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

Approved By: Philip Hayes

Report Highlights: In March 2021, the Government of Canada published guidance on how Canada's Novel Food Regulations are applied to products of plant breeding. The Government also concluded industry consultations on draft guidance aimed to determine whether a plant is subject to Part V of Canada's Seeds Regulations and requires pre-market review. Canada planted approximately 11.6 million hectares of genetically engineered (GE) crops in 2021, mainly canola, soybeans, and corn, up seven percent from 2020.

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 (PNTs) 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).

In March 2021, HC published Guidelines for the Safety Assessment of Novel Foods. These new documents provide necessary guidance on how Canada's Novel Food Regulations are applied to products of plant breeding and are based on a new-tiered approach to evaluating products. It outlines the circumstances under which plants would require pre-market approval or are not considered PNTs.

The Novel Food Regulations were originally published in 1999 and last revised in 2006. Since then, new technologies for genetic modification of plants have been developed and innovators on both sides of the border have requested clear guidance on what triggers an in-depth regulatory review when a product is developed through plant breeding innovations.

Separate from HC's new guidelines, the CFIA recently concluded industry consultations on draft guidance aimed to determine whether a plant is subject to Part V of the Seeds Regulations and requires pre-market review. Final guidance is currently being penned. Further analysis will later be undertaken by the Government of Canada to assess the merits of updating the novel foods guidance as it pertains to foods derived from animals and microorganisms.

Since October 2020, the CFIA approved six PNTs for unconfined environmental release: one camelina product, one canola product, two corn products, and two soybean products. 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 planted approximately 11.6 million hectares of genetically engineered (GE) crops in 2021, mainly canola, soybeans, and corn. Area planted to biotech crops increased approximately seven percent from the previous year, driven by an increase in area planted to canola.

To date, Canada has approved only one animal product of biotechnology, a GE Salmon. The AquaBounty Salmon production facilities in Canada will shift to focus entirely on egg production. These eggs will be exported to grow out facilities in the United States. At this point, there are no indications the AquaBounty Salmon will be imported into Canada.

This report also explores the use of microbial biotech-derived food ingredients in Canada. These products 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.

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, transgenic and mutagenic methods unless referring to a specific technique or quoting legislation or regulation. In Canada, "genetically engineered crops" refers specifically to crops derived through transgenic techniques, as distinct from gene editing and mutagenesis techniques. The Canadian government uses "genetic modification" to encompass all these biotechnological methods.

Transgenic is a term used when a foreign gene is introduced into the crop. 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. Mutagenesis is the change in the genetic make-up of an organism caused by chemicals or radiation.

Part A: Production and Trade

a) PRODUCT DEVELOPMENT:

This section outlines plants with novel traits (PNTs) that are likely to be grown commercially within the next two of years. Information on these particular products is publicly available, while PNTs likely to be grown commercially at a later date 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. PNTs approved in Canada are posted in the Canadian Food Inspection Agency's (CFIA) PNT database; however, these varieties are not necessarily intended for commercial production. Hence, not all recently approved varieties are discussed in this report.

The CFIA has approved six events with novel traits for unconfined environmental release since our October 2020 report: one camelina event (Smart Earth Camelina Corporation's 14CS0851-01-14); one canola event (Bayer Crop Science's MON 94100); two corn events (Pioneer Hi-Bred Production Ltd's DP23211 and Monsanto Canada's GA21); and, two soybean events (Bioceres Crop Solutions Corp.'s IND-00410-5 and BASF's BCS-GM151-6). Each of these events have also received approval from CFIA and Health Canada (HC) to be sold for animal feed and human food. However, none of these six events are expected to be commercially available in the next two years.

BASF Canada (Soybean Event GMB151), Bayer CropScience (Dicamba Tolerant Canola – MON 94100), and Bioceres Crop Solutions Corporation (Abiotic Stress and Herbicide Tolerant HB4 Soybean) have requested safety assessments of corn or canola varieties, according to information from the CFIA.

