Required Report: Required - Public Distribution **Date:** January 05,2021

Report Number: CA2020-0098

Report Name: Agricultural Biotechnology Annual

Country: Canada

Post: Ottawa

Report Category: Biotechnology and Other New Production Technologies

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

Approved By: Philip Hayes

Report Highlights:

Responding to requests for clarity on Novel Food Regulations, Health Canada announced they will develop and publish new guidance regarding the regulatory interpretation and oversight of plant breeding. The guidance is expected to be published in January 2021, followed by a 60-day comment period. Estimated area planted to genetically engineered crops in Canada was down four percent in 2020, primarily due to less soybean and canola planted in the prairie provinces.

EXECUTIVE SUMMARY

Canada's system of regulating agricultural biotechnology rests on the novelty of the characteristics expressed in the final product, rather than the process used to develop the product (e.g. CRISPR). Plants or products developed with characteristics not previously observed in that plant, animal or microorganism are referred to as plants with novel traits (PNT) and novel foods, respectively. They are subject to a lengthy and complex approval process from the Canadian Food Inspection Agency (CFIA) and Health Canada (HC) and in some cases Environment and Climate Change Canada (ECCC).

Biotechnology industry groups in Canada and the United State have been asking for clarity regarding how the Canadian Government will approach innovative technologies. The Government has recognized the need to modernize its regulations to consider new innovative technologies. It has also cognizant of the need to improve guidance on novel food regulations, particularly in relation to plant breeding. HC has stated it will circulate draft guidance, in January 2021, for product developers on the interpretation of Canada's novelty-based regulatory trigger. This document will be open to stakeholder comment for 60 days.

HC has not indicated any changes to the animal biotechnology regulatory framework.

Since October 2019, the CFIA approved five plant products with novel traits for unconfined environmental release: two canola products, two corn products, and a sorghum product. Regulatory clearance or approvals in key importing countries and regions such as China and the European Union continue to have a significant influence on a company's decision to commercialize a product once domestic approvals are obtained.

Canada has only one approved biotech animal, a salmon. Production of this salmon is limited and not intended to be exported.

Canada planted approximately 10.9 million hectares of genetically engineered (GE) crops in 2020, mainly canola, soybean, corn, sugar beets and some alfalfa. Area planted to biotech crops fell roughly four percent from the previous year, marking a third consecutive year of decline. This contraction is attributed to reductions in area planted to canola and soybeans.

This report includes a new chapter on microbial biotech-derived food ingredients. Microbial biotech-derived products in Canada represent a growing industry and are used as enzymes, additives, flavoring, coloring, and vitamins. Most notably, they are used to produce cheese, infant formula, baked goods, and sweeteners.

TABLE OF CONTENTS

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

List of Tables

CHAPTER 1: PLANT BIOTECHNOLOGY

This report uses the terms "biotech varieties" and "biotech crops" to refer to any plant developed using biotechnological methods; including gene editing[1], transgenic[2], and mutagenic methods[3]; unless referring to a specific technique or quoting legislation or regulation. In Canada, "genetically engineered crops" refers to specific types of biotechnological techniques that are transgenic, distinct from gene editing and mutagenesis. The Canadian government uses "genetic modification" to refer to all products developed using biotechnological methods.

Part A: Production and Trade

a) PRODUCT DEVELOPMENT

This section outlines plants with novel traits (PNT) that are likely to be grown commercially within the next couple of years. Information on these particular products is publicly available. In contrast, PNT likely to be grown commercially in the next three or more years are typically considered confidential business information. In Canada, companies may start to consult with crop specific value chains several years prior to commercialization of new biotech crops. However, until they have a clear path to commercialization, it is often not publicized. PNT approved in Canada are posted in CFIA's PNT database; however, these varieties are not necessarily intended for commercial production. Hence, not all recently approved varieties are discussed in this report.

CFIA has approved five events with novel traits for unconfined environmental release since October 2019: two canola events (NuSeed America's B0050-027 and BASF Canada's LBFLFK); two corn events (Bayer Crop Science's MON87429 and Corteva's DP202216, developed by Pioneer Hi-Bred Canada's); and, one sorghum event (Advanta Seeds DMCC's ADV-IMI-R). Each of these events also received approval from CFIA and HC to be sold for animal feed and human food. However, according to industry sources, none of these are expected to be commercialized within the next two years.

[1] Gene editing is the use of biotechnological techniques to make changes to specific DNA sequences in the genome of a living organism. An example of gene editing technology is CRISPR.
[2] Transgenic is when a foreign gene is introduced into the crop.
[3] Mutagenesis is the change in the genetic make-up of an organism caused by chemicals or radiation. It is not regulated in most countries.

BASF Canada and Pioneer Hi-Bred have requested safety assessments of soy and corn varieties, respectively. The assessments are for unconfined release[4] and safety assessments of novel feeds and novel foods derived from PNT. The "notices of submission" on CFIA's website describe the product and the data CFIA has received from certain product developers who have requested safety assessments of PNT for unconfined release and safety assessments of novel feeds and novel foods derived from PNT. The notice of submission is completed by the developer on a voluntary basis.

Domestic approvals are only one aspect of a product's path towards commercialization. Regulatory clearance or approvals in key importing countries and regions such as China and the European Union continue to have a significant influence on a company's decision to commercialize a product. Such approvals can take several years.

Canola

The Canola Council of Canada's priorities for 2018 to 2023 include 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's potential for health attributes, benefits for food processors in terms of increasing the shelf-life of baked goods, and high oxidation rates for frying food. Industry sources estimate that area planted to high-oleic canola varieties has hovered between eight and ten percent over the past three years and has not grown significantly in recent years.

Soybean

Researchers in Ontario are developing high-linoleic soybean products. This focus responds to a shortfall in the market in linoleic oils due to a shift in sunflower production toward high-oleic oil varieties and away from the historically planted sunflower oil varieties, which are higher in linoleic oils. They have had success in development of high-linoleic soybeans with linoleic levels of 67-69 percent and 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 products commercially viable.

