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Report Highlights:
Canadian planting of biotech crops is estimated at about 10.3 million hectares for 2016, flat from the previous year. The main biotech crops remain canola, corn and soybeans, with small amounts of sugar beets added recently. Canada is one of a few countries to approve stacked traits, or to allow for multiple genetically engineered traits in a plant. In 2016, the AquAdvantage salmon was the first genetically engineered animal to receive food and animal feed approval in Canada.

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Section I. Executive Summary

In 2015, Canada was ranked fifth in the world for hectares of land planted with biotech crops, with 11 million hectares, according to the International Service for the Acquisition of Agri-biotech Applications. Countries ranking ahead of Canada are: the United States, Brazil, Argentina and India. Actual Canadian data on biotech production are limited, although estimates of area planted are available from Statistics Canada for corn and soybeans, and the Canola Council of Canada for canola.

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 allow multiple stacked traits in a plant for commercial use. . For example, farmers benefit with the option of planting corn seed that is herbicide-tolerant and resistant to two pests: corn borer and corn rootworm.

In March 2016, the Canadian Food Inspection Agency (CFIA) and Health Canada approved the unconfined environmental release for commercial planting purposes, livestock feed and food use for Innate potatoes, while in March 2015 similar approvals were granted for Arctic apples, all bio-engineered products with various novel traits.

With the 2012 changes to the Canadian Wheat Board that transitioned it from a monopoly organization that directed all marketing of western wheat produced in Canada to a smaller voluntary marketing agency, there may be increased opportunities for groups supporting the commercialization of biotech wheat to have more influence. In early June 2014, most of the Canadian grains organizations which represent the industry at the national level became signatories of an international joint-statement expressing support for the innovation in wheat, which includes the future commercialization of biotechnology.

In 2005, Roundup Ready® alfalfa underwent and passed livestock feed, environmental safety and food assessments conducted by the Canadian Food Inspection Agency and Health Canada. In 2013, the developer of pesticide-resistant alfalfa submitted an application for variety registration to the Canadian Food Inspection Agency. The application was assessed and the variety was registered on April 26, 2013. Variety registration enables Roundup Ready® alfalfa seed to be commercially sold in Canada. Forage Genetics International began selling its genetically modified alfalfa seed in Eastern Canada in the spring of 2016

In the fall of 2013, Canada introduced into Parliament Bill C-18, the Agricultural Growth Act, which seeks, among other things, to toughen enforcement of intellectual property rights for the creation or development of plant varieties. On February 25, 2015 Bill C-18 became law so that Canada's PBR Act is now harmonized with the 1991 International Convention for the Protection of New Varieties of Plants Convention (UPOV).

Based on the feedback received by industry stakeholders during its 2012 public consultation on Canada's "Proposed Domestic Policy on the Management of Low-Level Presence of Genetically-Modified Crops and Imports and its Associated Implementation Framework", Canada published in April 2015, revisions to the original draft and will continue to engage with stakeholders and international partners on the revised draft.

The AquAdvantage salmon is the first genetically engineered animal approved for use in Canada. On May 19, 2016 Health Canada released its decision stating that the salmon was approved for sale in Canada as food. The federal department determined that the changes made to the salmon did not pose a greater risk to human health than salmon currently available on the Canadian market. In addition, Health Canada also concluded that the AquAdvantage salmon would have no impact on allergies, and that there are no differences in the nutritional value of this salmon compared to other farmed salmon available for consumption.

Guidance from the three regulatory agencies in Canada (Health Canada, Environment Canada and the Canadian Food Inspection Agency) is still to be issued on the question of whether the offspring or progeny of clones fall under Canada's Novel Foods provisions of the Food and Drug Regulations. At this point, there is no indication that the decision will be made in the near future.

Section II. Plant and Animal Biotechnology

CHAPTER 1: PLANT BIOTECHNOLOGY

Part A: Production and Trade

a) PRODUCT DEVELOPMENT:

Apples

In March 2015, the Canadian Food Inspection Agency (CFIA) and Health Canada approved the unconfined environmental release for commercial planting purposes, livestock feed and food use for apple (*Malus x domestica*) events GD743 and GS784 which have been genetically engineered to be non-browning. The Canadian company, Okanagan Specialty Fruits from British Columbia, an agricultural biotechnology company, also submitted a risk assessment petition for non-browning apples to the United States Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) in late 2010. The U.S. approval came in February 2013.

The non-browning effect is achieved by silencing the polyphenol oxidase enzyme. Okanagan Specialty Fruits believes that non-browning apples will help apples capture a segment of the fresh-cut produce market which it has eluded them due to, the company believes, the unappetizing appearance of apples that have been pre-cut. The two approved varieties will be marketed under the name "Arctic Granny" and “Arctic Golden”. Okanagan Specialty Fruits has stated that it will try to put as many trees in the ground as possible to make increase production levels so that test market quantities would be available in late 2016.

