Required Report: Required - Public Distribution **Date:** February 05,2020

Report Number: CA2019-0050

Report Name: Agricultural Biotechnology Annual

Country: Canada

Post: Ottawa

Report Category: Biotechnology and Other New Production Technologies

Prepared By: Erin Danielson, Agricultural Specialist | Alex Watters, Agricultural Specialist

Approved By: Philip Hayes

Report Highlights:

The estimated area planted to Genetically Engineered (GE) crops in Canada was down 7 percent in 2019, due primarily to lower soybean and canola area in the prairie provinces. Since the 2018 biotechnology annual, Health Canada has approved one new GE cotton product for the use of feed.

EXECUTIVE SUMMARY

In 2019, Canada planted approximately 11.2 million hectares of genetically engineered (GE) crops, mainly canola, soybean, corn, sugar beets and some alfalfa. The area planted to GE crops fell roughly 7 per cent in 2019, marking the second consecutive year of decline. This can be attributed to reductions in area seeded to canola and soybean. Much of the soybean reductions were in Manitoba and Saskatchewan. Responding to lower soybean yields from dry planting conditions and expected moisture deficiency throughout the growing season, farmers continued to move away from soybeans in those two prairie provinces in favor of wheat, pulses, or other crops.

In marketing year (MY) 2019/20, total soybean area planted decreased by ten per cent across Canada, as declines in the prairie provinces of 274,500 hectares more than offset gains in Eastern Canada of 34,600 hectares.

Since the FAS Ottawa's last biotechnology report was published, the Canadian Food Inspection Agency (CFIA) and Health Canada (HC) approved the use for feedstock of one Bayer CropScience cotton product.

Development of high oleic and high linoleic varieties will continue to impact the balance between canola, soybean and sunflower within the oilseed industry. Price premiums for high oleic soybeans have not been favorable in the current or previous marketing year, and area planted continues to be less than high oleic canola. Greater production of high oleic soybeans would be needed before Canadian crushing facilities would have a strong incentive to crush high oleic beans. At this time, high oleic soybean varieties are shipped to the United States for crushing.

TABLE OF CONTENTS

List of Tables

List of Figures

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.

The CFIA has not approved any applications for unconfined environmental release in 2019, as of publication.

Corn

On January 25, 2019, Monsanto (now owned by Bayer), entered a submission for public comment for MON 87429 corn. MON 87429 is genetically engineered to tolerate four herbicides: dicamba, 2,4-D, quizalofop, and glufosinate. If approved by Health Canada and CFIA, it has the potential to become the first biotech crop on the Canadian market tolerant to both dicamba and 2,4-D. Until approved, it cannot be commercially grown in Canada. And even then, Bayer would likely wait until approvals are received in key export markets in Europe before it goes ahead with seed sales and commercialization.

The CFIA and Health Canada's "notices of submission" on the CFIA website describe the product and the data they receive from certain product developers who have requested safety assessments of plants with novel traits (PNTs) for unconfined release and safety assessments of novel feeds and novel foods derived from PNTs. The notice of submission is done by the developer on a voluntary basis.

Canola

On January 30, 2018, Health Canada approved an application by Bayer CropScience Inc. for unconfined environmental release of Brassica napus (canola), designated as Event MS11. MS11 received approval in the United States in September 2017 for food, feed and cultivation. This canola variety has been genetically engineered to exhibit a male sterile phenotype as well as tolerance to the herbicide glufosinate ammonium. MS11-containing canola is awaiting approvals from China and was not commercially grown in Canada in MY 2019/2020.

Monsanto has commercialized a new canola trait called TruFlex canola, equipped with Roundup Ready technology. This new canola trait was made available in Canada for the first time in the 2019 growing season, and roughly one million acres was seeded.

The Canola Council of Canada has announced various priorities for 2018 to 2023, including improvements in disease resistance, plant fertility and integrated pest management. Other areas of focus include the evaluation of new antibacterial technologies for canola meal as well as high oleic canola oil health attributes: blood glucose management, body weight control and inflammation and immunity health.

The emergence of high oleic and high linoleic varieties is one of the most influential developments in the oilseed sector over the past ten years. The growth of high oleic canola oil production in Canada has been rapid over the

last ten years, accounting for roughly 12 per cent of production in MY 2017/18. High oleic oils have benefits for food processors in terms of increasing the shelf-life of baked goods and high oxidation rates for frying food, i.e. oils that last longer in a deep fryer. There is supportive, but not conclusive evidence, that oils containing high levels of oleic acid may reduce the risk of coronary heart disease. There are also some other beneficial qualities such as less wear-and-tear on machinery when used as a lubricant.

Linoleic oils are primarily used for industrial material applications like paints, coatings, polyols and epoxies. Prior to the development of high linoleic varieties, the oil from commodity sunflower seeds was particularly sought after for its naturally high linoleic content and its clarity. The oil from sunflowers was ideal for applications such as paint and primer because it does not darken over time. However, with the emergence of sunflower varieties that prioritize high oleic content over high linoleic content, the supply of linoleic rich oil for industrial applications has reduced.

Soybean

Researchers in Ontario are developing high linoleic soybean varieties to fill the current deficit in linoleic oils. High linoleic soybean oil varieties are achieving linoleic levels between 67-69 per cent (close to commodity sunflower oil) while also maintaining the clarity needed for industrial material applications, such as paints and primers. Having achieved desired levels of linoleic acid, researchers have begun to focus on improved yields that would make these high linoleic soybean varieties commercially viable.