[4] Unconfined release involves the release into the environment with limited or no restrictions, generally towards commercialization.

Corn

Industry sources have highlighted two new corn hybrids released in 2020 - QROME by Corteva and Trecepta by Bayer. Each were limited releases due to pending E.U. approvals[5] on the stacked traits (NK603; DP4114; MIR604; and, MON89034, MIR162, NK603, respectively). Sources expect area planted to QROME will expand in 2021 and become a mainstream product in Ontario over the next several years. Trecepta is designed to help producers protect corn plants from attacks by insects including fall armyworm, corn earworm, corn borers and cutworms. QROME products feature a novel molecular stack of multiple insect protection traits and include two modes of action to control corn rootworm.

b) COMMERCIAL PRODUCTION:

Canada is one of the top five countries in terms of biotech area planted. In 2020, GE varieties of grains and oilseeds occupied an estimated 40 percent of total area planted to grains and oilseeds in Canada.

Table 1: Area planted to genetically engineered crops in Canada

Area Seeded (1,000 hectares)	2015	2016	2017	2018	2019	2020
Canola	8,411	8,411	9,313	9,232	8,572	8,409
GE canola	7,991	7,990	8,848	8,771	8,143	7,988
GE canola, % of total	95.0%	95.0%	95.0%	95.0%	95.0%	95.0%
Soybeans	2,239	2,269	2,947	2,558	2,313	2,052
GE soybeans	1,595	1,706	2,413	2,076	1,837	1,605
GE soybeans, % of total	71%	75%	82%	81%	79%	78%
Corn for Grain	1,359	1,452	1,447	1,468	1,496	1,423
GE corn	1,133	1,253	1,269	1,291	1,340	1,278
GE corn, % of total	83%	86%	88%	88%	90%	90%
Sugar Beets	7	12	11	19	17	17
GE sugar beets	7	12	11	19	17	17
GE sugar beets, % total	100%	100%	100%	100%	100%	100%
Area seeded to GE crops	**10,726**	**10,961**	**12,540**	**12,156**	**11,337**	**10,888**

Source: Statistics Canada, Manitoba Agricultural Services Corporation, Saskatchewan Ministry of Agriculture, FAS Ottawa; **Notes**: Excludes products developed using mutagenesis. Sum does not equal national total, as provinces growing less than 800 hectares of canola, corn and soybeans were not included in the above table. GE canola area for the year 2020 is an estimate; total GE corn area in Saskatechewan is also an estimate.

[5] The Canadian Seed Trade Association maintains a corn hybrid database that tracks E.U. approvals and lists "GM" events.

Canola

Canadian (and U.S.) canola farmers began planting Bayer's MON88302 canola (developed by Monsanto) in 2019 following confirmation that China's Ministry of Agriculture and Rural Affairs (MARA) granted safety certificate approval for the import and food/feed use of TruFlex canola with Roundup Ready technology. In 2019, roughly one million acres were planted and, according to industry, one million acres were planted again in 2020. Two new TruFlex varieties are expected to be registered for 2021.

Ninety-nine percent of Canada's canola production is in the western provinces of Manitoba, Saskatchewan and Alberta. Statistics Canada survey results show that 2020 total canola area planted decreased by eight percent to 8.5 million hectares.

Approximately 95 percent of total canola area planted was of GE varieties in 2020, consistent with the last five years. Area planted to GE canola varieties in 2020 was an estimated 8.0 million hectares, slightly down from the 8.1 million hectares planted in 2019. Approximately 98.5 percent of area planted was of biotech varieties (i.e. varieties developed using genetic engineering, gene editing or mutagenesis).

Canola oil accounts for about 50 percent of the total vegetable oil consumed by Canadians. In general, only about ten percent of the Canadian canola crop is consumed in Canada, as nearly 90 per cent of Canadian canola seed, oil, and meal are exported. In 2020, high oleic varieties accounted for roughly 10 percent of the area planted in Canada, consistent with the three-year average, according to industry sources.

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 over the next four to six years. On December 30, 2018 the CPTPP entered into force among the first six countries to ratify the agreement (Canada, Australia, Japan, Mexico, New Zealand, and Singapore) with entry into force applying to Vietnam on January 14, 2019.

As Japanese crushing equipment continues to age, export opportunities for canola oil are expected to grow. Canola oil exports to Japan are forecast to increase in MY 2020/21, due to heightened demands ahead of the Summer Olympic Games currently scheduled for July 2021. For more information on projected Japanese oil trade dynamics, see FAS/Tokyo's 2020 Annual Oilseeds and Products Report GAIN JA2020-0067.

Soybeans

Table 2: Area planted to genetically engineered soybeans by province

Area Seeded (hectares)		2016	2017	2018	2019	2020
Ontario	Soybeans	1,126,400	1,244,400	1,222,200	1,260,400	1,153,400
	GE soybeans	736,500	890,300	894,200	940,400	870,900
	GE soybeans, % total	**65%**	**72%**	**73%**	**75%**	**76%**
Manitoba	Soybeans	634,515	870,330	719,756	522,521	414,568
	GE soybeans	621,825	861,627	712,558	517,295	406,276
	GE soybeans, % total	**98%**	**99%**	**99%**	**99%**	**98%**
Quebec	Soybeans	351,700	398,000	370,300	366,700	358,300
	GE soybeans	221,700	265,000	261,600	247,700	245,100
	GE soybeans, % total	**63%**	**67%**	**71%**	**68%**	**68%**
Saskatchewan	Soybeans	97,100	344,000	164,900	60,700	51,300
	GE soybeans	95,158	340,560	163,251	60,093	50,787
	GE soybeans, % total	**98%**	**99%**	**99%**	**99%**	**99%**
Total	**Soybeans**	**2,209,715**	**2,856,730**	**2,477,156**	**2,210,321**	**1,977,568**
	GE soybeans	**1,675,183**	**2,357,487**	**2,031,609**	**1,765,488**	**1,573,063**
	GE soybeans, % total	**76%**	**83%**	**82%**	**80%**	**80%**

SOURCES: Statistics Canada CANSIM Table 001-0072; CANSIM Table 001-0010; Manitoba Agricultural Services Corporation

NOTE: Saskatchewan area planted to biotech varieties in 2020 is an estimate; The national total area does not sum to the total reported by Statistics Canada, because provincial crop insurance data was used to determine area planted in Manitoba.

