, in 2008, Ontario farmers reported planting 400.6 THT of GM corn, a .5% decrease from year 2007 levels of 402.7 THT. GM corn in 2008 as a percentage of the total provincial corn acreage (fodder corn and grain corn) accounted for 48.5%, a significant increase from 41.5% in 2007. Ontario farmers also report planting 491.7 THT of GM soybeans in 2008, an increase of 10.4% from year 2007 when Ontario farmers reported planting 445.2 THT of GM soybeans. The total area of GM soybean area as a percentage to the total provincial area increased from 49.1% in 2007 to 57.9% in 2008.

In Western Canada[1], the primary canola-growing region in Canada, in 2008, over 30% of the field crop acreages were dedicated to canola, most of which were of the herbicide tolerant variety. In 2008, 6.399 million hectares (MHT) were seeded to canola, representing an 7.4% increase over 2007 levels. With the continual development of new GM varieties, the expectation is that the area sown to GM crops in Canada will continue to increase. This is especially true with the development of GM 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. In addition, the acreage planted to spring wheat developed through mutagenesis is increasing in Canada and this trend is expected to continue as varieties of wheat resistant to fusarium are developed. Monsanto had applied for regulatory approval for Roundup Ready wheat, but has since withdrawn plans to introduce the crop on the market as a result of strong opposition from groups like the Canadian Wheat Board (CWB) and the National Farmers Union (NFU).

According to an independent study on the commercial success of GM crops in Canada released by Crop Life Canada, there are several other biotech crops being grown in Canada. According to Crop Life Canada's press release, PEI farmers, in 2008, expect to grow 1,400 hectares of GM sugar beets in 2008, and the expectation is that that number will double by 2009.

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 to the CFIA as of August 2008 in attempt to get regulatory approval.

Table 1. Crops Submitted and Awaiting Regulatory Approval

Product for Submission	Developer
Brassica juncea which has been developed for herbicide tolerance using conventional methods (mutagenesis and breeding)	BASF Canada Inc.
Durum wheat ALS3 which has been bred for herbicide tolerance (mutagenesis procedure)	BASF Canada Inc.
Durum wheat ALS2 which has been bred for herbicide tolerance (mutagenesis procedure)	BASF Canada Inc.

[1] Western Canada consists of Manitoba, Saskatchewan, Alberta, and British Columbia.

Wheat (ALS1b) which has been bred for herbicide tolerance (mutagenesis procedure)	BASF Canada Inc.
Wheat (ALS3) which has been bred for herbicide tolerance	BASF

Source: Canadian Food Inspection Agency
http://www.inspection.gc.ca/english/plaveg/bio/pbopnte.shtml

Several biotech crops received approval in 2007/2008. Livestock feed use of cotton event GHB614 was authorized as of April 4, 2008. The Canadian Food Inspection Agency issued a press release in May 2008 to announce the approval and the conditions under which cotton event GHB614 can be used. Cotton event GHB614 and any cotton lines derived from it may be used as livestock feed provided (i) no inter-specific crosses are performed, (ii) the intended use(s) are similar, (iii) it is known, following thorough characterization, that these plants do not display any additional novel traits and are substantially equivalent to currently commercialized cotton, in terms of their specific use and safety for the environment and for human and animal health and (iv) the novel genes are expressed at a level similar to that of the authorized line. Note, cotton is not grown in Canada.

The unconfined release into the environment and use as livestock feed of corn event MON 89034 was authorized by Plant Biosafety Office of the Plant Products Directorate and the Animal Feed Division of the Animal Health Directorate as of June 19, 2008. A press release issued in June 2008 outlines the conditions. Any corn lines derived from event MON 89034 may also be released into the environment and used as livestock feed, provided that (i) no inter-specific crosses are performed, (ii) the intended uses are similar, (iii) it is known based on characterization, that these plants do not display any additional novel traits and are substantially equivalent to currently grown corn varieties in Canada, in terms of their potential environmental impact and livestock feed safety, (iv) the novel genes are expressed at a level similar to that of the authorized line and (v) the insect resistance management requirements described in the present document are applied.

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 rely on the large supply of 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 rely on corn and soybean imports from the United States. As a majority of the corn and soybeans grown in U.S. are GM, this is what Canada imports. In addition, Canada also imports GM 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 GM 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 GM 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. 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:

1. A substance, including a microorganism that does not have a history of safe use as a food.

2. 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.

3. 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.

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,	*Consumer Packaging and Labeling Act,* *Feeds Act,* *Fertilizer Act,* *Food and Drugs Act,* *Health of Animals Act,* *Seeds Act,*	*Feeds Regulations,* *Fertilizer Regulations,* *Health of Animals Regulations,* *Food and Drug Regulations*

	Livestock feeds	*Plant Protection Act*	
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	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	X		
• Animal feeds	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:

1. 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.