Currently, there is no production of any Arctic apple in Canada, but there are an estimated 15 acres planted to Arctic Golden in Washington State, British Columbia’s neighbor. The intent is to expand the planted area to 50 acres by 2017. The company also plans to expand the offerings with other varieties, as it has already applied for approval in the United Sates for “Arctic Fuji”, and indicated it would submit an application for “Arctic Gala” in 2017.

Health Canada’s approval status of the Arctic apples can be viewed at the following URL address:
http://www.hc-sc.gc.ca/fn-an/gmf-agm/appro/arcapp-arcpom-eng.php

With growing public interest in the topic, the CFIA has provided a web-page offering more information about the Artic apples, which can be found at the following URL address:
http://www.inspection.gc.ca/plants/plants-with-novel-traits/general-public/arctic-apple-faq/eng/1426884802194/1426884861294

Additionally, Health Canada has created a fact sheet on Genetically Modified Food Myths and Facts:
http://www.hc-sc.gc.ca/fn-an/gmf-agm/fs-if/gm-myths-facts-eng.php

Flax

Canadian flax producers face obstacles with exporting 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. However, 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. 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 and exports have been steadily increasing after falling sharply in 2010. Exports of flax from Canada peaked in the 1990's with volumes in 1997 topping 897 million tonnes. Exports of flax seed reached 640 million tonnes in 2015, down 4 percent from 2014 (CY).

Wheat

In 2002, when Monsanto was seeking regulatory approval for its Round-up Ready (RR) wheat, the issue of biotech wheat in Canada became very divisive among farmers with some strongly believing in the benefits of growing RR wheat and supporting its regulatory approval, and others fearing the approval and commercialization of RR wheat would cost Canadian wheat farmers their international markets. Fear over uncertain 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. At this time, there are no wheat varieties being considered for regulatory approval in Canada.

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.

With the 2012 changes to the Canadian Wheat Board that transitioned it from single-desk marketer of western Canadian wheat to a voluntary marketing agency, there may be increased opportunities for groups supporting the commercialization of biotech wheat to have more influence. In June 2014, a number of Canadian grains organizations signed an international joint-statement with American and Australian organizations in support of innovation in wheat, which includes the future commercialization of biotechnology. Canadian signatories included the Canadian National Millers Association, Cereals Canada, the Grain Growers of Canada, Grain Farmers of Ontario and the Western Canadian Wheat Growers Association.

The move to biotech wheat is not without its opponents. Canadian producers are wary after the trade disruption caused by trace amounts of biotech flax. When biotech wheat comes, Canadian producers are arguing that it would need to be done in 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.

Alfalfa

Monsanto Canada Inc. and Forage Genetics International LLC have jointly developed Roundup Ready® alfalfa for use in the commercial production of forage for livestock feed. In 2005, Roundup Ready® alfalfa underwent and passed livestock feed, environmental safety and food assessments conducted by the CFIA and Health Canada. Since 2005, the CFIA has continued to review new science as it has become available and has determined that Roundup Ready® alfalfa is as safe as conventional alfalfa.

In 2013, Gold Medal Seeds Inc., a wholly owned subsidiary of Forage Genetics International LLC, submitted an application for variety registration to the CFIA. The application was assessed and the variety was registered in 2013. Variety registration enables Roundup Ready® alfalfa seed to be commercially sold in Canada. Forage Genetics International completed a co-existence plan in early 2016. The plan focused on the stewardship necessary to keep the GM alfalfa from moving through Eastern Canada (Quebec and Ontario) to Western Canada. Forage Genetics International also received approvals from CFIA and Health Canada for its HARVXtra alfalfa which is the Roundup Ready Trait stacked with a reduced lignin trait. The end result is alfalfa with better nutritional and digestibility benefits for cattle.

In spring 2016, FGI began selling its genetically modified alfalfa seed in Eastern Canada. The area planted to GM alfalfa is estimated to be less than 5,000 acres of hay. The product is not yet available in Western Canada. Canadian growers are required to keep hay produced from the genetically modified alfalfa in Canada.
http://www.betterfarming.com/online-news/engineered-alfalfa-seeds-%E2%80%98adds-some-complexity%E2%80%99-ontario-hay-export-venture-says-forage

Potatoes

On March 18, 2016 Health Canada announced the approval of several varieties of the Simplot Innate potato as food. The department concluded that the changes made to these genetically engineered potato varieties do not pose a greater risk to human health than potato varieties currently available on the Canadian market. In addition, Health Canada also concluded that these Simplot Innate potato varieties would have no impact on allergies, and that there are no differences in the nutritional value of these potatoes compared to other traditional potato varieties available for consumption. On the same day, the CFIA approved the Innate varieties for unconfined environmental release for commercial planting purposes and for use as animal feed.