Two 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 and food and feed use in Canada, as well as food and feed use in China and the EU Despite key approvals, there has not been a notable increase in demand nor a subsequent expansion of area planted in Canada. The food industry in Canada appears disinclined to pay the price premium associated with high oleic oils produced in Canada. Vistive Gold soybean seed was not available for purchase by farmers in 2020. Due to lack of sufficient supply, the Canadian crushing industry did not process high-oleic varieties through their facilities. At current levels of supply in Canada the economics do not appear to justify dedicating crush capacity to high oleic soybeans once facility cleaning costs are taken into account.

Area planted to GE soybeans as a percentage of total area planted is estimated at 80 percent in 2020. National soybean area planted (including GE and conventional varieties) declined 11 percent from 2019.

In MY 2019/20, 61 percent of Canada's soybean production took place in Ontario, followed by Manitoba (18 percent). Production of soybeans in Manitoba trended upwards until 2018. Area planted declined in 2019 and 2020, falling below 2013 levels. Industry sources suggest poor soybean prices at the time of planting, forecasts of dry weather, and relatively attractive prices of alternative crops all contributed to reduced area planted to soybean in Manitoba.

Corn

GE corn accounted for approximately 90 percent of all area planted to corn in Canada, the same as the previous year. Ontario and Quebec are the primary corn-growing regions, accounting for 62 percent and 25 percent of total Canadian corn area, respectively. Manitoba grew ten percent.

Area planted to biotech corn has increased in Ontario and Quebec, approaching levels found the prairie provinces. In 2020, Ontario had 88 percent of total corn crop planted in GE varieties, up from 47 percent in 2007 and 80 percent in 2015. Quebec had 92 percent of its total corn crop in GE varieties, up from 52 percent in 2007 and 84 percent in 2015. Meanwhile, Manitoba farmers are estimated to have planted 99 percent of the total corn crop in GE varieties, consistent with the past nine years.

Starting with 2011 data, FAS/Ottawa includes all provinces when estimating total GE corn area planted. This is due to recent increases in provinces that have not traditionally grown corn, primarily Manitoba. 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 100 percent of commercial sugar beet production in Canada are biotech varieties. Sugar beets are commercially grown in Ontario and Alberta for processing into refined sugar and animal feed ingredients. Over 60 percent 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. Ontario growers export their sugar beet crop to the United States for processing in Michigan. Statistics Canada reports 2020 sugar beet area planted at 17,400 hectares, up four percent from 2019. Area planted in Alberta expanded while area in Ontario declined.

Improved growing conditions supported higher yields in the 2020 crop. Additionally, unlike in 2019 when weather conditions prevented a large portion of the Alberta crop from being harvested, the 2020 harvest saw significantly fewer adverse weather impacts.

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. Producers have not planted GE alfalfa in Western Canada. 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 biotech wheat in Canada. For an overview of biotech wheat's history in Canada, please refer to GAIN report: CA16053.

Flax

There is no commercial production of biotech flax in Canada. While an herbicide tolerant variety of biotech flax was approved and grown in Canada in the mid-1990s, Canadian flax producers had the biotech variety deregistered and pulled from the market in 2001 after European buyers indicated that they would not purchase biotech or commingled flax.

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. At the time of writing there are no known immediate plans for commercial scale planting and production in Canada.

Potatoes

Simplot has nine GE Innate® potato (five first-generation and four second-generation) varieties approved for commercial planting purposes, livestock feed and food use in Canada. Test acreages have been planted in

Canada but large-scale commercial plantings have not occurred. Acreage and commercial production development in Canada will be market dependent.

c) EXPORTS:

Exports of canola seed to China declined in 2019 and 2020 due to market access issues and reduced feed demand due to African Swine Fever (ASF). China alleged that inspectors found pests in some shipments of canola and, in March 2019, two of Canada's largest canola handlers lost their permit to deliver canola to China.

Exports to non-traditional markets have offset Canada's export losses to China. The EU[6] more than tripled its purchases of Canadian canola exports since MY 2018/19, most notably because of increased purchases by France. The U.A.E., doubled its purchases of seed. Exports to the U.A.E. are largely dependent on E.U. vegetable oil demand.

Table 2: Canada: Canola seed exports (tons)

Partner	08/2017 - 07/2018	08/2017 - 07/2018 % Share	08/2018 - 07/2019	08/2018 - 07/2019 % Share	08/2019 - 07/2020	08/2019 - 07/2020 % Share
World	10,848,360	100	9,202,499	100	10,301,996	100
Japan	2,584,020	23.82	2,136,573	23.22	2,267,369	22.01
EU 28	390,401	3.60	642,484	6.98	2,176,518	21.13
China	4,392,001	40.49	3,119,093	33.89	1,925,865	18.69
Mexico	1,473,980	13.59	1,266,417	13.76	1,221,777	11.86
United Arab Emirates	636,961	5.87	456,544	4.96	988,713	9.60
Pakistan	678,452	6.25	777,980	8.45	754,991	7.33
United States	653,446	6.02	513,886	5.58	497,881	4.83

Source: Trade Data Monitor, LLC

Canola oil exports to the United States in MY 2019/20 were in line with the three-year average. Shipments of Canadian canola oil to China have strengthened since the Chinese government limited seed imports in 2019. Oil demand remains at this higher level.

[6] 'E.U.' in this report refers to E.U.27+UK, the current E.U. Customs Union.

CPTPP entered into force in late 2018, expanding Canadian access to CPTPP member markets 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. For more information and for a tariff elimination schedule, see FAS Ottawa's Canada: Oilseeds and Products Annual.