Two varieties of high oleic soybeans are approved in Canada: Corteva's (DowDupont) Plenish soybeans and Monsanto's (Bayer) Vistive Gold soybeans. Both are approved for unconfined environmental release in Canada as well as in China, which is the main export market after the European Union. Despite key approvals, we have not seen increase in market demand or area planted in Canada. As a result, the Canadian crushing industry is not yet willing to do high oleic specific runs through their facilities. This is because they would need to clean their entire facility in order to dedicate crush capacity to high oleic varieties, and this is not economical at current levels of supply in Canada. Farmers need to adopt these new high oleic varieties before there is a strong incentive for crushers to dedicate plant capacity to high oleic crush.

Industry sources have expressed some frustration with sluggish demand growth from the food industry, given the level of investment to develop high-oleic soybeans. Increased food industry demand for high oleic oils would incentivize more production and more crushing capacity in Canada. Currently, seed developers are frustrated because they have developed the high oleic varieties and established some farmers as growers, yet the food industry has not been willing to pay the price premium associated with the new varieties. The hesitancy from the food industry likely reflects trends towards non-Genetically Engineered (GE) foods.

b) COMMERCIAL PRODUCTION:

Canada is one of the top five countries for biotech acres planted. In 2019, biotech area occupied about 18 per cent of area seeded to all crops in Canada.

Table 1: Estimated Seeded Areas of Biotech Crops

Area Seeded (1,000 hectares)	2015	2016	2017	2018	2019
Canola	8,411	8,411	9,313	9,232	8,479
Biotech Canola	7,991	7,990	8,848	8,771	8,055
Biotech Canola, percentage of total	95%	95%	95%	95%	95%
Soybeans	2,210	2,241	2,913	2,522	2,283
Biotech Soybeans	1,595	1,706	2,413	2,076	1,837
Biotech Soybeans, percentage of total	72%	76%	83%	82%	80%
Corn for Grain	1,359	1,452	1,447	1447.5	1478.8
Biotech Corn	1,133	1,253	1,269	1,291	1,340
Biotech Corn, percentage of total	83%	86%	88%	89%	91%
Sugar Beets	7	12	11	19	17
Biotech Sugar Beets	7	12	11	19	17
Biotech Sugar Beets, percent of total	100%	100%	100%	100%	100%
Total area seeded to biotech crops	**10,726**	**10,961**	**12,540**	**12,156**	**11,249**

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

Canola

Ninety-nine per cent of Canada's canola production is in the western provinces of Manitoba, Saskatchewan and Alberta. Statistics Canada survey results show that 2019 total canola area planted decreased by 8 per cent to 8.5 million hectares.

According to the Canola Council of Canada, approximately 95 per cent of total canola area planted was GE varieties, consistent with the last five years. That puts the 2019 GE area at just over 8 million hectares, less than the 8.8 million hectares planted in 2018.

Canola oil accounts for about 50 per cent of the total vegetable oil consumed by Canadians. In general, only about 10 per cent of the Canadian canola crop is consumed in Canada, as nearly 90 per cent of Canadian canola seed, oil, and meal are exported. In 2018, high oleic varieties accounted for roughly 12 per cent of the area seeded in Canada, but closer to one third of the domestic crush. Industry is no longer making this data publicly available until its official release in Spring 2020.

Data on GE canola is not available from Statistics Canada. FAS/Canada used information obtained from the Canola Growers Association to estimate area planted.

Canadian canola oil production is expected to increase over the longer-term in Canada, especially as the Comprehensive and Progressive Trans-Pacific Partnership (CPTPP) trade agreement brings down tariff rates in key markets like Japan and Vietnam. As Japanese crushing equipment continues to age, export opportunities for canola oil are expected to grow, particularly in MY 2020/21 after the Summer Olympic Games is completed, reducing the bolstered demand for Japanese food products driven by Olympic procurement requirements. For more information on projected Japanese oil trade dynamics, see FAS/Tokyo's 2018 Annual Oilseeds and Products Report GAIN.

Soybeans

Table 2: Area Seeded to Biotech Soybeans by Province

Area Seeded (hectares)		2015	2016	2017	2018	2019
Ontario	Soybeans	1,185,700	1,126,400	1,244,400	1,222,200	1,260,400
	Biotech soybeans	744,600	736,500	890,300	894,200	940,400
	Biotech soybeans, percentage of total	**63%**	**65%**	**72%**	**73%**	**75%**
Manitoba	Soybeans	570,600	665,900	926,700	764,900	594,700
	Biotech soybeans	553,482	652,582	917,433	757,251	588,753
	Biotech soybeans, percentage of total	**97%**	**98%**	**99%**	**99%**	**99%**
Quebec	Soybeans	344,000	351,700	398,000	370,300	366,700
	Biotech soybeans	191,000	221,700	265,000	261,600	247,700
	Biotech soybeans, percentage of total	**56%**	**63%**	**67%**	**71%**	**68%**
Saskatchewan	Soybeans	109,300	97,100	344,000	164,900	60,700
	Biotech soybeans	106,021	95,158	340,560	163,251	60,093
	Biotech soybeans, percentage of total	**97%**	**98%**	**99%**	**99%**	**99%**
Total	**Soybeans**	**2,209,600**	**2,241,100**	**2,913,100**	**2,522,300**	**2,282,500**
	Biotech soybeans	**1,595,103**	**1,705,940**	**2,413,293**	**2,076,302**	**1,836,946**
	Biotech soybeans, percentage of total	**72%**	**76%**	**83%**	**82%**	**80%**

SOURCE: Statistics Canada CANSIM Table 001-0072; CANSIM Table 001-0010; Manitoba Agricultural Services Corporation; Saskatchewan Ministry of Agriculture

National soybean area planted (including GE and conventional varieties) for all provinces including the lesser-producer provinces of Alberta and those in the Maritimes, declined to 2.31 million hectares in 2019, a ten per cent drop from MY 2018/19. Consultations with industry reveal that poor soybean prices at the time of planting, forecasts of dry weather and relatively attractive prices of alternative crops were the cause of reduced area seeded to soybean in the Prairies.

