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Agricultural Biotechnology Annual

Canadian GE Planting Reaches 8 Million Hectares

Approved By:
Robin Gray

Prepared By:
Mihai Lupescu

Report Highlights:
Canadian planting of biotech crops is forecast at about 8 million hectares in 2011, up from about 6.9 million hectares in 2010. The main biotech crops remain canola, corn, soybeans, and, most recently a small amount of sugar beets. Canada remains one of a handful of countries which has approved stacked traits, or planting up to three traits in one crop. On the animal side, guidance from the three regulatory agencies in Canada may be issued within the next year on the issue of whether the offspring or products of clones fall under Canada's novel food act.

SECTION I. EXECUTIVE SUMMARY

Canada was ranked fifth in the world for hectares of land planted with biotech crops according to the International Service for the Acquisition of Agri-biotech Applications in 2010, behind the United States, Brazil, Argentina and India. Actual data on biotech production are limited, although estimates of area planted are available from Statistics Canada and the Canola Council of Canada and suggest almost 8 million hectares in 2011, up from about 6.9 million hectares in 2010. Major Canadian biotech crops remain canola, corn, soybeans and, most recently, sugar beets.

Canada's strong research system and proximity to the United States facilitate collaboration and advances in biotechnology. Canada is one of a handful of countries, along with the United States, Australia, Mexico and South Africa which includes up to three traits in one crop, so that farmers have the option of planting corn seed that is herbicide-tolerant and resistant to two pests: corn borer and corn rootworm.

In August 2011, Monsanto's Roundup Ready soybean trait will be the first widespread plant biotechnology trait to go off patent. The first year Canadian farmers may plant Roundup Ready soybeans saved from their own seed production is 2013. This creates the potential for confusion in the exporting regulatory process. In some countries the approval processes for biotech crops can often take three or four years and may also have a time limit once approval is granted. All these varying timetables could cause complications for Canadian soybean exports.

In September 2009 routine testing indicated trace amounts of a biotech variety, Triffid, in Canadian flax imported into the European Union. Canada supplied about 70 percent of European imports. Canada negotiated a testing and certification protocol but exports have been slow to resume.

On the animal side, guidance from the three regulatory agencies in Canada may be issued within the next year on the issue of whether the offspring or product of clones fall under Canada's novel food act. Meanwhile, EnviroPig, the transgenic pig with reduced phosphorus waste production, cleared the first of several regulatory hurdles in February 2010 when the Canadian Environmental Protection Agency approved reproduction of the animal in confined conditions.

SECTION II. PLANT BIOTECHNOLOGY TRADE AND PRODUCTION

Biotech Production:

Statistics Canada data combined with information from the Canola Council of Canada provides the best estimate of the level of biotechnology adoption in Canada. The Statistics Canada data provide indications from the annual June farm surveys for corn and soybeans. Comparable data are not available for canola but the Canola Council estimates adoption at about 80 percent of planted area. For sugar beets, little data is available, but it is probably fair to say that most of the total acreage, amounting to less than 20,000 hectares, is planted with biotech varieties. The following table combines information from Statistics Canada and the Canola Council to provide an overview of biotech planting in Canada.

Table 1: Estimated Seeded Area of Biotech Crops

Area Seeded ('000 hectares)	2007	2008	2009	2010	2011
Corn for Grain	1,391.5	1,204.0	1,203.5	1,214.3	1,230.8
Fodder Corn	246.4	244.9	312.2	244.6	201.8
Total Corn	1,637.9	1,448.9	1,515.7	1,458.9	1,432.6
Biotech Corn	636.7	632.6	743.0	795.1	825.3
Biotech Corn - % of Total	**39%**	**44%**	**49%**	**54%**	**58%**
Soybeans	1,180.1	1,211.3	1,395.3	1,483.0	1,572.4
Biotech Soybeans	529.7	604.7	604.6	658.1	728.7
Biotech Soybeans - % of Total	**45%**	**50%**	**43%**	**44%**	**46%**
Canola	5,959.5	6,398.9	6,555.8	6,806.1	8,012.6
Biotech Canola*	4,767.6	5,119.1	5,244.6	5,444.9	6,410.1
Biotech Canola - % of Total	**80%**	**80%**	**80%**	**80%**	**80%**

Source: Statistics Canada / *No data available from Statistics Canada; Canola Council estimates 80 percent of Canadian canola is planted with biotech varieties so figures supplied here are calculated based on Statistics Canada data on total planted area.