Table 3: Canada: Canola oil exports (tons)

Partner	08/2017 - 07/2018	08/2017 - 07/2018 % Share	08/2018 - 07/2019	08/2018 - 07/2019 % Share	08/2019 - 07/2020	08/2019 - 07/2020 % Share
World	3,170,256	100	3,155,165	100	3,429,384	100
United States	1,872,016	59.05	1,730,694	54.85	1,852,223	54.01
China	871,102	27.48	1,003,891	31.82	969,733	28.28
Chile	108,510	3.42	103,008	3.27	150,373	4.39
South Korea	133,037	4.20	136,032	4.31	142,854	4.17
Mexico	69,359	2.19	78,087	2.48	100,990	2.95
Malaysia	47,170	1.49	27,399	0.87	49,038	1.43
EU 28	312	0.01	71	0.00	48,257	1.41
Netherlands	-	0	-	0	48,218	1.41
Japan	10,940	0.35	18,358	0.58	45,872	1.34

Source: Trade Data Monitor, LLC

In MY 2019/20, total soybean exports were 7.5 million metric tons (MT), down 13 percent from the previous year. China accounted for just 15 percent of Canada's soybean sales, in volume, down from 48 percent the previous year. Healthy soybean exports to key E.U. markets; namely Italy, the Netherlands, and Germany; helped to partially offset reduced exports to China.

Canada exported 141,000 MT of soybean oil in MY 2019/20, down 15 percent from the previous year. More than 98 percent of soybean oil exports are typically destined for the United States.

Canada's corn exports for MY 2019/20 were 706,000 MT, with the EU (57 percent), and United States (42 percent) being the top destinations. Exports were down 63 percent due to lower production.

Canada exports Innate® potatoes grown in Ontario for processing in the United States. The finished product is marketed domestically in the United States. Canada exports biotech sugar beets grown in Ontario to the United States for refining.

d) IMPORTS:

Canada is an importer of biotech crops and products, including grains and oilseeds, such as corn and soybeans. More than 90 percent of biotech crops imported into Canada are sourced from the United States. Table 5 shows total imports of five commodities, from the U.S., using any method of development.

Industries such as ethanol production and the livestock feed industry import U.S. corn and soybeans.

PNT imports require advanced approval from HC and CFIA for use as human consumption and animal. There are currently 130 plant products with novel traits approved for human consumption. There are 123 plant products with novel traits approved for animal feed.

Canada began importing GE apples in late 2019. Imports will continue in 2020 based on market demand. There are no known imports of GE potatoes in 2020. Canada has approvals to enable import of GE papayas and GE squash.

e) TRADE BARRIERS:

There are no significant biotechnology-related trade barriers that negatively affect U.S. exports. However, uncertainty surrounding what Canadian regulatory agencies may consider to be novel and therefore what is regulated, combined with the slow pace of pre-market authorization, has the potential to impact trade.

Part B: Policy

a) REGULATORY FRAMEWORK:

Canada's Regulatory System

Canada has an extensive 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 counterparts are referred to as PNT or novel foods in the Canadian regulatory guidelines and legislation.

CFIA defines PNT 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 species of seed in Canada and that have been intentionally selected, created or introduced into a population of that species through a specific genetic change. The PNT can either be derived from recombinant DNA technologies or from traditional plant breeding. Regulated field testing is necessary when the PNT have traits of concern, i.e., the traits themselves, their presence in a particular plant species or their use are: (1) considered unfamiliar when compared with products already in the market; (2) not considered substantially equivalent to similar, familiar plant types already in use, and regarded as safe.

Health Canada defines "novel food" as:

> (a) a substance, including a microorganism, that does not have a history of safe use as a food;
>
> (b) 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
>
> (c) 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 that plant, animal, or microorganism. (aliment nouveau)

The Canadian Food Inspection Agency (CFIA) and Health Canada (HC) are the two agencies responsible for the regulation and approval of plants derived from biotechnology. The two agencies work together to regulate development of plants with novel traits not previously used in agriculture and food production.

Both CFIA and HC have authorities specifically applicable to PNT and/or novel foods. The CFIA is responsible for regulating the importation, environmental release, and the use in livestock feeds of PNT. HC is responsible for

assessing their human health safety in foods, and approving their use in commerce. PNT and novel food are also subject to the CFIA and HC overall authorities relative to plants and foods.

Table 4: Plant Biotechnology - 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	*Consumer Packaging and Labeling Act, Feeds Act, Food and Drugs Act, Seeds Act, Plant Protection Act*	*Feeds Regulations, Food and Drug Regulations*
Health Canada (HC)	Foods, Pest control products	*Food and Drugs Act, Canadian Environmental Protection Act, Pest Control Products Act*	*Novel Foods Regulations, New Substances Notification Regulations, Pest Control Products Regulation*

Sources: Health Canada, Canadian Food Inspection Agency

Table 5: Plant Biotechnology - Regulating Agencies' Responsibilities

Category	CFIA	Health 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		
Seeds	X	
Plants	X	

Sources: Health Canada, Canadian Food Inspection Agency

During the development process, prior to approval for unconfined release, PNTs are subjected to examination under Canada's regulatory guidelines. These include:

- Scientists work with GE organisms, including the development of PNT, 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 oversees the transportation of seed to and from trial sites, the movement of all harvested plant material, and import of novel seeds, living plants and plant parts.

At the time of writing, the CFIA had not released its 2020 summary of field trial breeding objectives by individual crop. The CFIA summary lists all new PNT submissions and field trials currently being conducted in Canada. In 2019, Canada had 78 PNT submissions and 99 field trials, primarily of wheat, canola, corn and camelina compared to 78 submissions and 145 field trials in 2018.

All PNTs must be authorized prior to their release into the Canadian environment as per the Seeds Act and Seeds Regulations. 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).

Using its 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)

Once environmental, feed and food safety authorizations are granted, the PNT and feed and food products derived from it are still subject to the same regulatory scrutiny that applies to all conventional products in Canada before they can enter the marketplace. Products intended for livestock feed require additional assessments under the Feeds Act by the Animal Feed Division at the CFIA. Products intended for human food use require additional assessments under the Food and Drugs Act by the Food Directorate at Health Canada.