Canada's soybean producing leader is Ontario, which has a soybean area of 48 per cent of the national total, followed by Manitoba, which has 30 per cent. Production of soybeans in the Prairies has trended upwards over the past seven years but appears to be levelling off and it remains to be seen if it will continue its westward push. GE soybean production in Canada as a per centage of total area seeded was estimated at 80 per cent for MY 2019/20.

Corn

GE corn area planted currently accounts for 91 per cent of all corn planted in Canada. Quebec and Ontario have been the primary corn-growing regions, accounting for over 85 per cent of total Canadian corn area. Quebec farmers planted 350,000 hectares of GE corn, and Ontario farmers planted 786,000 hectares of GE corn. According to sources at the Manitoba Ministry of Agriculture, farmers in Manitoba planted roughly 184,239 hectares of GE corn.

Area seeded to GE variety corn, as a percentage of area seeded to all corn, has been increasing in Ontario and Quebec to be more consistent with the Prairie Provinces. In 2019, Quebec farmers are estimated to have 92 per cent of their total corn crop in GE varieties, up from 52 per cent in 2007 and 88 per cent in 2018. Ontario farmers are estimated to have 88 per cent of total corn crop planted in GE varieties, up from 47 per cent in 2007 and 87 per cent in 2018. Manitoba farmers are estimated to have planted 99 per cent of the total corn crop in GE varieties, consistent with the past eight years.

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 186,100 hectares, 12 per cent of national corn area in 2019. Statistics Canada only provides data from corn surveys in Ontario and Quebec. FAS/Canada collected data on corn area planted in the Prairies from sources at the Manitoba Department of Agriculture, the Alberta Ministry of Agriculture, and from industry.

Sugar Beets

Essentially one hundred percent of commercial sugar beet production in Canada are GE varieties. Sugar beets are commercially grown in Ontario and Alberta for processing into refined sugar and animal feed ingredients. Approximately 2/3 of total Canadian production is concentrated in Alberta with a large percentage of Alberta sugar beets refined at the Lantic Inc. facility in Taber, Alberta. Conversely, Ontario growers export their sugar beet crop to the United States for processing in Michigan. Statistics Canada reports that 2019 sugar beet production is 1.14 million MT for Canada, down slightly from 2018 owing to less planted area and lower yields.

Alfalfa

In Spring 2016, Forage Genetics International LLC (FGI) began selling its GE alfalfa seed, designated as Event KK179 (Harv-Xtra Alfalfa with Roundup Ready technology), in Eastern Canada. The industry-developed and administered co-existence plan in Canada stipulates that alfalfa grown in Eastern Canada must be cut before it blooms to avoid cross-pollination with non-GE varieties. Alfalfa is typically harvested at 50 per cent bloom in order to get the best quality livestock feed. Industry estimates 10,000 acres seeded in Ontario in 2019, which would indicate a doubling of growth since the Harv-Xtra was first made available three years earlier. FGI produces seven varieties of Harv-Xtra Alfalfa for sale in Canada.

There has been no GE alfalfa planted in Western Canada, and FGI has indicated no intention of westward expansion. During its Summer of 2019 board meeting, the Alberta Forage Industry Network reaffirmed its 2016 position that Alberta should remain GE alfalfa free.

Wheat

There is no commercial production of GE wheat in Canada.

Flax

There is no commercial production of GE flax in Canada. However, an herbicide tolerant variety of GE flax was temporarily approved and commercialized in Canada for livestock feed in 1996 and for food in 1998. At that time, Canada's largest export market for flax was Belgium in the European Union. After European buyers indicated that they would not purchase GE or commingled flax, Canadian flax producers had the GE variety deregistered and pulled from the market in 2001. However, in 2009, the European Union detected a GE variety during inspection of a shipment, causing imports to cease and temporary loss of a large market. An overview of the current flax export statistics is available in the following section.

Apples

Three varieties of GE apple are currently approved for commercial planting purposes, livestock feed and food use in Canada: Arctic® Golden Delicious, Arctic® Granny Smith, and Arctic® Fuji. Currently there is no commercial production of any of these three varieties of apple in Canada; commercial production is occurring in the United States. Currently there are no plans for commercial scale planting and production in Canada in the next few years as expansion will be focused in the United States. Given expanded production in the United States, there are plans for Arctic® apple exports to Canada beginning in 2019. There is currently no target for quantity of exports to Canada.