2. 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.

3. 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 2007, Canada had 346 field trials of various crops from numerous companies. Of the 346 field trials conducted in 2006, 316 (91%) of them involved plants with "stacked" traits.

Table 4. Field Trials in 2007 (excluding canola)

Crop	alfalfa	brown mustard							camelina	corn					ethiopian mustard	safflower	soybean						sunflower	tobacco	trees
Number of Traits	2	1	2	2	3	3	4	4	2	1	2	2	2	3	2	2	1	2	2	2	3	3	1	3	2
Number of Field Trials	1	9	4	4	1	4	3	4	12	2	2	2	5	3	6	1	10	1	14	25	3	18	4	1	1
Traits																									
Selection Marker														x											
Yeild Increase									x			x								x		xx			
Tolerance		x	x	x	x	xx	xx	xx	x	x	xx	x		x		x	x	x	xx		xx		x		
Anitbiotic Resistance	x												x		x					x		x		x	x
Male Sterility			x		xx		xx																		
Genetic Research	x																								x
Stress Tolerance													x	x										xx	
Modified Oil Composition															x			x			x				
Fertility Restoration				x		x		xx																	
Precusor																x									

Source: Canadian Food Inspection Agency
http://www.inspection.gc.ca/english/plaveg/bio/dt/dt_07e.shtml

Table 5. Canola Field Trials in 2007

Number of Traits	1	2								3					4	
Number of Field Trials	5	2	2	4	4	8	8	10	107	2	7	8	8	15	8	8
Traits																
Selection Marker										x						
Yeild Increase									x		x			xx		
Herbicide Tolerance	x			x	x	x				x		x	xx		xx	xx
Anitbiotic Resistance		x	x				x	x	x		xx			x		
Insect Resistance																
Fertility Restoration													x			xx
Male Sterility						x									xx	
Stress Tolerance		x		x												
Genetic Research			x													
Improved Agronomics					x											
Fungal Resistance							x									
Modified Oil Composition								x		x		xx				

Source: Canadian Food Inspection Agency
http://www.inspection.gc.ca/english/plaveg/bio/dt/dt_07e.shtml

4. 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)

5. 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.

6. 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 17th, 2007. The government has announced its intention to replace the CBAC with a Science, Technology and Innovation Council, as part of a broader effort to consolidate external advisory committees and strengthen the role of independent export advisors. In November of 2006, the CBAC released an annual report to guide the federal government on policy issues associated with biotechnology, and in March of 2007, it released a memorandum conveying its views about a report released October of 2006 entitled BioPromise?, Biotechnology, Sustainable Development and Canada's Future Economy. These reports are available at the following web addresses: http://cbac-cccb.ca/epic/site/cbac-cccb.nsf/en/ah00617e.html (annual report) and http://cbac-cccb.ca/epic/site/cbac-cccb.nsf/en/ah00609e.html (BioPromise?).

CFIA, in the fall of 2006, began consulations 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. While CFIA has made it clear that this proposed change in no way changes the safety assessment of novel genetically modified crops, it does have potential to allow for a quicker registration. Although not the specific focus of these consultations, various farm groups such as the Canadian Federation of Agriculture and the Canadian Wheat Board have used the opportunity to push for additional improvements of the Seed Regulatory Framework. There is a concentrated push from these farm groups for modifications of the regulatory system to include a type of cost-benefit as a part of the regulatory process prior to the release of a novel plant, with specific focus on those crops produced through genetic modification. These groups are not

proposing that this change be applied to all novel food and PNTs, but more specifically be applied only to field crops. In addition, these groups also propose that a cost-benefit analysis only be applied to certain crops. The argument put forth by the groups striving for this change is that the current regulatory system allows for the introduction of a new product created through biotechnology without taking into consideration what impact the product may have on the marketplace. These groups want to ensure that potential market impact, system compatibility, economic benefits and costs to farmers are considered and adequately addressed prior to the unconfined release and production of new agricultural products in Canada. They argue that at this time, there are markets where transgenetic products may not be acceptable, and feel that Canada, due to its high dependence on export markets, is particularly vulnerable. They argue that it may be difficult at times to maintain separation between a genetically engineered (GE) product and a non-GE product and that uncertainties remain over the full implications of the Biosafety Protocol. On other hand, farm groups like the Grain Growers of Canada, Agricore United and many others strongly oppose a mending Canada's regulatory framework by adding a cost-benefit analysis as a requirement for the approval of any plant or foods with novel traits. These groups believe that Canada has one of the best regulatory processes in the world and it should remain science-driven, with the decision for or against approval be science-based, not market-based. These groups forecast that adding a cost-benefit analysis to the regulatory approval process will only bog it down, and add unnecessary additional layers to the already complex and intricate approval process. The addition of a cost-benefit analysis could further delay the introduction of crops that could be beneficial to Canadian producers, putting them at a competitive disadvantage with competing countries, which have already approved the product, including the United States. During the debate regarding the approval of Round-up Ready wheat, the groups that opposed the changes to the regulatory process conceded to include a market impact study done in addition to the regulatory approval, but approval of the product was not contingent on findings of the market impact study.