Further, if the plant is a type of crop that requires variety registration (e.g. canola and soybeans), it must be registered after being authorized for environmental, livestock feed and food safety. Canada's variety registration system for all newly developed crop varieties ensures that only varieties with proven benefits are sold.

In addition, any new information arising about the safety of a PNT or its food products must be reported to HC and/or CFIA who, upon further investigation, may amend or revoke authorization and/or immediately remove the product(s) from the marketplace if it is being sold.

The timeline from development to the point at which the product has been approved for human consumption generally takes between seven to ten years, according to industry sources. In some instances, the process has taken longer than ten years. According to the leading crop biotechnology association in Canada, the development of a new product typically takes 5 to 7 years of company research, 2 to 3 years of field trials, and 1 to 3 years of government evaluation.

Industry has long held that the length of time it takes for a product to get to market has affected the competitiveness of Canadian companies. Now, using CRISPR and other modern gene-editing technologies, developers can produce cutting-edge products more quickly yet the length of time it takes to get the products to market can diminish the technological advantage.

Since 2018, regulatory reform to support Canadian competitiveness has been a recurrent theme of government and of advisory committees. Key examples include:

- Economic Strategy Tables: This is an industry-led model created to explore sector-specific plans for economic growth. With respect to biotechnology, The Report of Canada's Economic Strategy Tables (2018) states that in order for Canada to address ongoing regulatory barriers, it must:

    - *Modernize Canada's regulatory approach for new technologies, with particular focus on precision breeding techniques (e.g., CRISPR), to ensure it continues to provide an efficient and predictable pathway to commercialization by:*
        - *Improving guidance and clarity for product developers on the interpretation of Canada's novelty-based regulatory trigger*
        - *Streamlining data requirements for assessment of bio-similar*

- *products (e.g., crop protection and animal health products)*
- *Undertaking greater cooperation with key trading partners—especially the United States—to reduce overlap and maximize efficiency by participating in joint reviews and work-sharing documents and information relating to the review of pesticides and other emerging technologies, products and processes*
- *Identifying efficiencies and enhanced coordination of requirements across the three separate safety assessments (i.e., human food, animal feed and environmental safety for novel products of biotechnology)*

- 2018 Fall Economic Statement: Responding to the recommendations of the Economic Strategy Tables and other advisory bodies, the government announced that it would create an External Advisory Committee on Regulatory Competitiveness to assist Minsters and regulators to identify regulatory changes that promote economic growth and innovation. The Statement indicated the Government will take immediate action to, "Improve guidance on how new and novel plant varieties are regulated in Canada in order to provide clarity to Canadian and foreign firms interested in investing in Canada's biotechnology sector."

- The Agri-Food and Aquaculture Roadmap: Formed in 2019, the government took this initiative in follow up to the 2018 Fall Economic Statement. As part of the roadmap exercise, in partnership with departments and agencies, the Treasury Board of Canada Secretariat led national engagement efforts with businesses, Canadians, academia, and other stakeholders. Based on input from industry, documentation notes that the CFIA and Health Canada are working together to address issues raised by: "Providing more clarity around Canada's novelty triggers as they related to Plant Breeding Innovations, through written guidance." An AAFC-led Biotech Working Group under the Grains Roundtable met in 2020 and identified priority challenges to plant breeding innovation.

- External Advisory Committee on Regulatory Competitiveness: Also formed in 2019 in follow up to the 2018 Fall Economic Statement, this Committee was made up of eight members of academia and

industry. They met five times, in 2019. In the first round of the Committee's sectoral reviews, The Deputy Ministers of Health Canada and Transport Canada, as well as the President of the Canadian Food Inspection Agency, shared their perspectives on the first round of Regulatory Reviews. A key point expressed by the group is the need to "design agile regulatory frameworks that can keep pace with changing technology and the economy." However, there is no record of the Committee ever discussing agricultural biotechnology specifically.

In response to the 2018 Fall Economic Statement, the 2019 Agri-Food and Aquaculture Roadmap, and other work previously completed, in August 2020 the Government of Canada issued two notices. One notice announces new guidance to add clarity and predictability to regulations and oversight of novel products of plant breeding. The guidance is expected to be published in January 2021, followed by a 60-day comment period. The guidelines are an interpretation of the regulations and are not required to be published in Canada's Gazette. It is not yet known what will be in the guidelines. Canada is required to notify the WTO if the guidelines may affect trade.

A second notice is to announce HC's intention to publish on its website a list of non-novel determinations to improve transparency of the agency's decisions. The list, now available, is expected to be completed by March 2021.

Additional information on the regulation of biotechnology 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 October 2019, CFIA and HC have approved the following submissions:

Table 6: CFIA and HC Approvals Since Last Publication (Oct. 2019 – Oct. 2020)

Product/ Designation	LMO Status	Applicant at time of application	Novel trait(s)	CFIA			Health Canada - Food Safety Approval
				Approval for unconfined release	Approval for use as livestock feed	Variety registration	
Canola LBFLFK	LMO	BASF Canada Inc.	Imidazolinone tolerance, Synthesis of EPA (eicosapentaenoic acid) and DHA (docosahexaenoic acid)	Yes (Dec. 9, 2019)	Yes (Dec. 9, 2019)	No varieties registered	Yes (Dec. 9, 2019)
Canola B0050-027	LMO	Nuseed Americas	Modified fatty acid profile and glufosinate ammonium tolerance	Yes (July 28, 2020)	Yes (July 28, 2020)	No registered varieties	Yes (July 28, 2020)
Corn MON87429	LMO	Monsanto Canada ULC (now Bayer CropScience Inc.)	Tolerance to glufosinate 2,4-D, dicamba,and glyphosate herbicides	Yes (August 26, 2020)	Yes (Aug. 26, 2020)	Not subject to variety registration	Yes (Aug. 26, 2020)
Corn DP202216	LMO	Pioneer Hi-Bred Canada Company	Increased ear biomass potential / glufosinate ammonium tolerance	Yes (September 30, 2020)	Yes (Sept 30, 2020)	Registration not required	Yes (Sept. 30, 2020)
Sorghum ADV-IMI-R	Non-LMO	Advanta Seeds DMCC	Imidazolinone tolerance	Yes (April 24, 2020)	Yes (April 24, 2020)	Not subject to variety registration	Yes (April 24, 2020)

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:

Stacked products, defined in Canada as plant lines developed by conventional crossing of two or more authorized PNT, do not require further assessment of their environmental safety. Developers of plants with stacked traits, which were created from previously authorized PNT, 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.