The Simplot Innate potatoes are resistant to browning and bruising, therefore reducing the amount of potatoes consumers throw away, and also have a lower level of asparagine, an amino acid which produces acrylamide. A second generation of the Innate potatoes that the Simplot company seeks approval for will be resistant to blight, a potato disease, therefore reducing the need for pesticides to prevent this disease.

The approval decisions for the Innate potato varieties have arrived too late for the current growing season. It is expected that Canadian producers will be able to plant these varieties during the 2017 season.

With growing public interest in the topic, the CFIA has provided a web-page offering more information about the Innate potatoes, which can be found at the following URL address: http://www.inspection.gc.ca/plants/plants-with-novel-traits/general-public/innate-potato-faq/eng/1458835515028/1458835687626

b) COMMERCIAL 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 on seeding intentions provide indications from farm surveys for corn and soybeans. Comparable data are not available from Statistics Canada for canola, therefore information from the Canola Council is used to estimate seeded areas. For sugar beets, little data is available, but it is fair to say that most of the total area is planted with biotech varieties.

In 2012, Post updated the methodology for estimating Canada's biotech planted areas. First, based on recent information from the Canola Council, Post estimated the seeded acreage of biotech canola at 95 percent of total seeded canola. Second, Post has begun calculating genetically engineered (GE) corn and soybean production using all provinces, not just Quebec and Ontario for which there is specific data on GE production available through Statistics Canada. GE soybean and corn production in the rest of Canada as a percentage of total seeded area is estimated at 66 and 80 percent, respectively. This percentage is based on discussions with industry. Due to the development of new varieties, production of corn and soybeans has increased in provinces which have not traditionally grown these crops. For instance, corn and soybeans are showing increased importance in Manitoba and Saskatchewan. Post will maintain these assumptions and apply the same methodology as used in 2012. The following table combines information from Statistics Canada and the Canola Council to provide an overview of biotech planting of canola in Canada.

Table 1: Estimated Seeded Areas of Biotech Crops

Area Seeded (1,000 hectares)	**2012**	**2013**	**2014**	**2015**	**2016**
Corn for Grain	1,434	1,493	1,246	1,325	1,347
Biotech Corn	1,179	1,216	1,010	1,077	1,129
Biotech Corn, percentage of total	82%	81%	81%	81%	84%
Soybeans	1,680	1,869	2,251	2,202	2,212
Biotech Soybeans	1,100	1,196	1,366	1,357	1,433
Biotech Soybeans, percentage of total	65%	64%	61%	62%	65%
Canola	8,912	8,197	8,407	8,363	8,102
Biotech Canola	8,466	7,787	7,987	7,944	7,697
Biotech Canola, percentage of total	95%	95%	95%	95%	95%
Sugar Beets	10	9	8	7	8
Biotech Sugar Beets	10	9	8	7	8
Biotech Sugar Beets, percentage of total	100%	100%	100%	100%	100%
Total area seeded to biotech crops	10,755	10,208	10,370	10,385	10,267

Source: Statistics Canada / Canola Council

Canola

Most of Canada's canola production is centered in the western provinces of Manitoba, Saskatchewan and Alberta. Statistics Canada survey results show that acreage seeded to canola in the spring of 2016 decreased by 3 percent from 8.4 million hectares in 2015.

According to the Canola Council of Canada, approximately 95 percent of total canola area is seeded with biotech varieties. That would put the 2016 biotech area just under 7.7 million hectares, marginally lower from 7.9 million hectares planted in 2015. Roughly calculated, canola oil accounts for 50 percent of the vegetable oil consumed by Canadians. In general, only about 15 percent of the Canadian canola crop is consumed in Canada in various forms. This means nearly 85 percent of Canadian canola seed, oil, and meal are exported to destinations such as the United States, Japan, Mexico and China.

With regards to production practices, it was previously thought that 3- to 4-year rotations were ideal for best yields and soil conservation. However, in their latest agronomic guide, the Canola Council highlighted new research findings showing that "Growers have taught us that more intensive rotations can be managed sustainably." Meaning that shorter rotations were now deemed to be acceptable. This represents a significant departure from the organization which used to caution farmers against shortening their rotations. The Canola Council's explanation for the turnabout was that growers have

proven that more intensive crop rotations can be managed sustainably and profitably in many soil zones and regions in the Prairies.

The Canola Council also set a new industry objective of reaching 26 million tons produced per year by 2025. More information on the strategy and the science behind how the target will be met is available on the website http://keepitcoming.ca/.