Canola

Most of Canada's canola production is centered in the western provinces of Manitoba, Saskatchewan and Alberta. Statistics Canada reports that Prairie farmers had either planted, or intended to plant, a record area of canola. Current estimates show record 2011 plantings up by 17.7 percent from an already 2010 record year. However, these estimates may change with the next official release of data in August 2011, due to a very wet seeding season in the west. According to the Canola Council of Canada, about 80 percent of total canola area is seeded to biotech varieties. That would put 2011 biotech acreage at about 6.41 million hectares up from 5.44 million hectares planned in 2010. Roughly calculated canola oil accounts for 70 percent of the vegetable oil consumed by Canadians, but that requires only about 25 percent of Canadian canola crop. This means nearly 75 percent of Canadian canola seed, oil and meal are exported to destinations such as the United States, Japan, Mexico and China.

Corn

Biotech corn plantings have been steadily increasing, and biotech corn currently accounts for 58 percent

of all corn planted in Canada, an increase from 54 percent in 2010. Quebec and Ontario are the primary corn-growing regions, accounting for 90 percent of total Canadian corn acreage. In these two provinces the adoption of biotech varieties in 2011 totaled 283 thousand hectares for Quebec and 542 thousand hectares for Ontario. Quebec has 65 percent of their total crop as biotech (up from 47 percent in 2007), and in Ontario 64 percent of total corn planted is biotech (up from 41 percent in 2007).

Soybeans

Biotech soybeans increased on a national scale from 658 thousand hectares in 2010 to 729 thousand hectares in 2011, a 10.7 percent increase. Quebec and Ontario are also the primary soybean growing regions in Canada, accounting for 80 percent of soybean acreage in Canada in 2011 (down from 92 percent in 2007, primarily due to increased production in Manitoba over the past five years). At 148 thousand hectares in 2011 Quebec's biotech soybeans represent 52 percent on the province's total soybean acreage (up from 49 percent in 2010), while in Ontario soybean biotech amounts to 581 thousand hectares in 2011, or 59 percent of the total soybean acreage in the province (up from 54 percent in 2010). In 2011 Manitoba increased their soybean seeded area to 279 thousand hectares from 210 thousand hectares in 2010 but recorded no planting of biotech varieties.

Sugar Beets

The first herbicide tolerant sugar beets were approved in the United States, Australia, Canada, and the Philippines in 2005. In 2009, after four years of trial fields, biotech sugar beets were planted in Taber, Alberta, by the sugar company Lantic Inc. Alberta has had the largest share of the country's sugar beet area since 1951 with production concentrated near Taber, where Canada's only sugar beet processing plant is located. In 2010, approximately 12,000 hectares of sugar beets were seeded in Alberta, with an additional approximately 3,500 hectares in Ontario. It is fair to assume that most of this sugar beet is biotech and that same acreage is seeded in 2011.

Biotech Trade:

Canada is an importer of biotechnology crops and products, including grains and oilseeds such as corn and soybeans. Industries such as ethanol production and the livestock feed industry import U.S. corn and soybeans. In marketing year 2009/2010 Canada imported 2.1 million metric tons (MMT) of corn, 1.08 MMT of soybean meal and 375,000 MT of soybeans from the United States. Most corn and soybeans grown in United States are biotech, so a majority of Canada imports are biotech as well. Canada also imports biotech papaya from Hawaii.

SECTION III. PLANT 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.

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.

Provincial governments support the leadership role played by the federal government in regulating agricultural products of biotechnology. There are ongoing consultations between federal and provincial governments (e.g. the 1995 Federal/Provincial workshop on the Regulation of Agricultural Products of Biotechnology) to discuss the regulation of agricultural products of 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, 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

Sources: Health Canada, Environment Canada, Canadian Food Inspection Agency, Fisheries and Oceans Canada

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

Sources: Health Canada, Environment Canada, Canadian Food Inspection Agency, Fisheries and Oceans Canada

Plants with novels traits are subjected to examination under Canada's regulatory process. The 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 2010, Canada had 159 submissions and 797 field trials of various crops from numerous companies. The following link leads to a table including a summary of all 2010 field trials' breeding objectives by various crops: Table 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)
- 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.
- 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 June 2011, the Science, Technology and Innovation Council released its second public report, entitled State of the Nation 2010 - Canada's Science, Technology and Innovation System which tracks the progress on innovation in Canada since the first report from 2009. State of The Nation 2008 - Canada's Science, Technology and Innovation System was the first report issued by the Council which benchmarked Canada's science, technology and innovation system against the world's innovating countries.