The assessments are to determine the environmental safety of unconfined release,[1] and the safety to humans consuming novel foods, and animals consuming novel feeds.

The "notices of submission" on CFIA's website describe the product and the data CFIA has received from certain product developers who have requested assessments. 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. Approvals from key markets 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. The Canola Council indicated they continue to explore 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.

Canola industry sources estimate that area planted to high-oleic canola varieties has hovered between 8 and 10 percent over the past four years. Area has not grown significantly in recent years and is not expected to experience significant growth.

Soybean

Syngenta has the highest market share of all soybean lines in Manitoba and lines coming out of their program will still see significant acreage in the future.

Corn

Industry sources state that Enogen corn from Syngenta may see an increase in market share in Canada over the next couple years. Enogen corn was specifically developed for ethanol production. Enogen was approved in the United States in 2011, and approved for import into Canada shortly after. It was also approved for cultivation in Canada but earlier maturing hybrids suitable to northern geography were approved only more recently, according to industry.

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

b) COMMERCIAL PRODUCTION:

In 2021, GE varieties of grains and oilseeds occupied an estimated 35 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	2021
Canola	8,411	8,411	9,313	9,232	8,572	8,410	9,097
GE canola	7,991	7,990	8,848	8,771	8,143	7,990	8,642
GE canola, % of total	95%	95%	95%	95%	95%	95%	95%
Soybeans	2,239	2,269	2,947	2,558	2,313	2,052	2,130
GE soybeans	1,595	1,706	2,413	2,076	1,837	1,605	1,706
GE soybeans, % of total	71%	75%	82%	81%	79%	78%	80%
Corn for Grain	1,359	1,452	1,447	1,468	1,496	1,423	1,397
GE corn	1,133	1,253	1,269	1,291	1,340	1,278	1,275
GE corn, % of total	83%	86%	88%	88%	90%	90%	91%
Sugar Beets	7	12	11	19	17	17	18
GE sugar beets	7	12	11	19	17	17	18
GE sugar beets, % total	100%	100%	100%	100%	100%	100%	100%
Area seeded to GE crops	**10,726**	**10,961**	**12,540**	**12,156**	**11,337**	**10,889**	**11,641**

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 2021 is an estimate; 2021 GE corn area in Saskatechewan is also an estimate.

Canola

Approximately 95 percent of total canola area planted was of GE varieties in 2020, consistent with the last several years. Area planted to GE canola varieties in 2021 is estimated at 8.6 million hectares, up from the 8.0 million hectares planted in 2020. Approximately 98.5 percent of area planted was of biotech varieties (i.e. varieties developed using genetic engineering, gene editing or mutagenesis). Twenty-three new varieties of canola were available for planting in 2021.

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 percent of Canadian canola seed, oil, and meal are exported. In recent years, high oleic varieties accounted for roughly 10 percent of the area planted in Canada, according to industry sources.

Canadian canola oil production is expected to increase in Canada. In 2021, four companies (Viterra, Richards, Cargill and Ceres) announced plans for expansion of existing canola processing facilities and/or development of new facilities. If these projects are completed, processing capacity will increase by an estimated 41 percent from the current capacity of 11 million MT by 2024. The Saskatchewan provincial government states the province will process 75 percent of Saskatchewan-grown canola by 2030.

Export opportunities are expected to grow. The Comprehensive and Progressive Trans-Pacific Partnership (CPTPP) trade agreement continues to bring down tariff rates in key markets like Japan and

Vietnam. 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), followed by the addition of Vietnam on January 14, 2019.