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 and 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 95 percent of land planted in canola in Western Canada. In February 2103, the Canola Council of Canada launched a new market access strategy .

Corn

Biotech corn planting has been steadily increasing, and biotech corn currently accounts for 84 percent of all corn planted in Canada. Traditionally, Quebec and Ontario are the primary corn-growing regions, accounting for more than 90 percent of total Canadian corn areas. The June 2016 farm survey suggests that Quebec farmers have planted 309 thousand hectares to biotech corn and Ontario farmers have planted 688 thousand hectares to biotech corn. In 2016, Quebec farmers are estimated to have 86 percent of their total corn crop as biotech; up from 51% in 2006. Ontario farmers are estimated to have 85 percent of total corn crop planted as biotech, up from 40 percent 10 years ago.

Starting with year 2011 data, Post includes all provinces in the calculation of the estimate for the total biotech corn seeded in Canada. This is due to recent trend in increased corn seeding intentions reports in the provinces that have not traditionally grown corn. Statistics Canada does not provide a provincial breakout for every province; however, the data is captured in the Canadian total. Manitoba, for which Statistics Canada now provides data for, has shown increase corn acreage in recent years. For 2016, however, acreage seeded to corn in Manitoba is up from the last two years to 136 thousand hectares. Acreage seeded to corn in Quebec and Ontario is down slightly from 1,197 in 2015 to 1,190 in 2016. Both Ontario and Quebec have scaled back marginally from 2015 levels.

Soybeans

In 2016, area seeded to biotech soybeans is estimated at 1.43 million hectares, up 5 percent from 2015. Traditionally, Quebec and Ontario have been the primary soybean growing regions in Canada, accounting for more than 90 percent of total soybean acreage . With the rise of Manitoba as a soybean producing province, the combined share for Quebec and Ontario has slowly declined over time. In 2016, Ontario and Quebec account for 64 percent of total soybean acreage, while Manitoba's 658 thousand hectares accounted for 30 percent of total area planted to soybeans up from 15 percent just five years before in 2011.

At an estimated 204,000 hectares planted in 2016, Quebec's biotech soybeans represent 53 percent of the province's total soybean area. In Ontario, biotech soybeans amount to 718,300 hectares in 2016, or 65 percent of the total soybean area in the province. In 2016, Manitoba increased their soybean seeded area to 657,600hectares, up from 650,500 hectares in 2015. The 2016 estimated area planted to biotech varieties in this province is about 430,000 hectare, or 66 percent of Manitoba's total soybean crop.

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 field trials, 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. Production concentrated near Taber, where Canada's only sugar beet processing plant is located. In 2016, approximately 8,100 hectares of sugar beets were seeded in Canada, all of which are reported by Statistics Canada as being in the province of Alberta.

c) EXPORTS

Canada is an exporter of biotechnology crops and products, including grains and oilseeds such as canola, soybean and corn. In marketing year 2015/2016, Canada exported nearly 10.3 million metric tons (MMT) of canola, 4.1 MMT of canola meal and 2.8 MMT of canola oil. Canada also exported 4.3 MMT of soybeans, 145 thousand metric tons (TMT) of soybean oil and 316, TMT of soybean meal. Canada's corn exports in 2015/2016 amounted to 1.7 MMT.

d) IMPORTS:

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 2015/2016, Canada imported 1.2 million metric tons (MMT) of corn, 560 TMT of soybean meal and 280 TMT of soybeans from the United States. Most corn and soybeans grown in the United States are biotech, so a majority of Canada's imports are biotech as well. Canada also imports biotech papaya from Hawaii.

e) FOOD AID RECIPIENT COUNTRIES:

Canada is not a food aid recipient country.

Part B: Policy

a) REGULATORY FRAMEWORK:

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 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/	Products Regulated	Relevant	Regulations

Agency		Legislation	
Canadian Food Inspection Agency (CFIA)	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 (EC)	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 (HC)	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 2016, Canada had 72 PNT submissions and 173 field trials of various crops from numerous companies — compared to 64 submissions and 129 field trials in 2015. A summary of all 2016 field trials' breeding objectives by various crops is available at the following URL address: http://www.inspection.gc.ca/plants/plants-with-novel-traits/approved-under-review/field-trials/spring-2016/eng/1471356206996/1471356272132

- 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.

The timeline from development to the point at which the product has been approved for human consumption can take anywhere between seven to ten years. In some instances, the process takes longer than 10 years. In order to maintain the integrity of Canada's regulatory system, several advisory committees have been established to monitor and advise the government of current and future regulatory needs. The Canadian Biotechnology Advisory Committee (CBAC) was established in 1999 to advise the government on ethical, social, scientific, economic, regulatory, environmental and health aspects. The mandate of the Canadian Biotechnology Advisory Committee (CBAC) ended on May 17, 2007. The government replaced the CBAC with the Science, Technology and Innovation Council, as part of a broader effort to consolidate external advisory committees and strengthen the role of independent export advisors. The Council is an advisory body that provides the Government of Canada with external policy advice on science and technology issues, and it produces regular national reports

that measure Canada's science and technology performance against international standards of excellence.