Since Post's last annual biotechnology report, no new biotech crops have received approval from the Plant Biosafety Office of the Plant Health and Biosecurity Directorate and the Animal Feed Division of the Animal Health Directorate, both under CFIA; here is a link to Table 5 listing the recent approvals as well as the recent submissions that are pending approval. Finally, here is a Database containing information on the status of regulated plants with novel traits in Canada, including whether products have been approved for unconfined environmental release, novel livestock feed use, variety registration and novel food use.

Regulation of Stacked Plant Products in Canada

Similarly to these new varieties, many stacked products, defined in Canada as plant lines developed by conventional crossing of two or more authorized PNTs, do not require further assessment of their environmental 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. However, as a precaution, the PBO requires notification of all stacked products before they are introduced into the marketplace. These notifications are required so that regulators may determine if:

- Any conditions of authorization placed on the parental PNTs are compatible and appropriate for the stacked plant produce
- Additional information is required to assess the safety of the stacked plant product

Additional information and further assessment will be required if:

- The conditions of authorization of the parental PNTs would not apply to the stack (for example, a product developed is applying for alterations to stewardship requirements, or the conditions described in the stewardship plans of parental PNTs are no longer effective for the stack)
- The novel traits of the parental PNTs are expressed differently in the stacked plant product (e.g. greater of lower expression)

- The stacked product expresses an additional novel trait

Table 6 provides a list of stacked products authorized for unconfined release into the Canadian environment.

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 biotech 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 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 Biotech 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.

The Cartagena Protocol on Biosafety

In 2001, Canada signed onto the Cartagena Protocol, 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:

- Proceed to immediate ratification of the Protocol with the intent to participate as a Party in the first meeting of the Parties;
- 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;
- Decide not to ratify the Protocol.

The position the Government of Canada has taken follows along the line of the second option and industry sources indicate that this is likely to remain the course for at least the medium term. Canada and Canadian industries rely heavily on imports of United States 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.

During the next year there are several breeders whose patent protection will expire, for instance, Roundup Ready soybeans patent will expire in August, 2011, the first widespread plant biotechnology with novel traits to go off patent (Monsanto Stakeholder Letter July). However, Canadian Soybean Exporters Association (CSEA) cited a few factors that decrease the impact of the expirations. First, most soybeans are used for crush (not food), and exported, placing a majority of the change on the seed companies. Second, Monsanto has already developed and begun advertising a second-generation Roundup Ready soybean technology–Genuity™ Roundup Ready 2 Yield® (RR2), developed in 2009, advertising 7-11% higher yields than Roundup Ready soybeans, and many farmers have begun preparing to make the transition. Third, corn is a much more important market for biotech expiration

dates as the consumption is largely domestic, and a majority of biotech corn is devoted to food products. However, corn biotech seeds have a quicker shelf life than soybeans, and famers are prohibiting from retaining their seeds, which encourages the introduction of new varieties every season to create a constant approval of new corn seeds.

In August 2011, Monsanto's Roundup Ready soybean trait will be the first widespread plant biotechnology trait to go off patent. The first year Canadian farmers may plant Roundup Ready soybeans saved from their own seed production is 2013. This creates the potential for confusion in the exporting regulatory process. In some countries the approval processes for biotech crops can often take three or four years and may also have a time limit, which may be difficult for Canadian soybean exports. There is increased potential for exporting nations to block Canadian imports until the approval is confirmed. However, farmers may chose to take advantage of the farmers' ability to buy certified seed from any company that held a valid license for original Roundup Ready soybeans without any contractual obligations or royalty due Monsanto for the trait, which could balance out the lapse in approval processes.

