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Report Highlights:
The first commercial sales of products of a genetically engineered animal, the AquAdvantage salmon, occurred in Canada in 2017. Canadian genetically engineered crop area is estimated at 12.53 million hectares for 2017, up 17 percent from 2016. Canola area reached a record high in 2017, surpassing wheat area for the first time ever. Since the 2016 annual biotechnology report, Canada has approved five new genetically engineered crop varieties: three potatoes and two corn.

Keywords: agriculture, biotechnology, CA17042, Canada, GE, genetically engineered

REPORT OUTLINE

Section I. Executive Summary

In 2017, Canada planted approximately12.5 million hectares of genetically engineered (GE) crops, mainly canola, soybeans, corn, sugar beets and some alfalfa. Canada ranked fourth in the most recent International Service for the Acquisition of Agri-biotech Applications (ISAAA) global ranking of area planted with GE crops.

In May and August 2017, the Canadian Food Inspection Agency (CFIA) and Health Canada approved the unconfined environmental release of two Syngenta GE corn products for commercial planting purposes, livestock feed and food use. In July 2017, similar approvals were granted for three varieties of the J.R. Simplot Company's GE Innate potatoes.

Total corn and soybean area has recently expanded in Manitoba and Saskatchewan, largely due to the commercialization of new GE varieties that are better adapted to prairie growing conditions. Farmers continue to plant GE corn and soybeans in the "traditional" growing areas across Quebec and Ontario.

Following approval for commercial sale in 2016, the first sales of AquAdvantage salmon products occurred in Canada in June 2017 in Quebec and/or Ontario. Due to Canadian labeling regulations, products of AquAdvantage salmon do not need to be labeled as GE, and, largely due to opposition from environmental groups, the sales were not publicized.

Guidance from the three regulatory agencies in Canada (Health Canada, Environment Canada and the Canadian Food Inspection Agency) on the question of whether the offspring or progeny of clones fall under Canada's Novel Foods provisions of the Food and Drug Regulations remains under the interim policy; offspring or progeny of clones are currently defined as a novel food. At this point, there is no indication that an alternate 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:
This section outlines genetically engineered (GE) plants or crops under development that Canada may commercialize within the next five years.

Apples

Okanagan Specialty Fruits continues to develop new GE tree fruits in its British Columbia facilities. GD 743 and GS784, more commonly known as Arctic Golden Delicious and Arctic Granny Smith, have been genetically engineered to be non-browning and are approved by the Canadian Food Inspection Agency (CFIA) and Health Canada for commercial planting purposes, livestock feed and food use. At the time of writing, there were no regulatory approval submissions for the already developed Arctic Fuji or for the Arctic Gala variety under development. Arctic Golden Delicious, Arctic Granny Smith, and Arctic Fuji have all received approval for production and sale in the United States.

Health Canada's approval of Arctic Golden Delicious and Arctic Granny Smith can be viewed at: http://www.hc-sc.gc.ca/fn-an/gmf-agm/appro/arcapp-arcpom-eng.php

Additionally, the CFIA has provided an information page about Arctic apples at: http://www.inspection.gc.ca/plants/plants-with-novel-traits/general-public/arctic-apple-faq/eng/1426884802194/1426884861294

Canola

In 2017, Bayer CropScience Inc. applied for unconfined environmental release (including for import purposes) and for livestock feed and food use of a GE canola variety, designated as Event MS11, which has been genetically engineered for tolerance to glufosinate-ammonium herbicide and male sterility. MS11 received approval in the United States in September, 2017 for food, feed and cultivation.

Cargill has developed a new type of GE canola that produces long chain omega-3 fatty acids and claims to give aquaculture farmers a more sustainable way to raise fish rich in EPA/DHA omega-3 fatty acids. Testing and regulatory approval for both the canola and the EPA/DHA enhanced canola oil is underway in the United States. The GE canola variety is currently grown only in Montana and the oil product is not expected to be commercially available in Canada before 2020, according to a Cargill representative. According to CFIA's list of submissions posted for public comment, Cargill has not yet requested a safety assessment from CFIA and Health Canada.

Soybean

High oleic canola may face competition from high-oleic soybean within the next five years after China approved Monsanto's Vistive Gold soybeans, designated as Event MON 87705, for the import and food/feed use, in June 2017. Vistive Gold received approval for food, feed and cultivation in both the United States and Canada in 2011, and received approval for food and feed in the European Union in 2015. With China's key approval in place, Monsanto will begin commercial preparation for the full-scale launch of Vistive Gold in 2018. Its traits include modified oil/fatty acid and glyphosate herbicide tolerance. FAS/Ottawa expects Vistive Gold to be commercially grown in Canada within the next five years.