In May 2015, the Science, Technology and Innovation Council released its fourth public report, entitled State of the Nation 2014 - 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.

Additional information on how biotechnology is regulated in Canada can be found on these websites:

CFIA:
http://www.inspection.gc.ca/english/sci/biotech/bioteche.shtml

Health Canada:
http://www.hc-sc.gc.ca/sr-sr/biotech/index-eng.php
http://www.hc-sc.gc.ca/fn-an/gmf-agm/index-eng.php

Environment Canada:
http://www.ec.gc.ca/subsnouvelles-newsubs/default.asp?lang=En&n=AB189605-1
http://www.ec.gc.ca/subsnouvelles-newsubs/default.asp?lang=En&n=E621534F-1

b) APPROVALS:

Since Post's last annual biotechnology report, there have been approvals by CFIA for the following submissions:

Product / Designation	LMO Status	Applicant at time of application	Novel Trait(s)	CFIA			Health Canada - Food Safety Approval
				Approval for un-confined release into the environment	Approval for use as livestock feed	Variety Registration	
Potatoes E12, F10, J3, J55	LMO	J.R. Simplot Company	Low Acrylamide Potential and Reduced Black Spot	Yes (Nov. 2, 2015	Yes (Nov. 2, 2015	n/a	Yes
Maize MON 87403	LMO	Monsanto Canada Inc.	Increased ear biomass	Yes (Dec 27, 2014)	Yes (Dec 27, 2014)	n/a	Yes (Dec 27, 2014)
Maize MON 87419	LMO	Monsanto Canada Inc.	Tolerance to herbicide	Yes (Jan 23, 2015)	Yes (Jan 23, 2015)	n/a	Yes (Jan 23, 2015)
Soybeans MON 87411	LMO	Monsanto Canada Inc.	Insect resistance and herbicide tolerance	Yes (Sept. 3, 2014)	Yes (Sept. 3, 2014)	n/a	Yes (Sept. 3, 2014)

Information on recent submissions can be found at the following URL address: http://www.inspection.gc.ca/plants/plants-with-novel-traits/notices-of-submission/eng/1300143491851/1300143550790

Additionally, for more 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, and variety registration, please see this database: http://active.inspection.gc.ca/eng/plaveg/bio/pntvcne.asp.

c) FIELD TESTING:

Canada allows field testing. In 2016, Canada had 72 PNT submissions and 173 field trials of various crops from numerous companies — compared to 64 submissions and 129 field trials in 2015. A summary of all 2016 field trials' breeding objectives by various crops is available at the following URL address: http://www.inspection.gc.ca/plants/plants-with-novel-traits/approved-under-review/field-trials/spring-2016/eng/1471356206996/1471356272132

d) STACKED EVENT APPROVALS:
Similar 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

Follow this link for a list of stacked products authorized for unconfined release into the Canadian environment.

e) ADDITIONAL REQUIREMENTS:
Re-registration of approved events is not required. No other additional registration requirements are required.

f) COEXISTENCE:
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 implementation of 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 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. Demand by consumers is what drives the the growth or lack thereof in the organic industry, 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. However, the lack of complete information indicating the actual levels of the biotech crops in organic crops, the frequency of testing of organic crops, the location of crops relative to biotech crops, the origin of seed, the measures taken to minimize adventitious presence occurring, are all reasons why it is not possible to fully assess whether there have been or may be coexistence problems between organic and biotech crops in Canada.

g) LABELING:

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 Canada (AAFC), 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.

h) TRADE BARRIERS:
None.

i) INTELLECTUAL PROPERTY RIGHTS (IPR):
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 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 states that the holder of the plant breeders' rights is able to collect royalties on the product. 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.