Potatoes

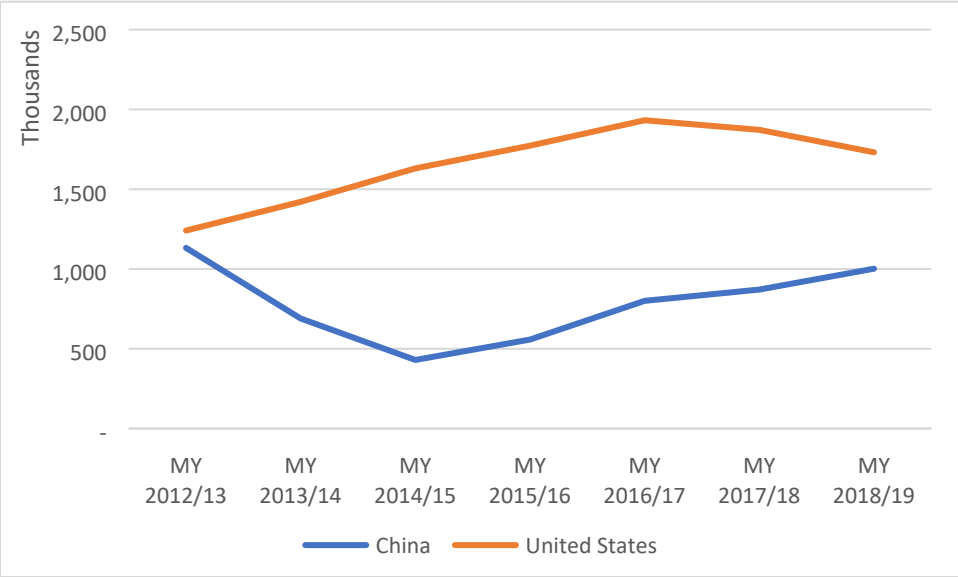
The J.R. Simplot Company has eight GE Innate® potato (five first-generation and three second-generation) varieties approved for commercial planting purposes, livestock feed and food use in Canada. Test acreage of 300-400 acres of Innate potatoes was planted in Canada in 2019. Production from acreage in Ontario is exported to the United States for potato chip processing; quantity of export for 2019 will be dependent on harvest. Acreage and commercial production are expected to increase in the next five years as market development continues.

c) EXPORTS:

Canada exported 9.1 million metric tons (MMT) of canola, 3.2 MMT of canola oil, and 4.6 MMT of canola meal in MY 2018/19. The provinces of Saskatchewan and Alberta are the top exporters of canola seed and canola products.

Canola oil exports to the United States fell by 8 per cent for the second consecutive year of decline, due to increased demand from China. Exports to China increased 15 per cent to 1.0 MMT. Prior to 2017, exports of canola oil to the United States increased steadily, demonstrating the impact of the U.S. Environmental Protection Agency's (EPA) approval of Canadian crops in U.S. biofuels as well as the increased demand for canola oil because of its lower saturated fat content in comparison with soybean oil (**Error! Not a valid bookmark self-reference.**).

Figure 1: Canola Oil Exports to China and the U.S.



Source: Trade Data Monitor, LLC; FAS Ottawa

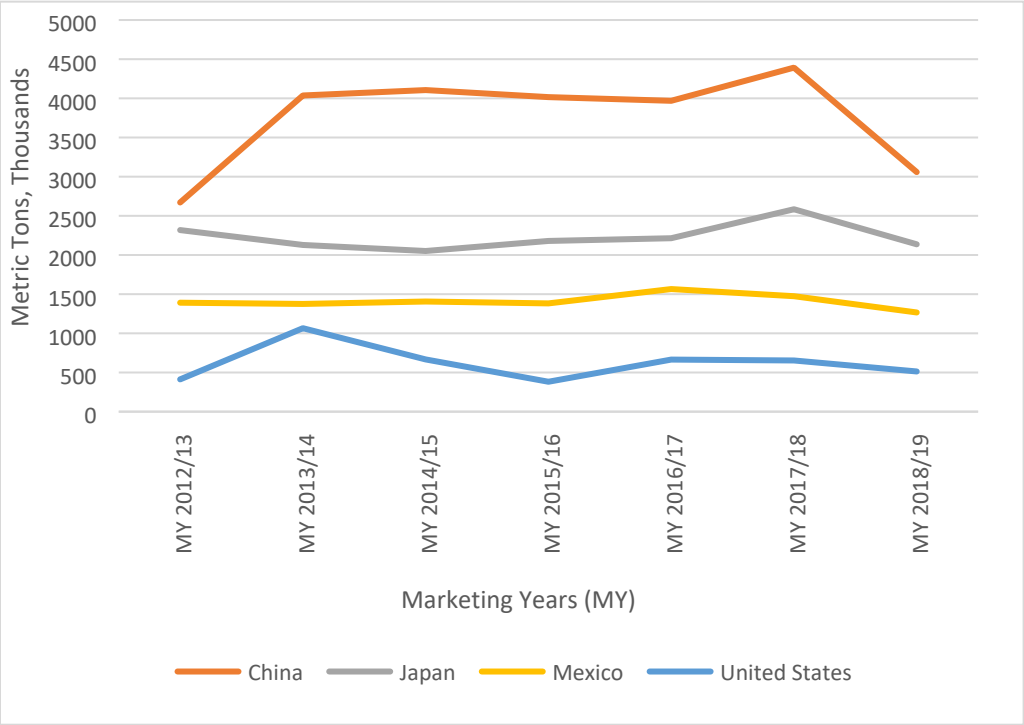
China, Japan and Mexico are the top three importers of Canadian canola seed. China agreed to allow further imports into their crusher in Nantong in Jiangsu province in 2013, dramatically increasing their imports after giving their first inland plant permission to process Canadian canola seed (Figure 2). As Japanese crushing facilities continue to age, export opportunities for canola oil are expected to accelerate.