Meanwhile, DuPont Pioneer has been waiting for the European Union to approve its Plenish soybeans, designated as event DP 305423, since 2009 when it was approved for food, feed and cultivation in the United States and Canada. In 2015, the European Commission approved the Plenish high oleic trait; however, according to DuPont Pioneer's website, "both the high-oleic and glyphosate-resistant traits are approved individually, and the European Food Safety Authority–GMO Panel has delivered a positive safety opinion on the stack, but adoption of the panel's recommendation by the European Commission is still forthcoming." China approved Plenish soybeans for food and feed in 2011, renewing it in 2014.

Potatoes

In July 2017, three more varieties of the J.R. Simplot Company's GE Innate potatoes (Gen2-W8, Gen2-X17, and Gen2-Y9) were approved by CFIA and Health Canada for commercial planting purposes, livestock feed and food use. Similar to the first generation of Innate potatoes approved in Canada, Gen2 varieties are resistant to bruising and have reduced levels of asparagine, glucose, and fructose which leads to a reduction in acrylamide formation during heating events (e.g. baking or frying). Additionally, these varieties are resistant to late blight disease caused by *Phytophthora infestans* which may lead to reduced pesticide applications to prevent late blight disease.

CFIA has provided an information page about Innate potatoes, and Health Canada approvals for the three Gen2 varieties can be viewed here.

Robert Potter Consulting conducted field trial tests for four GE potato varieties in Canada in 2017. Two of these varieties contained modified secondary metabolites, carbohydrates, and amino acid content, while the other two varieties were fungus resistant. Information on the size of trial fields was not available. Field trials in Manitoba and Prince Edward Island (PEI) each consisted of one variety of the fungus resistant potato and one variety of the modified secondary metabolites, carbohydrates and amino acid profiles, such that all four varieties were tested.

b) COMMERCIAL PRODUCTION:

Table 1: Estimated Seeded Areas of Biotech Crops

Area Seeded (1,000 hectares)	2012	2013	2014	2015	2016	2017
Canola	8,912	8,197	8,407	8,363	8,236	9,274
Biotech Canola	8,466	7,787	7,987	7,944	7,824	8,810
Biotech Canola, percentage of total	95%	95%	95%	95%	95%	95%
Soybeans	1,680	1,869	2,251	2,230	2,241	2,947
Biotech Soybeans	1,303	1,476	1,596	1,597	1,696	2,441
Biotech Soybeans, percentage of total	78%	79%	71%	72%	76%	83%
Corn for Grain	1,434	1,493	1,246	1,325	1,345	1,447
Biotech Corn	1,204	1,247	1,033	1,100	1,147	1,269
Biotech Corn, percentage of total	84%	84%	83%	83%	85%	88%
Sugar Beets*	10	9	8	7	10	11
Biotech Sugar Beets*	10	9	8	7	10	11
Biotech Sugar Beets, percentange of tota	100%	100%	100%	100%	100%	100%
Total area seeded to biotech crops	**10,983**	**10,520**	**10,624**	**10,648**	**10,677**	**12,531**

Source: Statistics Canada, Canola Council, Manitoba Agricultural Services Corporation, Saskatchewan Ministry of Agriculture, FAS Ottawa

* Notes: Alberta only, as reported by Statistics Canada

Corn

GE corn area has been steadily increasing and currently accounts for 88 percent of all corn planted in Canada. Quebec and Ontario have been the primary corn-growing regions, accounting for 86 percent of total Canadian corn areas. Statistics Canada's Table 001-0072 provides indications from the November 2017 farm survey that Quebec farmers have planted 325,000 hectares of GE corn, and Ontario farmers have planted 737,000 hectares of GE corn. According to sources at the Manitoba Ministry of Agriculture, farmers in that province planted 164,000 hectares of GE corn.

In 2017, Quebec farmers are estimated to have 86 percent of their total corn crop in GE varieties, up from 52 percent in 2007. Ontario farmers are also estimated to have 86 percent of total corn crop planted in GE varieties, up from 47 percent in 2007. Manitoba farmers are estimated to have planted 99 percent of the total corn crop in GE varieties (2007 percentage area was unavailable).