In the fall of 2013, Canada introduced into Parliament Bill C-18, the Agricultural Growth Act, which seeks, among other things, to toughen enforcement of intellectual property rights for the creation or development of plant varieties. While Canada became a signatory to the 1991 UPOV Convention in 1992, the PBR Act, which became law in Canada in 1990, only adhered to the requirements of the 1978 revision of the International Convention for the Protection of New Varieties of Plant. On February 25, 2015 Bill C-18 became law so that Canada's PBR Act is now harmonized with the 1991 International Convention for the Protection of New Varieties of Plants Convention (UPOV). More on this development can be found in GAIN report "Agricultural Growth Act Now Law" which is available at the following URL:
http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Growth%20Act%20Now%20Law_Ottawa_Canada_3-3-2015.pdf

During the past couple of years, several patents on plant biotechnology expired, including the patent on Monsanto's Roundup Ready soybeans. 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 selling a second-generation Roundup Ready soybean technology– Genuity™ Roundup Ready 2 Yield® (RR2), developed in 2009, advertising 7-11 percent higher yields than Roundup Ready soybeans, and many farmers have begun 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 prohibited from retaining their seeds, which encourages the introduction of new varieties every season to create a constant approval of new corn seeds.

j) CARTAGENA PROTOCOL RATIFICATION:
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.

k) INTERNATIONAL TREATIES/FORA:
Canada leads a group of countries working collaboratively to develop a globally accepted solution to LLP. For more details, please see section n)
Canada takes part in the Like-Minded (LM) Group Supportive of Innovative Agricultural Production Technologies.

l) RELATED ISSUES:
None.

m) MONITORING AND TESTING:
Canada does not have a monitoring program for GE products and does not actively test for GE products.

n) LOW LEVEL PRESENCE (LLP):
Canada has stated that zero-tolerance policies are not realistic, particularly given the increasing sophistication and sensitivity of testing capabilities. Domestically, various industry stakeholders are working with regulators to establish an LLP policy in which maximum amounts of GM material would be established for biotechnology events that are not approved in Canada and which are to be allowed in Canadian imports. Based on the feedback received by industry stakeholders during its 2012 public consultation on Canada's "Proposed Domestic Policy on the Management of Low-Level Presence of Genetically-Modified Crops and Imports and its Associated Implementation Framework", Canada has published in April 2015, revisions to the original draft and is seeking comment on these changes. Changes in the draft include:

- When the policy eligibility criteria are met, the **level for low-level presence (LLP) in imports below which a risk assessment will not normally be required has been set at 0.2%.** In the previous draft of this policy, this level was described as the Action level and it had not been set. This level will help to proactively mitigate potential risks posed by trace levels of LLP resulting from dust or other sources such as discontinued genetically-modified (GM) crops. Above this level, LLP risk assessments must be proactively completed to be eligible for the higher threshold level to apply.

- **One Threshold Level** will be set for all crops, rather than crop-specific threshold levels. Expert advice will be taken into account in setting this threshold level. This approach will significantly reduce potential for confusion with respect to application of the threshold level and will simplify implementation of the policy.
- To facilitate oversight activities to verify LLP levels in imports, **a requirement for detection methods and reference material** is now included as a condition for the policy to apply.
- A **questionnaire will be used to** assess if foreign regulatory authorities' food safety assessment procedures are consistent with the *Codex Guideline for the Conduct of a Food Safety Assessment of Foods Derived from Recombinant-DNA Plants*. This approach will be both proactive and transparent.
- The policy and implementation framework have been clarified to indicate that **measurement uncertainty** unavoidably introduced through laboratory testing activities **will be taken into account** when determining the level of LLP in imported grain.
- To be consistent with Canada's legislative framework, revisions were made to clarify that **risk-commensurate enforcement actions** would be taken when LLP is detected below 0.2% or, when applicable, the Threshold Level.
- Other minor changes were made to improve clarity and reduce repetition.

More information can be found following this link.

In recent years, the issue of low level presence (LLP) has become increasingly important for Canada. LLP refers to the incidental presence of tiny amounts of a GM material mixed in with a non-GM product. It specifically refers to cases in which the GM material has been approved in the exporting country but not the importing country. In September 2009, routine testing indicated trace amounts of a biotech variety, Triffid, in Canadian flax imported into the European Union. As a result, Canada's flax trade to the EU was completely disrupted for over a year and has been slow to resume to its previous levels. Prior to the disruption, Canada supplied about 70 percent of European imports of flax. This flax case is an example noted by Canada of an instance in which LLP caused major trade disruptions, because of the European Union's zero-tolerance policy for GM crops.

Internationally, Canada is working with a group of interested countries to develop a global solution to the issue of LLP. In March 2012, an international meeting of industry and government officials from the United States, Mexico, Costa Rica, Chile, Uruguay, Paraguay, Brazil, Argentina, South Africa, Russia, Vietnam, Indonesia, the Philippines, Australia and New Zealand took place in Vancouver to discuss the issue. With that occasion, the Canadian agriculture minister underscored the importance of a regulatory approach that keeps pace with agricultural innovation and indicated Canada's willingness to be a leader and facilitator in LLP discussions at international level. Canada's international engagement continues and incremental steps are made towards achieving the goal of establishing a global solution to the LLP problem.