The Comprehensive and Progressive Trans-Pacific Partnership (CPTPP) entered into force in late 2018, expanding Canadian access to CPTPP members for canola and soybean oil exports. Japan and Vietnam, which already have

zero tariffs for canola seed/meal and soybean seed/meal, will reduce their tariffs on Canadian oils over five to seven years.

Canada exported approximately $12.3 million of total canola oil (roughly 10,000 MT) to Japan in MY 2017/18. In MY 2017/18, 85 per cent of Japanese crude canola imports were sourced from Australia (also a CPTPP member state), while 85 per cent of Japanese refined canola oil came from Canada. For more information and for a tariff elimination schedule, see FAS Ottawa's Canada: Oilseeds and Products Annual.

Figure 2: Canola Seed Exports to Top Three Markets & United States



Source: Trade Data Monitor, LLC; FAS Ottawa

Canada exported 0.17 MMT of soybean oil and 5.3 MMT of soybeans. Over the last six years, 83-99 per cent of soybean oil exports have been destined for the United States. Total soybean oil exports have increased by 44 per cent over the last five years.

Sixty per cent of Canada's soybean exports, or 3.16 MMT, were destined for China in MY 2018/19, up from 35 per cent a year earlier. Ontario accounted for 50 per cent of Canada's soybean exports in MY 2018/19. In MY 2018/19, Manitoba, Saskatchewan and Alberta accounted for 26 per cent of Canada's total soybean exports, up from virtually zero exports ten years ago.

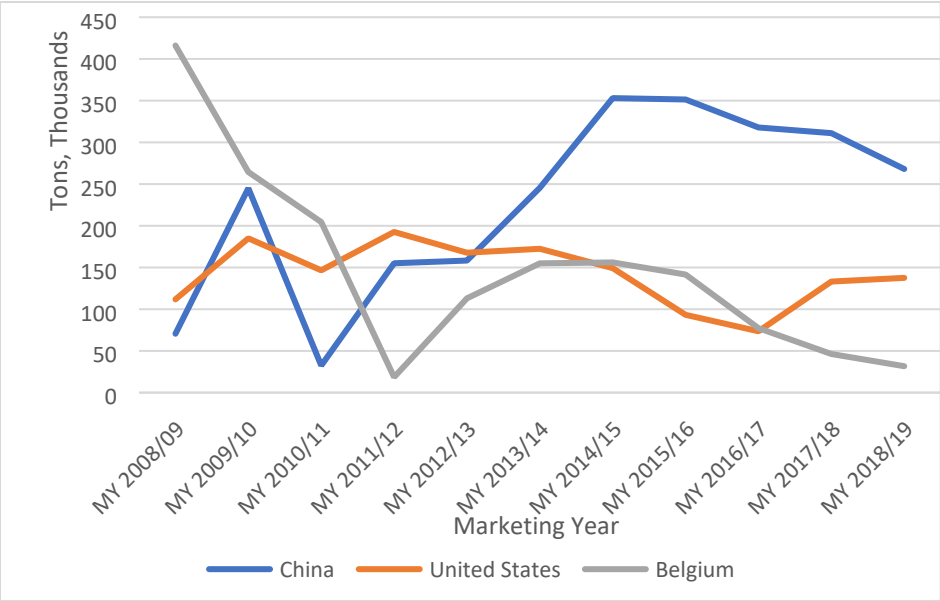
Canada's corn exports for MY 2018/19 were 1.8 MMT, with Ireland (48 per cent), Spain (20 per cent) and the United Kingdom (14 per cent) being the top importers. The top corn exporting provinces were Ontario and Quebec at 1.31 MMT and 0.46 MMT, accounting for 99 per cent of total exports.

Canada will export approximately 300,000 MT of GE sugar beets from Ontario to Michigan for processing at the Michigan Sugar refineries.

Canada will export a small volume of GE potatoes to the United States from Ontario in 2019/2020 for processing.

Canada exported roughly 0.47 MMT of flaxseed in MY 2018/19, with China accounting for 58 per cent of total exports. Saskatchewan accounted for 76 per cent of Canada's flaxseed exports in MY 2017/18, or 0.40 MMT. Canada's share of the valuable EU market in MY 2018/19 was about 15 per cent of what it was in 2008. Since the 2009 detection of an unregistered GE flax variety in a shipment of Canadian flax to the European Union (EU), China has picked up a greater share of Canada's flax exports. Canada's total flax exports in MY 2018/19 were just 80 per cent of what they were in 2008. Prior to this, 70 per cent of Canada's flax exports went to the EU, comprising a 57 per cent share of the EU import market.

Figure 3: Flaxseed Exports to Belgium, China and the United States



Source: Trade Data Monitor

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. Canada imported 16,448 MT of canola oil, and 6,116 MT of canola meal in MY 2018/19. Ontario was the largest