Canada has eliminated the kernel visual distinguishability (KVD) requirement on its wheat varietals grown in western Canada. The KVD requirement was initially part of the quality assurance system for western wheat. With new niche markets developing, and the emergence of a wheat-based biofuel industry in Canada, the KVD requirements were burdensome to seed developers. In early 2008, Canadian Agriculture Minister, Gerry Ritz, ordered the removal of the varietal control requirements as of August 1, 2008 in a bid for Canada to remain competitive in the emerging bio-based economy.

Table 6. Recently Approved Crops in Canada

Crop	Designation / Event	Applicant(s)	Trait	Reviewed and Approved Uses Within Canada	Approval and link to decision document	
Canola	Canol B. juncea	BASF Canada	Imidazolinone tolerance; ***non-LMO***	Environment, feed, food	2-May-08	DD2008-73
Corn	Corn Event 3272	Syngenta Seeds Canada Inc.	Expression of a thermostable alpha amylase enzyme	Environment, feed, food	13-Mar-08	DD2008-70
Cotton	Cotton Event GHB614	Bayer Crop Science	Glyphosate tolerance	not grown in Canada, feed, food	4-Apr-08	DD2008-72
Soybean	Soybeans Delicious Soybeans	Monsanto Canada Inc.	Reduced glycinin content; ***non-LMO***	Environment, feed, food (not considered novel)	11-Mar-08	DD2008-71

Sunflower	Sunflower Express Sun SU7	Pioneer Hi-Bred Production Ldt.	Sulfonylurea tolerance; **non-LMO**	Environment, feed, food (not considered novel)	3-Jan-08	DD2008-69

Table 7. Approved Biotech Crops in Canada

Crop	Designation / Event(s)	Applicant(s)	Trait	Reviewed Uses Within Canada
Alfalfa	J101,J163	Monsanto Canada Inc.	Glyphosate tolerance	Environment, feed, food
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	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 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 Bayer CropScience)	Glufosinate ammonium tolerance	Environment, feed, food
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	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 AgroSciences Canada Inc.	Lepidopteran resistance	Feed, food
Cotton	DAS-21023-5	Dow AgroSciences Canada Inc.	Lepidopteran resistance	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	A2704-12, A5547-127	AgrEvo Canada Inc. (currently Bayer CropScience)	Glufosinate ammonium tolerance	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
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 turgidum L.) events DW2, DW6, and DW12	BASF Canada Inc.	Imidazolinone tolerance	Environment, 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, current as of Augst, 2008
http://active.inspection.gc.ca/eng/plaveg/bio/pntvcne.asp

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 fight in Canada for mandatory labeling of genetically engineered food continues despite the creation and implementation of the Standard. In May of 2008, a private member's bill seeking mandatory labeling on foods containing genetically modified components (Bill C-517) was introduced in the House of Commons, and, to many people's surprise, was called forward for debate at second reading. The bill sought to amend the Food and Drug Act by adding a narrow definition of the term "genetically modified" (GM), and adding to the duties of the Minister of Health. The additional duties were to involve being responsible for establishing which foods contain genetically modified components, and then publishing this information on a publicly available website. The bill also required that sixteen days after the initial publication date, sales of the products on the list would be prohibited unless a label is affixed to the product stating "This product or one or more of its components has been genetically modified" and a sign be posted near the GM-containing foods that states "genetically modified". The fact that the bill was being debated raised enough concern by biotechnology stakeholders that a coalition was formed to strongly lobbying key Parliamentarians and prevent the bill from proceeding. The bill was ultimately defeated.