Part C: Marketing

a) MARKET ACCEPTANCE:
GE plants and products are widely produced and consumed in Canada.

b) PUBLIC/PRIVATE OPINIONS:
Consumer surveys find public opinion on biotech in agriculture divided. A 2002 Pew Global Attitudes Project survey reported that only 31 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. In addition, 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 and 86 percent agreed that it would bring benefits to health sciences. Thus, more uniform and long-term surveys must be administered before firm conclusions can be drawn about public opinion.

c) MARKETING STUDIES:
Post is not aware of any marketing studies conducted in Canada.

Part D: Capacity Building and Outreach

a) ACTIVITIES:
None.

b) STRATEGIES AND NEEDS:
None.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

The regulatory framework in Canada is designed to ensure environmental protection, animal health, plant protection and human health. Provided that these objectives are met, a GE animal, once approved for environmental release, and a GE animal product, once approved as feed or food, are treated no differently than the respective conventional animal or animal product. Regardless of the technological process involved in raising, growing, producing or manufacturing, all animals and animal products are subject to the same requirements and regulations when it comes to environmental and plant protection, animal and human health and feed and food safety. Currently, there is no commercial production of a GE animal approved in Canada, and there are no GE animal products approved as feed or as food. Clones, their offspring and the products derived from clones and their offspring would be subject to the same requirements and regulations as those applicable to GE animals and GE animal products. However, there remains the question of whether clones and their offspring and/or the products of clones and their offspring meet the definition of a novel food. The three main governmental bodies with jurisdiction on biotechnology (Health Canada, Environment Canada and the Canadian Food Inspection Agency) have yet to give their opinion on this matter.

Part E: Production and Trade

a) PRODUCT DEVELOPMENT:

AquAdvantage Salmon

The AquAdvantage salmon is the first genetically engineered animal approved for use in Canada. On May 19, 2016 Health Canada released its decision stating that the salmon was approved for sale in Canada as food. The federal department determined that the changes made to the salmon did not pose a greater risk to human health than salmon currently available on the Canadian market. In addition, Health Canada also concluded that the AquAdvantage salmon would have no impact on allergies, and that there are no differences in the nutritional value of this salmon compared to other farmed salmon available for consumption.

The science behind the salmon involved the introduction of a growth hormone gene from Chinook salmon into the genome of Atlantic salmon. This resulted in a salmon which grows faster and reaches market size quicker. In every other way, the AquAdvantage salmon is identical to other farmed salmon.

Also on May 19, the Canadian Food Inspection Agency (CFIA) released its decision approving the genetically engineered salmon for use as animal feed. The CFIA has determined that feed ingredients derived from the AquAdvantage salmon do not present livestock feed safety or nutrition concerns when compared to feeds derived from salmon currently permitted to be used as livestock feed in Canada.

As per Canada's policy with respect to novel foods or feed, the AquAdvantage salmon is subject to the same commercialization and import requirements as unmodified salmon, including requirements emerging from the Feeds Act and Regulations and the Food and Drugs Act and Regulations.

According to Health Canada, the department assesses novel food events based on the guidelines established by Codex Alimentarius. The federal department also indicates that the approach taken in the safety assessment of genetically engineered foods is based upon scientific principles developed through expert international consultation over the last 20 years with agencies such as the World Health Organization (WHO), the Food and Agriculture Organization of the United Nations (FAO), and the Organization for Economic Co-operation and Development (OECD). Moreover, the approach taken by Canada seems to be currently applied by regulatory agencies around the world such as in the European Union, Australia, New Zealand, Japan, and the United States.

With growing public interest in the topic, Health Canada has provided a web-page offering more information about the AquAdvantage salmon which can be found here.

Aqua Bounty Technologies 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 growth hormone gene construct (transgene) used to create a new type of farm-raised salmon. 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 (AAS) grow faster and reach mature size earlier than standard salmon, but they do not grow to be larger. In November 2013, AquAdvantage Salmon received an approval for confined environmental release from Environment Canada. This approval comes with strict conditions under which the organism can be released. Basically, the company can produce salmon eggs for export to a production facility in Panama.

For the time being, AquaBounty Canada has indicated its intent to commercially produce sterile pressure-shocked female AAS eggs at its land-based facility in PEI for export to a land-based, grow-out facility in the highlands of western Panama. No more than 100,000 eggs will be exported to Panama in any given year. In Panama, AAS will be grown to a commercial weight of 1 to 3 kg, then harvested, euthanized and transported to a processing plant in close proximity to the Panamanian grow-out facility where they will be processed for retail sale or for supplying the food service sector in approved markets for food consumption, markets that have yet to be developed. Currently, Post is not aware of any presence of the AAS on the Canadian market.