Starting with 2011 data, FAS/Ottawa includes all provinces when estimating total GE corn area seeded. This is due to recent increases in provinces that have not traditionally grown corn. Most significantly, total corn area in Manitoba reached 166,000 hectares (up 26,000 hectares from 2016) and equal to 11 percent of national corn area in 2017.

Statistics Canada's Table 001-0072 provides indications from farm surveys for corn in Ontario and Quebec only. Seeded corn area in the Prairies comes from sources at Manitoba's Department of Agriculture, Alberta Ministry of Agriculture, and industry.

Soybeans

Table 2: Area Seeded to Biotech Soybeans by Province

Area Seeded (hectares)		2012	2013	2014	2015	2016	2017
Ontario	Soybeans	1,048,100	1,052,200	1,242,400	1,185,700	1,096,700	1,244,400
	Biotech soybeans	704,200	657,600	762,800	744,600	718,300	890,300
	Biotech soybeans, percentage of total	67%	62%	61%	63%	65%	72%
Manitoba	Soybeans	323,700	424,900	514,000	560,500	661,700	926,730
	Biotech soybeans	310,752	412,153	498,580	543,685	648,466	917,463
	Biotech soybeans, percentage of total	96%	97%	97%	97%	98%	99%
Quebec	Soybeans	280,000	288,500	348,000	343,000	353,000	398,000
	Biotech soybeans	165,000	200,000	202,000	180,000	210,000	265,000
	Biotech soybeans, percentage of total	59%	69%	58%	52%	59%	67%
Saskatchewan	Soybeans	580,000	688,800	109,300	109,300	97,100	344,000
	Biotech soybeans	550,000	668,136	106,021	106,021	95,158	340,560
	Biotech soybeans, percentage of total	95%	97%	97%	97%	98%	99%
Canada	**Soybeans**	**2,231,800**	**2,454,400**	**2,213,700**	**2,198,500**	**2,208,500**	**2,913,130**
	Biotech soybeans	**1,729,952**	**1,937,889**	**1,569,401**	**1,574,306**	**1,671,924**	**2,413,323**
	Biotech soybeans, percentage of total	**78%**	**79%**	**71%**	**72%**	**76%**	**83%**

SOURCE: Statistics Canada CANSIM Table 001-0072; Manitoba Agricultural Services Corporation; Saskatchewan Ministry of Agriculture

In 2017, GE soybean area is estimated at 2.41 million hectares, up 44 percent from 2016. Increases of more than 240,000 hectares of GE soybean in each of Manitoba and Saskatchewan, accounted for 69 percent of the total national GE area increase.

Traditionally, Ontario has been the primary soybean growing region in Canada, accounting for more than 50 percent of total soybean area in the past five years. With the rise of Manitoba as a soybean producing province, Ontario's share of total soybean area fell to 43 percent in 2017. By comparison, Manitoba's 927,000 hectares accounted for 32 percent of total area planted to soybeans, up from 15 percent just five years earlier.

At an estimated 265,000 hectares planted in 2017, Quebec's GE soybeans represent 67 percent of the province's total soybean area. In Ontario, GE soybean area was 890,300 hectares in 2017, or 72 percent of the total soybean area in the province. In 2017, total soybean area in Manitoba rose to 926,730 hectares, up from 661,700 hectares in 2016. The 2017 estimated area planted to GE varieties in Manitoba was 917,463 hectares, or 99 percent of Manitoba's total soybean crop.

GE soybean production in Canada as a percentage of total area seeded is estimated at 83 percent. While area seeded to GE soybean varieties in Ontario and Quebec averaged 70 percent, the average for Western Canada was much higher at 99 percent.

Statistics Canada's data table 001-0072 on seeding intentions provides indications from farm surveys for soybeans in Ontario and Quebec only. Seeded soybean area in Manitoba was estimated using data from the Manitoba Agricultural Services Corporation, and seeded area in Saskatchewan was provided by the Saskatchewan Ministry of Agriculture.

Canola
Most of Canada's canola production is in the western provinces of Manitoba, Saskatchewan and Alberta. Statistics Canada survey results show that 2017 canola area increased by 13 percent to 9.3 million hectares.

According to the Canola Council of Canada, approximately 95 percent of total canola area is seeded with GE varieties, consistent with the last five years. That would put the 2017 GE area at just over 8.8 million hectares, significantly higher than the 7.8 million hectares planted in 2016.

Canola oil accounts for about 50 percent of the total vegetable oil consumed by Canadians. In general, only about 10 percent of the Canadian canola crop is consumed in Canada, as nearly 90 percent of Canadian canola seed, oil, and meal are exported.