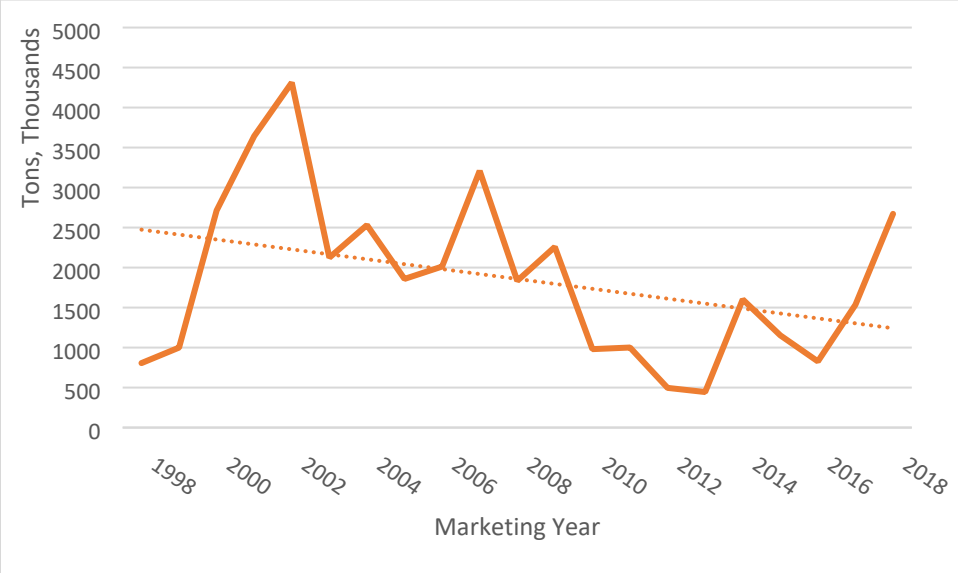
importer of canola oil from the United States at 10,893 MT, primarily imported from Tennessee (35 per cent), Ohio (20 per cent) and Illinois (11 per cent).

Canola meal imports into Canada are small given the large production domestically. Canola meal is an integral part of the ration of some livestock production systems in Canada. Imports from the United States come primarily from cross-border trade. British Columbia imported 78 per cent of canola meal, or 4,620 MT, primarily from Washington. Eleven per cent of imports entered through Quebec, and the remainder were imported through Ontario and Manitoba.

Canada imported over 2.7 MMT of corn in MY 2018/19, with 98 per cent of it coming up from the United States. The long-term trend shows that Canada's corn imports from the United States are decreasing over the past twenty years, coinciding with a steady increase in domestic corn production in Canada (

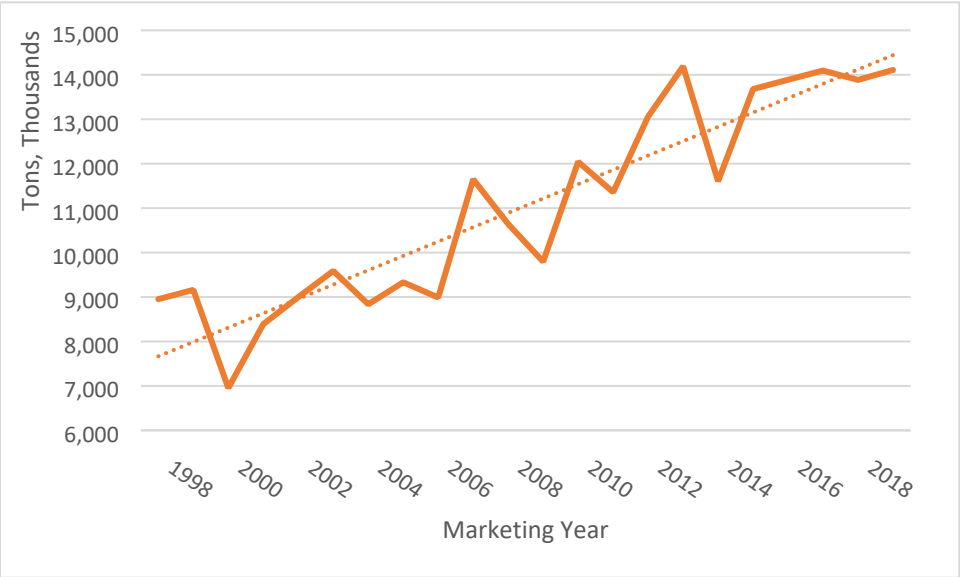
Figure and Figure). Manitoba, Alberta, Ontario and British Columbia imported the most corn in MY 2018/19. Fifty-five per cent of corn was imported from North Dakota, followed by 21 per cent from Minnesota.

Figure 4: Corn Imports from the United States



Source: Trade Data Monitor, LLC; FAS, Ottawa

Figure 5: Corn Production in Canada



Source: Statistics Canada; FAS, Ottawa

Canada also imported 1,171,583 MT of soybeans, 23,255 MT of soybean oil and 1.0 MMT of soybean meal. Over 80 per cent of all soybean products are imported from the United States. Iowa, South Dakota, Minnesota and North Dakota are the primary exporters of soybean meal to Canada. Iowa alone supplied almost half of Canada's imports of soybean meal, or 453,000 MT in MY 2018/19. Ontario imported the majority of their 335,000 MT of soybean meal from Iowa in MY 2018/19, and Manitoba imported the most of their 263,000 MT of soybean meal from South Dakota and Minnesota. Quebec also imported 33,193 MT of soybean meal from India in MY 2017/18.

Canada is expected to begin importing GE apples in late 2019; quantity is not yet known. There are no known imports of GE potatoes in 2019. Canada is an importer of GE papayas and GE squash.

e) 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.

CFIA defines plants with novel traits 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.