These notifications are required so that regulators may determine if:

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

Additional information and further assessment will be required if:

- The conditions of authorization of the parental PNT would not apply to the stack
- The novel traits of the parental PNT are expressed differently in the stacked plant product (e.g. greater or lower expression)
- The stacked product expresses an additional novel trait.

HC maintains a list of stacked products authorized for unconfined release into the Canadian environment.

d) FIELD TESTING:

An overview of PNT field trials is not yet available from CFIA for 2020. In 2019, Canada had 78 PNT submissions and 99 field trials, primarily of wheat, canola, soybeans, corn and camelina. A summary of annual field trials by

individual crop is typically available on the CFIA website in November of each year, but at the time of writing, the 2020 update has not been published.

e) INNOVATIVE BIOTECHNOLOGIES:

HC and CFIA regulate products developed using innovative biotechnologies on a product-basis (as opposed to process-basis). All plants with novel traits are regulated on a case-by-case basis by these agencies, regardless of how they are developed.

Several industry sources have questioned whether products developed using innovative technologies should face the same regulatory approvals process as products developed using older technologies such as some types of genetic engineering. Innovative technologies can target a gene with great precision resulting in a single, predictable change in a trait. In contrast, older technologies can result in many random, unknown and uncharacterized changes. Industry sources suggest that for innovative technologies to reach their potential, modernized regulations are required.

Crop varieties developed using innovative biotechnologies are being grown in Canada by U.S.-based companies, such as Yield 10 (on a trial basis) and Cibus (commercially). Post is not aware of any Canadian start-ups with similar results. However, research is happening at larger companies and academic institutions.

f) COEXISTENCE:

In Canada, the coexistence of biotech and non-biotech crops is not regulated by the government. Producers of traditional or organic crops wishing to achieve this objective are responsible for excluding biotech events from their production systems.

Biotechnology stewardship conditions apply to biotech crops in Canada. Some companies provide biotech crop farmers with coexistence recommendations for minimizing the chances of adventitious presence of biotech crop material found in non- biotech crops of the same species. In addition, some companies provide producers with weed management practice guides with advice to help improve the coexistence between biotech and non-biotech crops.

g) LABELING:

Health Canada and the CFIA are responsible for all federal food labeling policies under the Food and Drugs Act. Health Canada sets food labeling policies with regard 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 from fraud in food labeling, packaging and advertising, and for prescribing basic food labeling and advertising requirements applicable to all foods.

Established in 2004, the Standard for Voluntary Labeling and Advertising of Foods that Are and Are Not Products of Genetic Engineering provides labeling and advertising guidance for food companies, manufacturers and importers.

Under the Standard, the term "genetically engineered" food refers to: "…techniques by which the genetic material of an organism is changed in a way that does not occur naturally by multiplication and/or natural recombination." Prior to 2020, the definition of "genetically engineered" food provided by the Standard was "those foods obtained through the use of specific techniques that allow the moving of genes from one species to another." The definition was revised to capture gene editing and mutagenesis.

Key elements outlined in the Standard include:

- 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.
- A non-GE claim can be made if adventitious presence is less than five 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 within its scope sold to consumers in Canada, regardless of whether it is produced domestically or imported.
- The Standard applies to the voluntary 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.
- Processing aids, enzymes used in small quantities, substrates for microorganisms, veterinary biologics, animal feeds, and substrates for micro-organisms (where the substrate itself is not present in the finished food product) do not affect whether a food or ingredient is considered to be or not to be a product of genetic engineering.

Despite nearly 15 years of implementation of the voluntary standard, some groups in Canada continue to push for mandatory labeling of GE food. Over the years, most recently in 2017, private members' bills have been introduced into the House of Commons seeking to require the mandatory labeling of foods containing biotech components, although none have made it past a second reading, in which Members have an opportunity to debate the scope and principle of a bill before voting on it.

In Canada, products of biotech crops (e.g. soybean oil) can be labeled as "non-GMO" only if the product is indistinguishable from one derived from a non-GE crop. The Canadian General Standards Board states that foods derived from biotech varieties of crops like corn, soy and canola oil contain virtually undetectable amounts of genetic material or protein made from the genetic material.

h) MONITORING AND TESTING:

Canada does not have a monitoring program for biotech products and does not actively test for biotech products.

i) LOW LEVEL PRESENCE (LLP):

The issue of low-level presence (LLP) is important for Canada. LLP refers to the incidental presence of small amounts of "genetically modified" (GM) material mixed in with a non-GM product in international trade. LLP may cause trade disruptions in cases in which the low-level biotech material was approved in the exporting country but not the importing country, as evidenced by the Canadian flax case described in Chapter 1, Part A. Canada holds that zero-tolerance policies are not realistic, particularly given the increasing sophistication and sensitivity of testing capabilities. The Government of Canada has explored various approaches where LLP occurrences could be managed to increase trade predictability and transparency based upon maximum amounts of biotech material not approved in Canada. The Policy Model has been summarized here, and the 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. See section (l) International Treaties and Forums below for more information.