Data on GE canola is not available from Statistics Canada, therefore information from the Canola Council of Canada is used to estimate seeded areas.

Sugar Beets
Sugar beets are commercially grown in Ontario and Alberta. Sources indicate that one hundred percent of sugar beets planted in Canada are GE varieties. Statistics Canada only reports plantings in Alberta, with an estimated 10,500 hectares planted in 2017. Seeded area increased by four percent in 2017 to 10,500 hectares. Production area can vary significantly from one year to the next.

Alberta sugar beets are refined at the Lantic Inc. facility in Taber, Alberta. The facility has an annual production capacity of approximately 150,000 metric tons (MT) of refined product, which can be fulfilled by contracts with approximately 400 sugar beet producers in Alberta.

Sources indicate that approximately 4,000 hectares of sugar beets were planted in Ontario in 2017. Ontario sugar beets are processed across the border in Michigan.

Apples
Two varieties of GE apple are currently approved for commercial planting purposes, livestock feed and food use in Canada: Arctic Golden Delicious and Arctic Granny Smith. As of 2017, there was no commercial production of any GE apple variety in Canada, but there are an estimated 100 hectares planted to Arctic Golden Delicious in Washington State. Approximately 79 MT of Arctic Golden Delicious were harvested in 2017 and will be marketed predominately as consumer pack fresh apple slices in the United States. There are currently no plans for export to Canada in 2017, but exports may occur in the next few years.

Potatoes
The J.R. Simplot Company has eight GE Innate potato (five first-generation and three “gen 2”) varieties approved for commercial planting purposes, livestock feed and food use in Canada. Small, five-acre test plots of these potato types have been tested in the provinces of Manitoba, Ontario, and

PEI. There was no commercial production of any GE potatoes in Canada in 2017. However, grower interest indicates that commercial plantings could begin in spring 2018 for fresh consumption and potato chip production. Sources indicate that GE commercial plantings would be of the White Russet variety, which is currently being commercially produced in the U.S.

Alfalfa

In spring 2016, Forage Genetics International LLC (FGI) began selling its GE alfalfa seed, designated as Event KK179, in Eastern Canada. The product is not yet available in Western Canada, and FGI said in a January 2016 statement that it has no plans to sell the seed for hay and forage in Western Canada. The alfalfa seed is sold for producing pasture and hay for farm animals, not for use as sprouting seeds. The area planted to GE alfalfa is estimated to be less than 5,000 acres.

Wheat

There is no commercial production of GE wheat in Canada. For an overview of its history in Canada, please refer to last year's report.

Flax

An herbicide tolerant variety of GE flax was approved for commercial planting and livestock feed in 1996 and for food in 1998. However, European buyers indicated that they would not purchase GE or commingled flax. Rather than jeopardize its largest export market, Canadian flax producers pushed to have the GE variety deregistered and pulled from the market in 2001.

In September 2009, routine import testing detected presence of the GE flax variety in a shipment of Canadian flax to the European Union (EU). In 2008, 70 percent of Canada's flax exports went to the EU, comprising a 57 percent share of the EU import market; by 2011 Canada's exports to the EU had fallen to 20,000 MT.

Canada negotiated a testing and certification protocol (most recently updated in 2014) and total flax exports have since recovered, though Canada's share of the EU market was just 12 percent in 2016. Since 2012, China has been Canada's largest export market for flax. Canadian flax exports peaked in the 1990's, reaching a high of 897,000 MT in 1997. In 2016, exports were 621,000 MT, 18 percent above the five-year average, but still 31 percent below the 1997 peak.

c) EXPORTS

In marketing year 2016/2017, Canada exported nearly 11.1 million metric tons (MMT) of canola, 4.7 MMT of canola meal and 3.1 MMT of canola oil. Canada also exported 4.6 MMT of soybeans, 255,000 MT of soybean meal and 175,000 MT of soybean oil. Canada's corn exports in 2016/2017 amounted to 1.5 MMT. Canada exports GE sugar beets to the United States for processing at Michigan Sugar, however the amount varies considerably with no exports in 2014, 54,721 MT in 2015, and 59,760 MT in 2016. Canada has also exported approximately 14 MT of beet sugar to date in 2017, with the Philippines being the main export destination. Canada's beet sugar exports are

highly variable by year.