The CFIA defines novel food 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 and Climate Change Canada (ECCC) 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. HC is responsible for assessing the human health safety of foods, including novel foods, and approving their use in commerce. ECCC 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 and Climate Change Canada (ECCC)	All animate products of biotechnology for uses not covered under other federal legislation (the legislative regulatory "safety net") Biotechnology products under CEPA, such as microorganisms used in bioremediation, Fish products of biotechnology, Waste disposal, mineral leaching or enhanced oil recovery	*Canadian Environmental Protection Act*	*New Substances Notification Regulations* (Organisms)
Environment and Climate Change Canada and Health Canada (Under a Memorandum of	Fish products of biotechnology	*Canadian Environmental Protection Act*	*New Substances Notification Regulations (Organisms)*

Department/ Agency	Products Regulated	Relevant Legislation	Regulations
Understanding, Fisheries and Oceans Canada administers New Substance Notifications for fish products of biotechnology and undertake risk assessments)			
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 engineered 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.

At the time of writing, the CFIA has not yet released their summary of all field trial breeding objectives by individual crop, which is expected to be available in November 2019. The CFIA summary lists all new PNT submissions and field trials currently being conducted in Canada. In 2018, Canada had 78 PNT submissions and 145 field trials, primarily of wheat, canola and corn compared to 50 submissions and 137 field trials in 2016.

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 impact 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 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 generally takes between seven to ten years. In some instances, the process has taken 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 tracked 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 Government 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 2018 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	
Cotton GHB811	LMO	Bayer CropScience Inc.	Tolerance to glyphosate and isoxaflutole	Not grown in Canada	Yes (Oct 19, 2018)	n/a	Yes (Oct 19, 2018)

Source: CFIA

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. Information on recent voluntary submissions for public comment can be found on the CFIA website.

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 potentially 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 or 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:

An overview of PNT submission and field trials is not yet available from CFIA for 2018. In 2019, Canada had 78 PNT submissions and 145 field trials, primarily of wheat, canola and corn. A summary of all 2019 field trial breeding objectives by individual crop will be available on the CFIA website in November 2019.

e) INNOVATIVE BIOTECHNOLOGIES:

In Canada, all innovative biotechnologies are regulated on a case-by-case basis by CFIA, HC and ECCC. Products are subject to product-based regulatory oversight by these agencies, in the same way as conventional biotechnologies.

f) COEXISTENCE:

In Canada, the coexistence of 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 can 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 "Stewardship first" initiatives in order to manage the health, safety and environmental sustainability of the industry's products throughout their life cycle. "Stewardshipfirst" includes a Best Management Practices Guide for Growers of GE crops.

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 a 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 regarding 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 from fraud in 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 using specific techniques that allow the moving of genes from one species to another. The regulations outlined in the Standard are:

- Food label 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 per cent.
- 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.

Despite nearly 15 years of implementation of the voluntary standard, some groups in Canada continue to push for mandatory labeling of genetically engineered food. 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, in which Members have an opportunity to debate the scope and principle of a bill before voting on it.

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. As a result, it never made it past the second reading.

In Canada, products of GE crops (e.g. soybean oil) can be labeled as "non-GMO." The Canadian General Standards Board states 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. In other words, soybean oil producers may continue to label their oil as "non-GMO," even if the soybeans the oil is produced from are a GE variety, as long as the end product (the oil) is not distinguishable from oil produced from non-GE soybeans. 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.

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):

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-GE 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 per cent 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.

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 GE material would be established for biotechnology events that are not approved in Canada and which are to be allowed in Canadian imports. The Government of Canada has explored various approaches where LLP occurrences could be managed to increase trade predictability and transparency. The Policy Model has been summarized here, and their factsheet can be accessed here.

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 LLP. 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) 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 can 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 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.

k) CARTAGENA PROTOCOL RATIFICATION:

In 2001, Canada signed onto the Cartagena Protocol, but has yet to ratify it. There is 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. 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. 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.

l) INTERNATIONAL TREATIES and FORUMS:

In May 2019, a group of Ministers of Agriculture from Argentina, Brazil, Canada, Mexico and United States met in Niigata, Japan, and agreed that agricultural innovation, such as biotechnology, including precision biotechnology, will continue to play a substantial role in addressing such challenges and can improve farmers' productivity in a safe and sustainable manner.

In addition, Canada leads a group of countries working collaboratively to develop a globally accepted solution to LLP. For more details, please see section i). Canada is a strong advocate for the Like-Minded (LM) Group Supportive of Innovative Agricultural Production Technologies.

Trade is one of the most important issues for Canadian and U.S. grain and oilseed producers. The Canada imports 96 per cent of its imported grains and oilseeds form the United States, and likewise the United States imports 96 per cent of imported grains and oilseeds from Canada. As such, the industry in both countries have maintained the importance of preserving the benefits derived under NAFTA, while modernizing the trading relationship. The United States-Mexico-Canada Agreement (USMCA) Chapter 3, Section B on Agricultural Biotechnology specifically addresses agricultural biotechnology to support innovations in agriculture.

Part C: Marketing

a) PUBLIC/PRIVATE OPINIONS / MARKET ACCEPTANCE/STUDIES:

Dalhousie University in Halifax published a report on Canadian attitudes towards biotechnology in food on May 24, 2018. A link to the preliminary results can be accessed here. The study measures Canadian attitudes towards genetic engineering in food as well trust toward food safety and the regulatory system in Canada. Results show that 70 per cent of respondents strongly agreed that GE food and ingredients should be labeled in Canada. One other result of the study is that Canadians are generally unsure as to whether their food has GE ingredients, with roughly 50 per cent saying they are unsure either way. Canadians also appear to be more concerned about animal biotechnology associated with livestock and less with aquatic life, such as the new GE AquAdvantage Salmon approved for consumption in Canada.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

The regulatory framework for animal biotechnology in Canada is designed to assess and protect human, animal, and environmental health and safety. Provided that assessments do not indicate any concerns or risks with these objectives, 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 under Canada's regulatory processes. Regardless of the manner in which an animal is raised, grown, produced or manufactured, 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 in Canada. However, GE salmon has been approved as a human and animal feed and commercial production facilities are under construction in Canada. Clones, derived from nuclear transfer from embryonic and somatic cells, 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. Health Canada has maintained an interim policy on this issue since 2003, and currently captures these food products under the novel foods definition.