SECTION IV. PLANT BIOTECHNOLOGY MARKETING ISSUES

Consumer surveys find public opinion on biotech in agriculture divided. A 2002 Pew Global Attitudes Project survey reported that only 37 percent of Canadians viewed scientifically altered fruits and vegetables as good, whereas 63 percent thought these products were bad. A 2006 Decima Research survey concluded that, although Canadians embrace most types of new technology such as hybrid cars, biofuels and stem cell research, 58 percent of Canadians believed that biotech animals will make life worse over the next twenty years, 54 percent held the same view of biotech fish, and 50 percent believe their future will be negatively impacted by biotech food. Conversely, in a 2008 survey by BIOTECanada, 79 percent of Canadians agreed that biotechnology would bring benefits to agriculture. Thus, more uniform and long-term surveys must be administered before firm conclusions can be drawn about public opinion.

Canola

Canola is a “Made in Canada” crop, including its name, which stands for Canadian oil, low erucic acid. The canola industry reports 60,000 canola growers, 13 processing plants in five provinces, 2,800 employees and the industry estimates that canola contributes C$13 billion annually to the Canadian economy. The Canola Council of Canada is an industry group that promotes the benefits of consuming canola encourages canola exports.

Biotech canola varieties have been modified to be resistant to specific herbicide. Although the plants are modified, the industry points out that the oil is not modified, and therefore canola oil is the same whether from modified or conventional canola seed. The Canola Council stresses the health benefits of biotech canola, which is grown on about 80 percent of land planted in canola in Western Canada. In 2008, the Canadian government attempted to increase overall canola supply, as the Agriculture and Agri-Food Canada’s Agri-Marketing announced a C$ 3 million program to support the Canola Council of Canada’s (CCC’s) “Growing Great 2015” strategy to increase international demand for canola products. In 2011 it is estimated that farmers will plant a record area with canola – over 8 million

hectares, up almost 18 percent from 2010, while Canada is expected to export in the 2010/2011 marketing year over 2.3 million metric tons of canola oil, beating the previous year's record of over 1.8 million metric tons.

Flax

The issue facing Canadian flax producers has never been opposition to biotech flax at home, but in exports of flax to Canada's largest market, the European Union (EU). In the late 1990's a biotech flax seed, an herbicide tolerant variety, was registered and approved by the CFIA and Health Canada for commercial production and consumption. The variety was registered as Triffid. But consumers in the EU 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 in 2001. However, in September 2009 routine testing indicated trace amounts of the Triffid were found in Canadian flax imported into the EU. Canada supplied about 70 percent of European imports. Canada negotiated a testing and certification protocol but exports have been slow to resume.

Wheat

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. No varieties are in the regulatory approval pipeline.

In May 2009, pro-biotech wheat groups from the United States, Canada, and Australia announced plans to synchronize commercialization of biotech traits in the wheat, and simultaneously emphasized the importance of wheat to the world food supply and citing declining acreage of wheat in the three countries, which they attributed in part to competition from biotech crops. However, other Canadian wheat groups continue to oppose biotech wheat, including the National Farmers Union, the Canadian Biotechnology Action Network, Union Paysanne and Union Biologique Paysanne.

On April 19, 2010, Ian White, head of the Canadian Wheat Board, made the statement that more testing of the world's wheat would find biotech traces due to containment from other crops in the grain-handling system. White argued for the acceptance of low-level biotech materials in wheat, but recognized that biotech wheat would likely not become commercialized for a decade.

The Canadian Wheat Board did not sign the pro-biotech wheat petition; will not support genetically modified wheat until the follow conditions are satisfied:

- Widespread market acceptance;
- The establishment of achievable tolerance levels;
- The development of an effective segregation system;
- The availability of rapid, accurate and inexpensive detection technology; and
- A positive benefit-cost ratio in the wheat value chain, especially for farmers.

Currently, there is little movement to commercialize biotech wheat in Canada, as Canadian produces are wary after the trade disruption caused by trace amounts of biotech flax. Something to follow is the potential impact of proposed government changes to the Canadian Wheat Board on Canadian farmers' views on biotech wheat, but that impact would be slow and gradual. However, if and when the change does come, many Canadian producers are arguing for cooperation with the United States so that biotech wheat seed can be released throughout North America. Although slowed by more complicated licensing in Canada than the United States as well as contamination worries, biotech wheat could be helped by increasing numbers of niche markets and the growth of the Canadian biofuel industry.