d) IMPORTS:
Canada is an importer of GE 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 2016/2017, Canada imported 798 TMT of corn, 786 TMT of soybean meal and 396 TMT of soybeans from the United States. The majority of Canada's corn and soybean imports are GE. Canada also imports GE papaya from Hawaii. Canada imports sugar beets from the United States, the majority of which are GE sugar beet seed. The import amount has been increasing in recent years and is expected to reach 150 MT for 2017.

e) FOOD AID RECIPIENT COUNTRIES:
Canada is not a food aid recipient country.

f) TRADE BARRIERS:
There are no significant biotechnology-related trade barriers that negatively affect U.S. exports, or have the potential to do so, in Canada. Canada's strong research system and proximity to the United States facilitate collaboration and advances in biotechnology.

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.

Table 3: Regulating Agencies and Relevant Legislation

Department/ Agency	Products Regulated	Relevant Legislation	Regulations
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)	All animate products of biotechnology for uses not covered under other federal legislation (the legislative/ regulatory "safety net") Biotechnology products	*Canadian Environmental Protection Act*, 1999 (CEPA)	*New Substances Notification Regulations* (Organisms)

	under CEPA, such as microorganisms used in bioremediation, Fish products of biotechnology, Waste disposal, mineral leaching or enhanced oil recovery,		
Environment Canada and Health Canada (Under a Memorandum of Understanding, Fisheries and Oceans Canada administers New Substance Notifications for fish products of biotechnology and undertake risk assessments)	Fish products of biotechnology	*Canadian Environmental Protection Act, 1999*	*New Substances Notification Regulations(Organisms)*
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 4: Regulating 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 2017, Canada had 50 PNT submissions and 137 field trials, primarily of wheat and canola, compared to 72 submissions and 173 field trials in 2016. A summary of all 2017 field trial breeding objectives by individual crop is available on the CFIA website.

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. There have been no new public reports since the change of Administration in 2015.

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 the 2016 biotechnology report, CFIA has approved the following submissions:

Table 5: CFIA approvals

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 Registr-ation	
Maize MZHG0JG	LMO	Syngenta	Herbicide tolerance	Yes (May 16, 2016)	Yes (May 16, 2016)	n/a	Yes (May 16, 2016)
Maize MZIR098	LMO	Syngenta	Insect resistance and herbicide tolerance	Yes (Aug. 9, 2016)	Yes (Aug. 9, 2016)	n/a	Yes (Aug. 9, 2016)
Potato W8, X17, Y9	LMO	J.R. Simplot Company	Innate ™ potatoes with reduced acrylamide potential, reduced black spot bruising, and resistance to late blight of potato	Yes (October 11, 2017)	Yes (October 11, 2017)	n/a	Yes (July 31, 2017)

Information on recent submissions can be found on the CFIA website. Please refer to the CFIA PNT database 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.

c) STACKED or PYRAMIDED 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.

d) FIELD TESTING:

In 2017, Canada had 50 PNT submissions and 137 field trials, primarily of wheat and canola, compared to 72 submissions and 173 field trials in 2016. A summary of all 2017 field trial breeding objectives by individual crop is available on the CFIA website.

e) INNOVATIVE BIOTECHNOLOGIES:

In Canada, all innovative biotechnologies are regulated on a case-by-case basis, and products are subject to product-based regulatory oversight rather than a process-based one.

It appears that CFIA and Health Canada have received only one application for approval of products derived from innovative biotechnologies. A breeding system called RTDS (Rapid Trait Development System) uses oligonucleotide-directed mutagenesis (ODM) and was developed by U.S. company Cibus to create sulfonylurea-tolerant canola (Cibus 5715, 5720). Cibus canola traits were approved by Health Canada and the Canadian Food Inspection Agency in December 2013. However, the product has not yet obtained the varietal registration required to be grown commercially in Canada, as the product's oil content is lower than the minimum threshold of the Canadian canola quality standard.

f) COEXISTENCE:

In Canada, the coexistence between GE and non-GE crops is not regulated by the government, but

rather the onus is on the producers. For example, if producers of organic crops wish to exclude GE events from their production systems, then the implementation of measures to do so falls on the organic crop producer. Non-GE producers are able to charge a premium price for their product, having incurred costs associated with meeting the requirements of their customers and certification bodies.

Biotechnology stewardship conditions apply to GE crops in Canada, with some companies providing GE crop farmers with coexistence recommendations for minimizing the chances of adventitious presence of GE crop material found in non-GE crops of the same species. In addition, producers of GE crops are provided with weed management practice guides. These changes in management practices may help to improve the coexistence between GE and non-GE 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 GE crops.