Part D: Production and Trade

a) PRODUCT DEVELOPMENT:

Projects are being proposed but there is no indication that there will be any new GE animals submitted for approval in Canada within the next five years.

b) COMMERCIAL PRODUCTION:

AquAdvantage Salmon

Sterile, pressure-shocked female AquAdvantage Salmon eggs continue to be produced at a land-based facility in Prince Edward Island. The eggs are currently being transferred to a land-based, grow-out facility in Prince Edward Island as well as exported to a land-based, grow-out facility in the United States (Indiana). The first commercial harvests for distribution to customers from both the Canadian and American facilities are scheduled to occur in the second half of 2020. Production from both facilities is scheduled to remain in their respective domestic markets according to current business plans. The Canadian facility is slated to produce 250 MT annually while the U.S. facility is slated to be 1,200 MT annually.

c) EXPORTS:

GE Salmon eggs were exported to the United States in 2019 following the deactivation of an import alert by FDA. Exports from the Canadian egg production facility will continue as required to supply the GE salmon grow-out facility located in the United States.

d) IMPORTS:

The Panama facility exported GE salmon for human consumption to Canada in 2017 and 2018 but the facility was shuttered in early 2019. There are no GE salmon imports into Canada in 2019 as a result of this closure. There are also no planned GE salmon imports into Canada over the next few years as supply will be obtained from Canadian production facilities.

e) TRADE BARRIERS:

There are no known trade barriers.

Part E: Policy

a) REGULATORY FRAMEWORK:

In Canada, products of animal biotechnology may be 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 an alteration to the food that would result in that food now having characteristics outside of the accepted limits of natural variation in regard to its composition, structure, nutritional quality, the way it is metabolized, and/or that impacts the microbiological or chemical safety of the food. Furthermore, the Canadian Food Inspection Agency (CFIA) notes that animal biotechnology includes but is not limited to animals which are:

- genetically engineered or modified, meaning genetic material has been added, deleted, silenced or altered to influence expression of genes and traits
- clones derived by nuclear transfer from embryonic and somatic cells
- chimeric animals, have received transplanted cells from another animal
- interspecies hybrids produced by any methods employing biotechnology
- animals derived by *in vitro cultivation*, such as maturation or manipulation of embryos

Environment and Climate Change Canada (ECCC), Health Canada, and, in the case of aquatic species, the Department of Fisheries and Oceans are the three government bodies responsible for assessing and first point of approval for biotechnology derived animals. ECCC 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 has been in place since the development of the Food Directorate of Health Canada in 2003. 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 (CEPA)*, 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 ECCC with new submissions through the New Substances Notification package. Health Canada co-administers CEPA regulating aspects pertaining to human health. Under human health, this includes any health or safety implications for people working with animals derived using biotechnology. Additionally, Health Canada conducts all food safety assessments for biotechnology animal products intended for food use classified as novel foods.

The CFIA evaluates animals derived from biotechnology as it pertains to animal health; this applies to the health of the animal derived from biotechnology as well as any implications on health to other animals in Canada either through contact or use of products from the animal derived from biotechnology in feeds or veterinary biologics for other animals.

Sources have indicated to FAS/Ottawa that 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
Foods and drugs derived through biotechnology	Health Canada	*Food and Drugs Act*	*Food and Drug Regulations (Novel Foods)*
Veterinary biologics	CFIA	*Health of Animals Act*	*Health of Animals Regulations*
Feeds	CFIA	*Feeds Act*	*Feeds Regulations*
Fish products of biotechnology	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)*

*Industry, Science and Innovation Canada, Agriculture and Agri-Food Canada, and Natural Resources Canada do not act in a regulatory capacity regarding animal biotechnology but do act in an advisory function to the regulating agencies on non-regulatory implications such as trade and market access.

b) APPROVALS:

Canada has approved a GE salmon. All novel food decisions from Health Canada can be found on the agency's website.

c) 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 for animals, assuming developers are compliant with the *Canadian Environmental Protection Act* and the *New Substances Notification Regulations*.

d) 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 product 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.

e) 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.

f) 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 Organisation for Animal Health (OIE). Canada allows for the importation, production, and sale of approved animal biotechnologies as well as engaging in research. Canada also supports the Joint Statement on Innovative Agricultural Production Technologies.

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 Canadians' 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 potentially 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. A 2018 study from the University of Dalhousie on biotechnology noted similar findings: 70 percent of respondents indicated that GMO food and ingredients should be labeled with 38 percent of respondents indicating they believed GMO foods were safe while 35 percent believed they were not safe. Currently, government officials indicate that there are no plans to move forward with any kind GMO/GE labeling legislation at the federal level.

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. There have been no major developments since. 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, Sobeys, and Provigo have stated that they will not be selling GE products at their seafood counters, while Costco, Walmart, Whole Foods, and Loblaws have indicated they currently have no plans to sell GE seafood when questioned about retail sales of AquAdvantage Salmon. Reportedly the Aquaculture Stewardship Council has indicated that they will not certify AquAdvantage Salmon over environmental concerns.

Attachments:

No Attachments