Soybeans

Table 2: Area planted to genetically engineered soybeans by province

Area Seeded (hectares)		2016	2017	2018	2019	2020	2021
Ontario	Soybeans	1,126,400	1,244,400	1,222,200	1,260,400	1,153,400	1,188,200
	GE soybeans	736,500	890,300	894,200	940,400	870,900	899,300
	GE soybeans, % total	**65%**	**72%**	**73%**	**75%**	**76%**	**76%**
Manitoba	Soybeans	634,515	870,330	719,756	522,521	414,568	532,900
	GE soybeans	621,825	861,627	712,558	517,295	406,276	522,242
	GE soybeans, % total	**98%**	**99%**	**99%**	**99%**	**98%**	**98%**
Quebec	Soybeans	351,700	398,000	370,300	366,700	358,300	374,500
	GE soybeans	221,700	265,000	261,600	247,700	245,100	250,900
	GE soybeans, % total	**63%**	**67%**	**71%**	**68%**	**68%**	**67%**
Saskatchewan	Soybeans	97,100	344,000	164,900	60,700	51,300	34,300
	GE soybeans	95,158	340,560	163,251	60,093	50,787	33,957
	GE soybeans, % total	**98%**	**99%**	**99%**	**99%**	**99%**	**99%**
Total	**Soybeans**	**2,209,715**	**2,856,730**	**2,477,156**	**2,210,321**	**1,977,568**	**2,129,900**
	GE soybeans	**1,675,183**	**2,357,487**	**2,031,609**	**1,765,488**	**1,573,063**	**1,706,399**
	GE soybeans, % total	**76%**	**83%**	**82%**	**80%**	**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 2021 is an estimate.

Of the total soybean area planted in 2021, an estimated 80 percent is expected to be area planted to GE varieties, consistent with the previous two years.

Two high-oleic soybeans are currently 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 resistant to paying the price premium associated with high oleic oils produced in Canada. Bayer discontinued its Vistive Gold soybean in 2020.

Due to lack of sufficient supply, the Canadian crushing industry does 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.

Corn

In 2021, GE corn accounted for approximately 91 percent of all area planted to corn in Canada, up a percentage point from the previous year.

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. Conversely, Ontario growers export their sugar beet crop to the United States for processing in Michigan. Statistics Canada estimates the 2021 sugar beet seeded area as 18,800 hectares, up eight percent from 2020. Alberta is projected to have an acreage decline of four percent with Ontario acreage estimated to be up 56 percent but similar to 2019 acreage. Harvest of the Ontario crop has been hampered by higher moisture and rainfall events through the late summer and fall. While some fields were lost due to water damage, remaining fields are reported as having very strong yields; some fields are projected at over 37 tons per acre. Alberta is anticipating good production with yields of approximately 30 tons per acre and total production similar to 2020.

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, though commercial production is occurring in the United States. At the time of writing there are no known immediate plans for commercial scale planting and production in Canada as expansion will be focused in the United States. Exports of Arctic® apples to Canada from the United States are occurring based on market demand. There is currently no target for quantity of exports to 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 previously been planted in Canada but large-scale commercial plantings have not occurred. There was no acreage planted in Canada in 2021. Acreage and commercial production development in Canada will be market dependent.

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.

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

Pineapple
In March 2021, HC approved the PinkGlow™ pineapple for food use in Canada. The pink fleshed pineapple is not approved for any other uses in Canada at this point.

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.

c) EXPORTS:
Exports of canola seed to China were depressed in 2019 and 2020 due to market access issues[2] and reduced feed demand due to African Swine Fever (ASF). The EU[3] 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 3: Canada: Canola seed exports (tons)

Partner	08/2018 - 07/2019	08/2018 - 07/2019 % Share	08/2019 - 07/2020	08/2019 - 07/2020 % Share	08/2020 - 07/2021	08/2020 - 07/2021 % Share
World	9,202,499	100.0	10,041,143	100.0	10,517,453	100.0
EU 27	642,484	7.0	2,176,518	21.7	1,751,483	16.7
China	3,119,093	33.9	1,925,865	19.2	2,714,066	25.8
Japan	2,136,573	23.2	2,140,170	21.3	2,290,873	21.8
Mexico	1,266,417	13.8	1,154,712	11.5	1,346,241	12.8
United Arab Emirates	456,544	5.0	988,713	9.8	996,681	9.5
Pakistan	777,980	8.5	690,723	6.9	660,414	6.3
United States	513,886	5.6	495,560	4.9	428,381	4.1

Source: Trade Data Monitor, LLC

[2] 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 and the permits have not been reinstated.