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 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 made in developing their product. In February 2015, Canada amended its PBR Act to harmonize it with the 1991 International Convention for the Protection of New Varieties of Plants Convention (UPOV). 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 and therefore it is not in force in Canada. Many farm groups; including the Canadian Canola Council, the Grain Growers of Canada, Viterra and others; oppose ratification of the Protocol. Other groups like the National Farmers Union and Greenpeace support it. The Government of Canada continues to participate in Protocol processes as a non-Party. Industry sources indicate that this is likely to remain the course.

l) INTERNATIONAL TREATIES and FORUMS:

Health Canada and FSZANZ pilot: Health Canada and Food Standards Australia New Zealand (FSANZ) are working together on a "GM food safety" pilot. The initiative will assess the safety of a GM food that is not yet authorized for use in Canada or Australia and New Zealand. Health Canada is conducting the assessment of the GE food and FSANZ will review the assessment. If both agencies are satisfied with the results, they will use the safety assessment to authorize this GE food in their own country. The pilot is expected to be completed by early 2021.

The United States-Mexico-Canada Agreement (USMCA): Chapter 3, Section B on Agricultural Biotechnology specifically addresses agricultural biotechnology to support innovations in agriculture. Under USMCA, the countries have agreed to organize a tri-country council to discuss biotechnology issues. The group has yet to form.

Global Low-Level Presence Initiative (GLI): Canada is working with a group of interested countries to develop a global solution to the issue of low-level presence. The GLI was initiated by Canada (the secretariat and co-chair) and now has representation from 15 major grain exporting and importing countries.[7] Since the first meeting in March 2012 in Vancouver, the GLI has had six international meetings to date and has developed information and resources to help minimize asynchronous approvals and manage LLP. The GLI met in October 2020 and met again December 10, 2020 to discuss its workplan and how to bring these tools to other countries.

The GLI met to reflect on the outcomes of its 2020 virtual webinars and to set priorities for 2020/21. The GLI identified four areas for further action: 1) a proposal from Indonesia for a technical workshop on preventing and managing LLP for ASEAN countries, 2) a communication tools on best practices to address asynchronous approvals, to be led by Canada and the U.S., 3) the release of high-level messaging on LLP during 2021, recognizing the 10th anniversary of the GLI, to be led by Canada, the U.S and Australia, and 4) a proposal from Australia on compliance and enforcement related to LLP. These ideas will be further refined by the GLI membership. The next GLI meeting is expected to be held virtually, date to be determined.

[7] The GLI member countries are Australia, Argentina, Brazil, Canada, Chile, Colombia, Costa Rica, Indonesia, Mexico, Paraguay, Philippines, Russia, South Africa, United States, Uruguay.

Like-Minded Group (LMG) for Innovative Agricultural Biotechnologies: Canada is a member of the Like-Minded Group for Innovative Agricultural Biotechnologies, which formed in 2010. The key LMG principles are that regulation be science-based, that trade be no more restrictive than necessary, and that regulations be consistent with international obligations. The LMG work together to promote actions consistent with key principles and to address trade challenges. The LMG members are Argentina, Australia, Brazil, Canada, New Zealand, Paraguay, South Africa, United States, and Uruguay. Major exports of these countries include corn, soy, meat and bovine semen.

Ag5: In May 2019, a group of Ministers of Agriculture from Argentina, Brazil, Canada, Mexico and United States met in Niigata, Japan. They issued the following statement: "Together, we stand to work in partnership, and jointly with additional countries, to support regulatory approaches that are risk- and science-based, predictable, consistent, and transparent."

Part C: Marketing

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

Researchers from the University of Saskatchewan published the results of their survey of public and private breeders' attitudes on Canada's PNT system in October 2020. Remarkably, 77 percent of public and private plant breeders surveyed indicate that Canada's PNT system needs to be modernized to reflect "current levels of knowledge and advancements in plant breeding technologies."

The authors' survey of breeders also found:

- 22 percent experienced research proposals being turned down due to PNT uncertainty;
- 34 percent of breeders have ended research when self-determination indicated PNT status;
- 19 percent have altered research to ensure the variety was not deemed to be a PNT;
- 18 percent experienced a delay once PNT status was applied; and
- 26 percent disagreed that PNT regulations encourage investment.

Of the authors' survey respondents, 12 percent of public and 15 percent private breeders somewhat or strongly agree that Canada's novelty approach encourages investment and innovation in plant breeding. By comparison, 17 percent of public and nine percent of private breeders somewhat or strongly disagree.

Researchers from Dalhousie University in Halifax published a report on Canadian attitudes towards biotechnology in food November 2019. The study measures Canadian attitudes towards genetic engineering in food as well as trust toward food safety and the regulatory system in Canada. Results indicate that Canadians are divided on whether they believe genetically modified foods are safe with 38 percent believing them to be safe while 35 percent do not believe they are safe. The survey results were clear in demonstrating that the vast majority of Canadians favor GE food labeling.

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. A GE salmon is currently the only product of animal biotechnology approved for human and animal feed 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:

Currently, there are no new submissions of GE animals for approval in Canada. Within the next five years, Canada could see additional submissions of GE animals for approval.

b) COMMERCIAL PRODUCTION:

AquAdvantage Salmon

Sterile, pressure-shocked female AquAdvantage Salmon eggs, developed by AquaBounty, 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 the Canadian facility is expected in 2021. The Canadian facility is slated to produce 250 MT annually.

c) EXPORTS:

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

d) IMPORTS:

An AquaBounty facility in Panama exported GE salmon for human consumption to Canada in 2017 and 2018 but the facility was shuttered in early 2019. There are no longer GE salmon imports into Canada 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:

Canada does not have any significant barriers to trade of approved GE animals.

Part E: Policy

a) REGULATORY FRAMEWORK:

In Canada, products of animal biotechnology may be defined and regulated as novel foods.

Health Canada defines “novel food” as:

(a) a substance, including a microorganism, that does not have a history of safe use as a food;

(b) 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

(c) 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 that plant, animal, or microorganism. (aliment nouveau)

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 7: 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. The link for all novel food decisions from Health Canada can be found at: https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products.html

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 Organization 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 indicate a wide spectrum of opinions from Canadian consumers surrounding GE products as well as varying levels of understanding of biotechnology. However, a 2016 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.