EnvitoPigs

EnviroPigs, created at the University of Guelph, were all put down in May-June 2012. EnviroPig was created in 1999 with a snippet of mouse DNA introduced into their chromosomes. The inclusion of the mouse DNA caused the pigs to produce an enzyme in their saliva that resulted in reduced phosphorus in their feces with the goal to reduce the environmental impact of pork production. Enviropigs were under development for well over 10 years, with the aim that they could one day be sold to commercial hog farmers. The university submitted an application to Health Canada 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. Although the University of Guelph cleared the first regulatory hurdle when it received approval from Environment Canada to reproduce the animal in confined conditions in 2010, in the spring of 2012 funding for the program was cut and the University of Guelph euthanized the pigs, in spite of numerous offers by farmers and organizations to care for the pigs. Canadian policy forbids any adoption, donation, transfer, or release of the pigs. EnviroPig DNA is now in long-term cold storage, and further analytical tests may continue in the future. Similarly, while the submissions to CFIA and

Health Canada have been presently suspended, interested parties can re-open the files and continue the regulatory process at a future time.

b) COMMERCIAL PRODUCTION:
According to Aqua Bounty Technologies, AquAdvantage Salmon eggs are intended to be commercially produced in Canada for export to Panama (see previous section for more details). There is no other commercial production in Canada of GE animals or GE animal products. Post is not aware of any commercial production of clones, their offspring or products derived from clones and their offspring. Post is not aware of any clones in Canada's breeding herds of any livestock sector.

c) EXPORTS:
Post is not aware of any export restrictions or exports of GE animals or GE animal products, or of clones, their offspring, or products derived from clones and their offspring. It is likely that GE animals, possible clones too, are being exchanged between research facilities and laboratories in Canada and other countries, including the United States. Post is not aware of any exports of semen from clones.

d) IMPORTS:
Post is not aware of any import restrictions or imports of GE animals or GE animal products, or of clones, their offspring, or products derived from clones and their offspring. It is likely that GE animals, possible clones too, are being exchanged between research facilities and laboratories in Canada and other countries, including the United States. Post is not aware of any imports of semen from clones.

Part F: Policy

a) REGULATION:
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). In addition, the New Substances Notification Regulations (Organisms), under the Canadian Environmental Protection Act, apply to GE animals that seek environmental release in Canada. For more information please see Part B a) of this report.

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 bodies with jurisdiction on biotechnology (Health Canada, Environment Canada and the 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 products derived from clones or progenies, determining whether these animals, their progeny and/or their products meet the definition of novel foods.

b) LABELING AND TRACEABILITY:
This CFIA website explains the labeling requirements for products of biotechnology in Canada. In essence, there is no mandatory labelling requirement for products derived from GE animals or clones. However, voluntary labeling is allowed.

At this time, there are no specific traceability requirements for GE animals or products derived from GE animals, or for clones, their offspring or products derived from clones and their offspring. Such requirements would probably have to be developed once the first GE animal, clone, or clone progeny was approved for commercial production, or once products derived from GE animals, clones and clone offspring were approved as feed or food. In the meantime, the traceability requirements applicable to conventional animals and animal products would apply to the GE and cloned versions as well.

c) TRADE BARRIERS:
Post is not aware of any trade barriers.

d) INTELLECTUAL PROPERTY RIGHTS (IPR):
The Canadian intellectual property legislation (Patent Act, Trade-marks Act and Copyright Act) covers animal biotechnology and cloning. Post is not aware of any other legislation specific to these products.

e) INTERNATIONAL TREATIES/FORA:
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. Canada takes part in the Like-Minded (LM) Group Supportive of Innovative Agricultural Production Technologies.

Part G: Marketing

a) MARKET ACCEPTANCE:
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. That being said, the domestic livestock producers would probably be interested in maintaining a tight control, via traceability, over GE animals and their derived products. The reason is that the beef and pork sectors in Canada are heavily dependent on exports, and would not like to jeopardize the foreign markets where there is minimal or no acceptance for such products.

b) PUBLIC/PRIVATE OPINIONS:
In September 2016, the House of Commons Standing Committee on Agriculture and Agri-Food initiated a study on Genetically Modified Animals for Human Consumption. Various witnesses representing a large spectrum of stakeholders delivered presentations and answered questions on the topic. A Committee report is expected by the end of 2016.

Post is not aware of any public opinion studies or surveys on consumer attitudes towards animal biotechnology. The Canadian Biotechnology Action Network (CBAN) is a campaign coalition of organizations, including farmer associations, environmental groups and international development organizations, which have various concerns about genetic engineering.

c) MARKET STUDIES:
Post is not aware of any market studies.

Part H: Capacity Building and Outreach

a) ACTIVITIES:
None.

b) STRATEGIES AND NEEDS:
Continue to engage Canada collaboratively in the Like-Minded (LM) Group Supportive of Innovative Agricultural Production Technologies.