Canola oil exports to the United States in MY 2020/21 fell three percent from the previous year due to reduced demand. Shipments of Canadian canola oil to China have strengthened since the Chinese government limited seed imports in 2019 and remain high.

The Comprehensive and Progressive Agreement for Trans-Pacific Partnership (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 has reduced their tariffs on Canadian oils.

Table 4: Canada: Canola oil exports (tons)

Partner	08/2018 - 07/2019	08/2018 - 07/2019 % Share	08/2019 - 07/2020	08/2019 - 07/2020 % Share	08/2020 - 07/2021	08/2020 - 07/2021 % Share
World	3,155,165	100.0	3,429,467	100.0	3,439,439	100.0
United States	1,730,694	54.9	1,852,240	54.0	1,793,125	52.1
China	1,003,891	31.8	969,799	28.3	1,183,794	34.4
Mexico	78,087	2.5	100,990	2.9	160,457	4.7
South Korea	136,032	4.3	142,854	4.2	153,969	4.5
Chile	103,008	3.3	150,373	4.4	93,558	2.7

Source: Trade Data Monitor, LLC

In MY 2020/21, total soybean exports were 4.5 million metric tons (MT), up 16 percent from the previous year. About half of Canada's exports went to the EU, China, and Iran.

Canada exported 118,000 MT of soybean oil in MY 2020/21, down 17 percent from the previous year. 95 percent of soybean oil was exported to the United States.

Canada's corn exports in MY 2020/21 were 1.5 million MT, with the EU (66 percent), and United States (18 percent) being the top destinations.

Canada previously exported Innate® potatoes grown in Ontario for processing in the United States but this did not occur in 2021. 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. Industries such as ethanol production and the livestock feed industry drive imports of corn and soybeans from the United States.

PNT imports require advanced approval from HC and CFIA for use as human consumption and animal. There are currently 138 plant products with novel traits approved for human consumption. There are 133 plant products with novel traits approved for animal feed.

Canada began importing GE apples in late 2019 and has continued into 2021, with an estimated 1 MT imported year-to-date. Imports will continue based on market demand. In 2021, Canada has imported approximately 544 MT of GE potatoes. Canada has approvals to enable import of GE papaya, GE squash, and GE pineapple.

e) TRADE BARRIERS:

There are currently 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, and 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 PNTs or novel foods in the Canadian regulatory guidelines and legislation.

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 PNTs and/or novel foods. The CFIA is responsible for regulating the importation, environmental release, and the use in livestock feeds of PNTs. 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.

CFIA currently defines PNTs 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 PNTs can either be derived from recombinant DNA technologies or from traditional plant breeding. Regulated field testing is necessary when the PNT's 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.

HC currently 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)

Table 5: 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*

Table 6: Plant Biotechnology - Regulating Agencies' Responsibilities

Category	CFIA	HC
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 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 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.

An overview of PNT field trials is not yet available from CFIA for 2021. In 2020, Canada had 81 PNT submissions and 176 field trials, primarily of canola and corn, but also barley, borage, camelina, poplar,

soybean, sugar beet, and white mustard. 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.

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.
HC 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, HC 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 HC.

Further, if the plant is a type of crop that requires variety registration (eg. 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 5-7 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.

2021 Consultations on Proposed Guidelines

In 2021, HC concluded consultations on two proposed changes:

> *i) Proposed Changes to Health Canada Guidance on the interpretation of Division 28 of Part B of the Food and Drug Regulations (the Novel Food Regulations): When is a food that was derived from a plant developed through breeding a "novel food"?*
> *ii) Proposed Health Canada Guidance on the pre-market assessment of foods derived from Retransformants under Division 28 of Part B of the Food and Drug Regulations (the Novel Food Regulations).*

HC's proposal more narrowly defines "novel foods" than previous guidelines, to provide clarity in their requirements for plants. HC's position is that the following five categories of foods would not add to their body of knowledge about their safety, if assessed individually as novel foods in accordance with sections B.28.002-B.28.003 of the food and drug regulations (FDRs) because their safety is already well characterized for foods derived from plants with genetic modifications that:

> 1. do not alter an endogenous protein so that it now demonstrates significant homology with a known allergen or toxin relevant to human health; or

2. do not increase levels of an endogenous allergen, toxin, or an anti-nutrient beyond the documented range; or
3. do not have an impact on key nutritional composition and/or metabolism; or
4. do not change the food use of the plant; or
5. are not the result of the insertion of foreign DNA.