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. A 2019 study by Charlebois et al. on 'Canadian attitudes towards genetic engineering in both plant- and animal-based foods' observed that there is a limited understanding of the safety and availability of GE foods in Canada. Specifically, 40 percent of respondents indicated that they did not believe there was significant evaluation of GE foods to protect consumers. The majority of respondents (52 percent) indicated that they were unaware of their level of consumption of GE foods although ultimately 55 percent noted that price was the greatest determinant when choosing which food to purchase.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

Part G: Production and Trade

a) COMMERCIAL PRODUCTION:

Canada commercially produces several food ingredients derived from microbial biotechnology, including enzymes, coloring agents, flavoring, and sweeteners. Health Canada maintains several databases of permitted food additives. The sources of permitted food ingredients that are strains obtained by genetic engineering are not categorized any differently than classical strains, making them time-consuming to identify. This process could not be completed in time for publication.

b) EXPORTS:

Canada exports microbial biotech-derived food ingredients to the United States and other countries; however, this information is not tracked by any government agency or NGO. Export documentation does not necessarily declare such content. Canada may also export GE microbes themselves (referred to as "cells" or "seed stock"). Government sources indicate that there may be instances where GE labeling regulations or schemes require that products containing GE food ingredients be labeled to indicate their presence in food; however, no such instances were identified prior to publication.

c) IMPORTS:

Canada imports microbial biotech-derived food ingredients, such as enzymes, and processed products containing microbial biotech-derived food ingredients. Similar to exports, the quantity of these imports is not tracked by any government agency or NGO.

d) TRADE BARRIERS:

FAS/Ottawa is not aware of any specific barriers to trade (TBT) issues pertaining to these food ingredients. Any barriers would apply more broadly and not be focused solely on microbial biotech-derived food ingredients. Industry has expressed its desire for clarity over what constitutes a "novel" product in Canada and has also shared that they would like to see data requirements streamlined in order to reduce regulatory barriers and improve business competitiveness.

PART H: POLICY

a) REGULATORY FRAMEWORK:

Novel foods are outlined in Division 28 of the Food and Drug Regulations, which is also known as the Novel Foods Regulations. The regulations prohibit the advertisement or sale of a novel food before a notification is made to Health Canada by a petitioner.

Applicants are required to submit a request to HC for a novelty determination. A description of the pre-submission process specific to novel foods, novel feeds and plants with novel traits is available on the HC website. The description of how to request a novelty determination for a food or food ingredient is available here. HC strives to provide a written response on the novelty status of the food or food ingredient within 60 calendar days. If the product is determined to be

Division 28 of Part B of the Food and Drug Regulations (subsection B.28.002(1)) states that no person shall sell or advertise for sale a novel food unless the manufacturer or importer of the novel food has:

a) notified Food Directorate of their intention to sell or advertise for sale the novel food; and,

b) received a letter of no objection to the sale of the novel food in Canada as stated in B.28.002(1)(b).

Unlike PNT, novel food and food ingredients are not only regulated based on whether they are created with different or new traits from their counterparts but are also regulated based on the process used. If a food or food ingredient meets the "novel food" definition, as defined in Canadian regulations, they are subject to a lengthy and complex approval process from Health Canada.

Health Canada defines "novel food" as:

(a) a substance, including a microorganism, that does not have a history of safe use as a food;

(b) 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

(c) 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 that plant, animal, or microorganism. (aliment nouveau).

b) APPROVALS:

HC maintains a database of completed safety assessments of novel foods, including "genetically modified foods." Not all foods in the database are derived from biotechnology. As previously noted, HC also maintains a database of permitted food ingredients; however, the sources of permitted food ingredients that are strains obtained by genetic engineering are not categorized any differently than classical strains, making them time-consuming to identify.

As noted in Chapter 1, in August 2020 the Government of Canada issued two notices. The first notice was specific to plant breeding. The second notice is to announce HC's intention to publish on its website a list of non-novel food and food ingredients to improve transparency of HC's decisions.

When applicants submit a request to HC for a novelty determination, if the food is determined to be non-novel, HC will now publish the non-novel determination on the List of Non-Novel Determinations for Food and Food Ingredients. This list is being populated retroactively and is currently a work in progress. It is expected to be completed by March 2021 with the goal of including as many of the remaining determinations in the list as possible by that date.

c) LABELING and TRACEABILITY:

Refer to Chapter 1, section (g). In addition, specific to food and food ingredients, The National Standard of Canada Voluntary Labeling and Advertising of Foods That Are and Are Not Products of Genetic Engineering states that processing aids, enzymes below 0.01 percent by weight in a food as offered for sale (exception, see par. 6.2.7 a.) and substrates for micro-organisms (where the substrate itself is not present in the finished food product) do not affect whether a food or ingredient is considered to be or not to be a product of genetic engineering.

d) MONITORING AND TESTING:

Canada does not have a monitoring program for biotech products and does not actively test for biotech products.

e) INTELLECTUAL PROPERTY RIGHTS (IPR):

Intellectual property rights for microbial biotech in Canada can be protected under three different acts:

- *Patent Act*
- *Copyright Act*
- *Trade-marks Act*

FAS/Ottawa is not aware of any IPR issues related to microbial biotech.

PART I: MARKETING

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

Demand for foods that use microbial biotech for food ingredients or nutritional purposes is growing. Data indicates the popularity of plant-based proteins and the willingness to consume lab-grown meat as an alternative to regular meat is increasing. A 2019 Nielsen survey notes, "While only 20 percent of Canadian households consider themselves vegan or vegetarian, more than one-quarter (27 percent) of households buy meat and dairy alternative products." The popularity of meat alternative products can be attributed to a variety of factors, including cultural diets, diet trends, and concerns about human health and animal welfare.

In the 2019 edition of Canada's Food Guide, the government encouraged Canadians to "choose protein foods that come from plants more often." In 2018, researchers from Dalhousie University in Halifax conducted a survey on plant-based dieting and meat attachment.

Attachments:

No Attachments