Despite the fact that the government does not regulate the coexistence between GE and non-GE crops, the presence and increasing trend toward GE crops has not hindered the organic industry. Demand by consumers is what drives growth in the organic industry, rather than the presence or absence of GE crops. There have been disputes between the GE community and the organic community due to adventitious presence of GE crops (e.g. canola) in organic crops. However, the lack of complete information indicating the actual levels of the GE crops in organic crops, the frequency of testing of organic crops, the location of crops relative to GE 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 GE 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 standard 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 GE 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 National Standard of Canada on voluntary labelling and advertising of foods that are and are not products of genetic engineering. 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 GE components, although none have made it past a second reading. Most recently, in May 2017, a member of the National Democratic Party put forward a private members bill, Bill C-291, to require the mandatory labeling of foods containing GE components; it failed to secure enough votes at a second reading of the bill.

In Canada, products of GE crops (e.g. canola oil) can be labeled as "non-GMO." The online version of the National Standard of Canada on Voluntary Labelling and Advertising of Foods that Are and

Are Not Products of Genetic Engineering states:"… The Committee notes that foods derived from genetically engineered crops like corn, soy and canola oil contain virtually undetectable amounts of genetic material or protein made from the genetic material." However, CFIA's website states: "mandatory labelling for foods, including genetically engineered foods, can be required by Health Canada where there are health or safety concerns that could be mitigated through labelling, or to highlight a significant nutritional or compositional change."

What this means, is that canola oil producers may continue to label their oil as "non-GMO," while Monsanto, for example, may be required to label oil produced from their Vistive Gold soybeans as GE, because the company makes the claim that the soybean oil contains higher levels of oleic acid than a non-GE soybean.

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

i) 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 on the Agriculture and Agri-Food Canada website.

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 GE material mixed in with a non-GM product. It specifically refers to cases in which the GE material has been approved in the exporting country but not the importing country. In September 2009, routine testing indicated trace amounts of a GE variety, Triffid, in Canadian flax imported into the European Union. As a result, Canada's flax trade to the EU was disrupted for over a year and has been slow to resume to its previous levels. Prior to the disruption, in CY 2008 Canada supplied 57 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 GE crops.

Internationally, Canada is working with a group of interested countries, known as the Global Low Level Presence Initiative (GLI), to develop a global solution to the issue of LLP. The GLI was initiated by Canada (the secretariat and co-chair) and now has representation from 14 major grain exporting and importing countries/regions and four observer countries and regions. In March 2012, 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 met in Vancouver to discuss LLPO. At that meeting, 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 the international level. Canada's international engagement continues and incremental steps are being made towards achieving the goal of establishing a global solution to the LLP problem.

j) ADDITIONAL REGULATORY REQUIREMENTS:

There are no additional regulatory requirements.

k) 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. 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). 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. More on this development can be found in the March 2015 GAIN report CA15021.

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, and many farmers have made the transition. Third, corn is a much more important market for GE expiration dates as the consumption is largely domestic, and a majority of GE corn is devoted to food products. However, corn GE 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.

l) 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.

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

n) RELATED ISSUES:
None.

Part C: Marketing

PUBLIC/PRIVATE OPINIONS / MARKET ACCEPTANCE/STUDIES:
Recent consumer surveys find that many Canadian consumers remain anxious about GE foods. A 2016 survey and report study commissioned by Health Canada finds that 26 percent of respondents would be comfortable eating foods that have been genetically modified, and just 22 percent support the development and sale of GE foods in Canada. Sixty-one percent of Canadians say that when they hear the term 'genetic modification,' their thoughts and impressions are mostly negative (one-quarter say their impressions are extremely negative).

Another 2016 survey, this one commissioned by Ontario Science Centre, finds that, "one in five Canadians (19 percent) said they rely on intuition rather than science when it comes to forming opinions about GMOs. Fewer than one in five Canadians (19 percent) agree that GMOs are good for their health, and nearly three in five Canadians (57 percent) disagree."

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. Canada defines clones and their progeny or offspring as a novel food, and, once approval is received, Canada applies the same regulatory framework and treatment to clones and their offspring as to GE animals. 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 an approved GE animal in Canada. However, a variety of GE salmon has been approved for human and animal consumption. Retail cuts of that GE salmon entered the Canadian retail distribution network in 2017. A Prince Edward Island (PEI) facility produces GE salmon eggs from GE salmon breeding stock, and then ships the eggs to a grow-out facility in Panama, where commercial production and harvesting of the GE salmon occur.