HC proposes to interpret the Novel Food Regulations narrowly to classify foods within these categories as ones that do not meet the threshold of novelty of characteristics required for them to meet the definition of a "novel food" set out in section B.28.001 of the FDRs. The definition, interpreted narrowly in this way takes account of the precautionary safety objectives that underlie these pre-market safety assessment regulations.

HC has published on its website a list of non-novel determinations to improve transparency of the agency's decisions.

Separately, the CFIA concluded industry consultations on draft guidance aimed to determine whether a plant is subject to Part V of the Seeds Regulations and requires pre-market review. Final guidance is currently being penned.

The draft guidance states:

There are three reasons for a plant to be subject to Part V:

1. plants that are new crop species to Canada
2. plants where DNA from another species was introduced
3. plants that have the capacity to negatively impact the environment, as defined by four specific outcomes:
    a. a plant that is more difficult to control;
    b. a toxin, allergen, or other compound that would negatively affect plants, animals, or microbes;
    c. improved survival of plants in natural environments to a degree that ecosystems would be disrupted;
    d. increased ability to support the activity of a plant pest.

The guidance also states: "Most plants developed using conventional breeding are exempt from Part V, since breeding generally doesn't result in new characteristics that would affect safety."
Canada's product-based system captures some plants developed through conventional breeding if they are determined to possess novel traits, requiring pre-market authorizations for such products. Industry representing plant breeders responded to the guidance by stating that CFIA succeeds in recognizing the

safety of gene editing but does not rectify challenges which exist for conventional breeding, and in some instances creates more confusion.

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

b) APPROVALS:

Since October 2020, CFIA and HC have approved the following submissions:

Table 7: CFIA and HC Approvals Since Last Publication (Oct. 2020 – Oct. 2021) *Source: CFIA*

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	
Camelina (14CS0851-01-14)	Non-LMO	Linnaeus Plant Sciences (currently Smart Earth Camelina Corp.)	Sulfonylurea tolerance	Yes (March 15, 2021)	Yes (March 15, 2021)	Registration not required	Yes (March 3, 2021)
Canola (MON 94100)	LMO	Bayer CropScience	Tolerance to dicamba	Yes (April 23, 2021)	Yes (April 23, 2021)	No varieties registered	Yes (April 23, 2021)
Corn (DP23211)	LMO	Pioneer Hi-Bred Production Ltd.	Resistance to western and northern corn rootworms / Tolerance to glufosinate ammonium herbicide	Yes (Sept. 2 2021)	Yes (Sept. 2 2021)	Registration not required	Yes (Sept. 2 2021)
Corn (MON 95379)	LMO	Bayer CropScience	Lepidopteran resistance	Yes (Sept. 23, 2021)	Yes (Sept. 23, 2021)	Registration not required	Yes (Sept. 24, 2021)
Soybean (IND-00410-5)	LMO	Verdeca LLC (currently Bioceres Crop Solutions Corp.)	Increased yield; Drought tolerance; Glufosinate ammonium tolerance	Yes May 27, 2021)	Yes (May 27, 2021)	No varieties registered	Yes (May 27, 2021)
Soybean (GMB151)	LMO	BASF Canada Inc.	Tolerance to herbicides that inhibit HPPD (isoxaflutole); Resistance to soybean cyst nematode	Yes (May 26, 2021)	Yes (May 26, 2021)	No varieties registered	Yes (May 26, 2021)

Please refer to the CFIA PNT database for more information on the status of regulated PNTs 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 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.

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.