At this time, there are still two other biotech-related bills that, technically, could be called forward should they receive enough support. Private Member's bill C-456 calls on the government to implement mandatory labeling on products created through genetic modification (genetic engineering). The bill was presented before Parliament in December 2004, and went through first reading in the House of Commons on June 12th, 2007. While some Members of Parliament strongly endorse the need for mandatory labeling and will support this bill, most MP's will not vote in favor of implementing mandatory labeling and therefore will most likely defeat this bill if it were ever brought forward. A second private member's bill related to the marketing of biotechnology, Bill C-448, received first reading in the House of Commons on May 31st, 2007. Bill C-448 seeks to create an Act to prohibit the sale, importation and use of seeds incorporating or altered by variety-genetic use restriction technologies (V-GURTs), also called "terminator technologies". Parliamentary sources suggest that most members of Parliament would not vote in favor of such a bill either, but also state that most MPs feel it is an important issue to be discussed/debated. Also of note, V-GURTs is listed among CFIA's priority issues. More information on these Bills can be found at the following websites: http://www2.parl.gc.ca/HousePublications/Publication.aspx?Docid=3031012&file=4 and http://www2.parl.gc.ca/HousePublications/Publication.aspx?DocId=2987317&Language=e&Mode=1.

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, Agricore United and many others, to the ratification of the Protocol. There are also those groups like the National Farmers Union and Greenpeace, who 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 IV. 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 genetically modified (GM) crops, Canadian producers have been able to secure markets for their GM crops. For example, Japan is one of the largest importers of Canadian canola, of which a majority is GM. 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 GM 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 GM canola. Acreage seeded to GM canola continues to increase each year, which is a testament to the success and acceptance of GM 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 GM 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 GM flax. Canadian flax producers were concerned that they would be unable to keep GM and non-GM 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 GM varieties of flax into the Canadian market. But the health benefits of the GM 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.

The largest issue regarding market acceptance of a biotech crop was the recent uproar regarding the regulatory approval of Round-up Ready (RR) wheat by Monsanto. The issue of RR wheat in Canada became very divisive. Some producers believed in the benefits of growing RR wheat and supported its regulatory approval, while other producers feared the approval and commercialization of RR wheat would cost Canadian wheat farmers their international markets. This fear was fueled by the refusal of major customers to accept any RR wheat. As the only marketing agency for Western Canadian wheat in the international marketplace, the Canadian Wheat Board (CWB) was vehemently opposed to the regulatory approval and commercialization of RR wheat.

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 GM wheat in Canada. The position of the CWB is that the commercial release of GM wheat (including RR wheat) should not occur until the conditions developed by the CGIWG have been met. The conditions developed by the CWB and the working group for the commercial release of GM wheat are: market acceptance, segregation systems, agronomic information and cost-benefit analysis. The group defined market acceptance as:

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

The first condition for market acceptance was that GM 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 GM wheat.

The third condition for market acceptance was the ability to meet non-GM market requirements, including the establishment of achievable tolerance levels for the presence of GM material in non-GM 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 GM wheat and require certification stating shipments do not contain GM 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 GM and non-GM wheat prior to the release of GM 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 GM 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 GM 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 GM 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 GM wheat and for changes to the regulatory approval process will make Canada a less attractive place for the commercial introduction of GM wheat and possibly other GM crops.

The current state of play for GM 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 US, 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 GM wheat requirements. When approval for GM wheat was first sought, both the U.S. and Canadian grain industries advocated for the release of GM 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 has put a great deal of pressure on the system to change and may lead to an openness for GM wheat for industrial purposes.

It should be noted that the initial experience of one company with GM wheat approval has not deterred other companies from pursuing this approval. As reported earlier in this report, companies are conducting field trials of herbicide tolerate durum wheat and fungal (fusarium) resistant wheat in order to obtain approval for release in North America.

SECTION V. REFERENCE MATERIAL

AgBios
www.agbios.com

AGCare
www.agcare.org

Agricore United
www.agricoreunited.com

Agriculture and Agri-Food Canada
www.agr.gc.ca

AgWest Bio Inc.
www.agwest.sk.ca

BIOTECanada
www.biotech.ca

Canadian Biotechnology Advisory Committee
www.cbac-cccb.ca

Canadian Food Inspection Agency
www.inspection.gc.ca/english/toc/bioteche.shtml

Canadian General Standards Board
www.pwgsc.gc.ca/cgsb/home/index-e.html

Canadian Wheat Board
www.cwb.ca

Canola Council of Canada
www.canola-council.org

Council For Biotechnology Information
www.whybiotech.ca

Croplife Canada
www.croplife.ca/english/index.cfm

Dietetics @ Work
www.dieteticsatwork.com/index.asp

Environment Canada
www.ec.gc.ca

Genome Canada
www.genomecanada.ca

Grain Growers of Canada
www.ggc-pgc.ca

Health Canada
www.hc-sc.gc.ca

Ontario Soybean Growers
www.soybean.on.ca

Plant Biosafety Office
www.inspection.gc.ca/english/plaveg/bio/pbobbve.shtml

Plant Breeders' Rights Act
http://laws.justice.gc.ca./en/P-14.6/fulltoc.html

Royal Society of Canada
www.rsc.ca

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