Part D: Production and Trade

a) PRODUCT DEVELOPMENT:
None known at present.

b) COMMERCIAL PRODUCTION:
AquAdvantage Salmon
Currently, AquaBounty produces sterile, pressure-shocked female AquAdvantage Salmon eggs at its land-based facility in PEI for export to a land-based, hatchery and grow-out facility in Panama. Currently, Canada is the sole market for AquAdvantage Salmon. AquaBounty has plans to increase commercial production through the construction of a grow-out facility in PEI that would be capable of producing approximately 250 MT of salmon per year. Plans call for product to be ready to ship to retailers in the fourth quarter of 2019. Additionally, a facility has been acquired in Albany, Indiana that would be capable of producing approximately 1,200 MT per year. AquaBounty is pursuing regulatory approval of AquAdvantage Salmon in Argentina, Brazil, Chile, and China.

c) EXPORTS:
Approximately 5,000 AquAdvantage Salmon eggs were exported to Panama for grow-out in 2017.

d) IMPORTS:
In 2017, Canada imported approximately 5 MT of AquAdvantage Salmon from Panama. For 2018, sources indicate that import levels will remain similar.

In May of 2017, CBC reported that a Canadian first had occurred when two puppies cloned from a Toronto man's pet dog by a Texas company arrived in Toronto. There were no apparent restrictions to the importation of these cloned pets. There may be more imports of cloned pets into Canada should the process gain traction among consumers.

e) TRADE BARRIERS:
There are no known trade barriers.

Part E: Policy

a) REGULATORY FRAMEWORK:
In Canada, products of animal biotechnology are defined and regulated as novel foods. According to the Food and Drug Regulations, 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
    i) has not been previously applied to that food, and
    ii) causes the food to undergo a major change; and

- a food that is derived from a plant, animal or microorganism that has been genetically modified such that
    i) the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism,
    ii) the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or
    iii) one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for the plant, animal or microorganism [B.28.001, FDR].

A major change is defined as a change to the food that would result in that food now having characteristics outside of the accepted limits of natural variation in regards to its composition, structure, nutritional quality, the way it is metabolized, and/or impacts the microbiological or chemical safety of the food.

Environment Canada, Health Canada, and the Department of Fisheries and Oceans are the three government bodies responsible for assessing and first point of approval for biotechnology derived animals. Environment Canada is responsible for monitoring and evaluating any environmental impacts, Health Canada is responsible for monitoring and evaluating food safety, and the Department of Fisheries and Oceans is involved when there are any implications towards aquatic species or environments.

Regulation surrounding the use of animal clones and progeny of animal clones developed through somatic cell nuclear transfer (SCNT) for food is currently covered by an interim policy through the Food Directorate of Health Canada. According to this policy, all clones and progeny of clones developed through SCNT are classified as novel foods and subject to the novel food regulations contained within the Food and Drug Regulations [B.28]. As more evidence becomes available concerning food safety implications of SCNT derived products, Health Canada will re-evaluate their standing accordingly.

In 1999 the New Substances Notification Regulations (Organisms), under the Canadian Environmental Protection Act, were released to evaluate the toxicity status of any new animal biotechnologies before they could be released into the Canadian market. This process is administered by Environment and Climate Change Canada with new submissions through the New Substances Notification package. Sources have indicated to FAS/Ottawa that as of 2017, provincial governments are deferring exclusively to the federal legislation on GE and biotechnologically derived animals with no present timeline to develop province-specific legislation on this topic.

Table 6: Legislative Responsibility for the Regulation of Animal Biotechnology

Product	Agency	Act	Regulation
Veterinary biologics	CFIA	Health of Animals Act	Health of Animals Regulations
Fish products	Environment Canada Health Canada Department of Fisheries and Oceans (via a memorandum of understanding)	Canadian Environmental Protection Act, 1999	New Substances Notification Regulations(Organisms)
All animal products not covered under other federal legislation	Environment Canada Health Canada	Canadian Environmental Protection Act, 1999	New Substances Notification Regulations (Organisms)

b) INNOVATIVE BIOTECHNOLOGIES:
Canada regulates the commercial use, registration, and licensing of any biotechnology derived animal products. Information on these regulatory processes can be found in Part E, section a, Regulatory Framework. Currently FAS/Ottawa is unaware of any regulation of the development of novel biotechnology techniques.