SECTION V. PLANT BIOTECHNOLOGY CAPACITY BUILDING AND OUTREACH

Not applicable to Canada.

SECTION VI. ANIMAL BIOTECHNOLOGY

Development and Use

EnviroPig, the world's first transgenic animal created at the University of Guleph, was created in 1999 with a snippet of mouse DNA introduced into their chromosomes, which causes the pigs to produce reduced phosphorus feces. Enviropigs have been under development for well over 10 years, with the aim that they could be one day be sold to commercial hog farmers. However, despite the support from organizations such as Ontario Pork, EnviorPig has yet to sign a full commercial partner due to the complicated regulatory hurdles required to approve the meat for human consumption. The university has an application into Health Canada, submitted in 2009, asking the agency to declare the pigs fit for human consumption. Another application to the U.S. Food and Drug Administration is still pending. However, In February 2010, the University of Guelph cleared the first regulatory hurdle when it received approval from the Canadian Environmental Protection Agency to reproduce the animal in confined conditions. The University of Guelph hails this as an important milestone that means that other facilities can now start breeding the pigs for research but cautioned that EnviorPig has been patiently waiting for ten years, and will continue to wait until the pig is approved for human consumption. The university has identified both the United States and China as lucrative markets for EnviroPig.

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 fish hatchery on a 3.5 acre site on Prince Edward Island. AquAdvantage Salmon grow faster and reach mature size earlier than standard salmon, but they do not grow to be larger. In addition to salmon, AquaBounty is also developing advanced-hybrid trout, and tilapia designed to grow faster than traditional fish.

Nexia Biotechnologies changed leadership and expanded in 2006 after an agreement with Enesco

Energy Services Corps resulted in the amalgamation of Nexio, Private Enseco and Management Co to form "Enseco Energy Services Corp," a new oil and gas service industry company and the creation of New Nexia which will continue to pursue Nexia's biotechnology opportunities. They will continue to study transgenic biology to transfer specific genes of interest into mice (gene testing) or goats (protein production) through nuclear transfer or microinjection. Once a transgenic fertilized egg is transferred to the foster recipient, a normal pregnancy ensues, and gestation time 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. Nexia is 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.

In late July 2010, Canada's first cloned bull, born and raised in one of the country's premiere artificial insemination centers was made available to the public. Starbuck II was on display at the St. Hyacinthe Agricultural Expo, at ten years old weighing in at 1,100 kilograms and standing 6 feet tall at his shoulder. For the first time, the test tube animal is outside the bio-secure facilities at the Artificial Insemination Centre of Quebec (CIAQ). Three scientific groups (CIAQ, Alliance Bovine and the Veterinary Department of the University de Montreal) took part in the groundbreaking cloning. Two years after the death of Starbuck, Starbuck II came into the world via caesarean section. Starbuck II may be the clone of a prize winning and very profitable stud, but neither his semen nor his flesh can be sold in Canada due to Environment and Health Canada regulations. According to CIAQ at one time there were 13 different cloned bulls in Canada, but now there are none left. Starbuck II passed away in September 2010. Because of the time it takes to clone and the restrictions on the sale of the byproducts of the process, cloning is no longer a priority for CIAQ.

Regulation

The regulation of animal clones, their offspring and products of clones or offspring currently fall under the Novel Foods provision of Canada's Food and Drug Regulation (Division 28, Part B), the Feeds Regulations and the New Substances Notification Regulations (Organisms). Novel foods are defined as products that have not demonstrated a history of safe use, and have utilized a new method of manufacture that can lead to a significant change in the product from conventional counterparts. However, there remains a question on whether clones and their offspring and/or the products of clones and their offspring equally meet the definition of a novel food. To move towards a final regulatory policy, the three main governmental units with jurisdiction on biotechnology (Health Canada, Environment Canada and Canadian Food Inspection Agency) are reportedly drafting a scientific opinion paper meant to lay out the framework for the Government of Canada to then move forward on regulating clones, their progeny and product determining whether these animals, their progeny and/or their products meet the definition of novel foods.

The Animal biotechnology sector, despite new and specific regulations, 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).

Stakeholder/Public Opinions

As with crops developed through biotechnology, Canadian regulators will most likely 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.

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.