c) LABELING AND TRACEABILITY:
Canadian food labeling policies are governed by the Food and Drugs Act and Food and Drugs Regulations. Health Canada and CFIA carry joint responsibility according to these policies with Health Canada holding responsibility over labeling concerning nutritional content, special dietary needs, and allergens while CFIA is responsible for labeling related to non-health and safety food labeling as well as enforcing all food labeling legislation. Currently, Canada has two standards for labeling of GE animals, GE products, and clones. Health Canada can require mandatory labeling for a GE food or products if there are significant health or safety concerns that labeling could mitigate or in the case of highlighting a significant nutritional composition change. Unless specifically mandated by Health Canada, GE food or products can choose to voluntarily label by following the Voluntary Labelling and Advertising of Foods That Are and Are Not Products of Genetic Engineering standards.

In May 2017, a member of the National Democratic Party put forward a private members bill, Bill C-291, to require the mandatory labeling of foods containing GE components; it failed to secure enough votes at a second reading of the bill.

FAS/Ottawa is unaware of any traceability requirements specific to GE-derived animals or animal

products, however, the proposed Safe Food for Canadians Regulations contain provisions for traceability requirements for all food products in Canada.

d) INTELLECTUAL PROPERTY RIGHTS (IPR):
Intellectual property rights for animal biotechnologies in Canada can be protected under three different acts:

- Patent Act
- Copyright Act
- Trade-marks Act

Additionally, Canada has the Animal Pedigree Act, whereby a breed association may become incorporated and be governed by the Act in instances where they are representing a distinct breed(s) or an evolving breed(s) which have significant value.

e) INTERNATIONAL TREATIES and FORUMS:
Canada previously was part of the now dissolved Codex Alimentarius Commission Task Force on Foods Derived from Biotechnology through Health Canada's activities with the Commission. Canada is also part of the Organization for Economic Co-operation and Development (OECD) and Health Canada participates on the OECD Task Force for the Safety of Novel Foods and Feeds. Additionally, Canada is a member of the World Organization for Animal Health (OIE). To date, Canada has not officially declared a position on animal biotechnologies but does allow for the importation, production, and sale of approved animal biotechnologies as well as engaging in research. Canada maintains that GE animals need to be rigorously evaluated through evidence based processes before admittance for commercial approval. Canada also supports the Joint Statement on Innovative Agricultural Production Technologies.

f) RELATED ISSUES:
None.

Part F: Marketing

a) PUBLIC/PRIVATE OPINIONS:
Canada has groups lobbying the government against GE animals, most notable is the Canadian Biotechnology Action Network which has organic and ecological farming groups, environmental groups, and international anti-GE groups amongst its members. Popular press and social media would indicate a wide spectrum of opinions from Canadian consumers surrounding GE products as well as varying levels of understanding of biotechnology. However, a Nielsen Consumer Insights survey of Canadian's perceptions towards biotechnology indicated that 88 percent of respondents had a positive or neutral view towards biotechnology although only 46 percent indicated that they were familiar with GE animals. When specifically questioned on GE animals, respondents raised concerns around morals and ethics considering GE animals as potential having greater associated risks compared to other GE technologies. A recent Angus Reid polling survey noted that 83 percent

of Canadians surveyed would like to see at least some GE products labeled.

Government funding for laboratory and subsequently biotechnology announced in 2017 will remain stagnant potentially forcing labs to decrease innovation activities and potentially force closures.

In 2016, the House of Commons Standing Committee on Agriculture and Agri-Food initiated a study on Genetically Modified Animals for Human Consumption the results of which were delivered in April 2017. Four key recommendations were identified by the committee:

1. The Government of Canada should provide greater transparency of the regulatory system evaluating genetically modified animals intended for human consumption.
2. The Government of Canada should provide support for independent research into the health, environmental and other effects of new genetic modification technologies.
3. The Government of Canada should support the mandatory labeling of genetically modified organisms only for issues of food health and safety.
4. The Government of Canada should work with industry to establish tools to provide traceability for genetically modified animals.

b) MARKET ACCEPTANCE/STUDIES:
Currently major retail grocery chains such as Metro, IGA, and Provigo have stated that they will not be selling GE products at their seafood counters, while Costco, Walmart, and Loblaws have indicated they currently have no plans to sell GE seafood when questioned about retail sales of AquAdvantage Salmon. To date, FAS/Ottawa is not aware of any formal market acceptance studies for GE animals.