According to the CFIA web site, these notifications are required so that regulators may determine if:

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

The web site further states that additional information and further assessment will be required if:

1. *The conditions of authorization of the parental PNTs would not apply to the stack*
2. *The novel traits of the parental PNTs are expressed differently in the stacked plant product (e.g. greater or lower expression)*
3. *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 2021. In 2020, Canada had 81 PNT submissions and 176 field trials, primarily of canola and corn, but also barley, borage, camelina, poplar, soybean, sugar beet, and white mustard. 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.

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 guidance to help improve the coexistence between biotech and non-biotech crops.

g) LABELING:

HC and the CFIA are responsible for all federal food labeling policies under the Food and Drugs Act. HC 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. The standards were re-affirmed in May 2021.

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 Drug Regulations (FDR), 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. 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.

k) CARTAGENA PROTOCOL RATIFICATION:

In 2001, Canada signed onto the Cartagena Protocol, but has yet to ratify it and therefore it is not enforced in Canada. Many farm groups, including the Canadian Canola Council, the Grain Growers of Canada, Viterra and many 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:

Canada-Mercosur Free Trade Agreement (FTA) Negotiations: Canada is negotiating an FTA with Mercosur, a trading bloc and customs union consisting of Argentina, Brazil, Paraguay, and Uruguay. Chapter Five of the FTA, on Sanitary and Phytosanitary Measures, contains a biotechnology annex. The objective of the Agricultural Biotechnology provisions is to encourage innovation and facilitate trade in products of agricultural biotechnology. Seven rounds of negotiations have been held to date, most recently from July 29 to August 2, 2019.

HC and FSANZ pilot: HC and 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. HC 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 first product to be assessed under the new arrangement is herbicide tolerant canola-line MON94100. The joint food safety assessment was initially prepared by HC and then provided to FSANZ for FSANZ's review and confirmation that it met all relevant requirements for Australian and New Zealand purposes. Following confirmation that these requirements were met, the jointly prepared safety assessment was used as part of the FSANZ assessment.

The United States-Mexico-Canada Agreement (USMCA) specifically addresses trade in products of agricultural biotechnology and related innovations in agriculture. Under USMCA, the countries also agreed to form a Working Group for Cooperation on Agricultural Biotechnology.

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.[4] 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 December 10, 2020 to discuss its work plan and how to bring these tools to other countries.

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

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 tool 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 is yet to be determined.

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 members work together to promote actions consistent with key principles and to address trade challenges. Major exports of member 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

PUBLIC/PRIVATE OPINIONS / MARKET ACCEPTANCE/STUDIES:

A report published in April 2021 by researchers at the University of Saskatchewan (Williams et al, 2021) states that "Three-quarters of Canadians have high levels of trust in those who provide information about food, yet two-thirds believe that modern plant breeding technologies are unnatural."

Another report published by some of the same authors (Macall et al, 2021), found that of the people they surveyed in Canada, 52 percent reported to being worried about GM, and another 34 percent and 14 percent reported that they were not worried and did not know, respectively. However, the authors warn that investment in innovative new food products should be based on consumers purchase decisions within grocery stores, rather than the opinions expressed when they are not inside a grocery store. Survey respondents indicated that the main attribute determining their decision whether or not to buy produce is where it is grown.

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. HC 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, developed by AquaBounty, continue to be produced at a land-based facility in Prince Edward Island (PEI). The eggs are currently being transferred to a land-based, grow-out facility in PEI as well as exported to United States (Indiana). The 250 MT capacity grow-out facility in PEI is scheduled to be converted to a brood stock facility once the 2021 harvest is complete.

c) EXPORTS:

GE Salmon eggs are currently exported to the U.S. facility located in Indiana. Exports of eggs from Canadian facilities are estimated at approximately 400,000 eggs per year in 2021.

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.

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 FDR, 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 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), HC, 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, HC 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 HC 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, HC 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. HC 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, HC 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 8: Legislative Responsibility for the Regulation of Animal Biotechnology

Product	Agency	Act	Regulation
Foods and drugs derived through biotechnology	HC	*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 HC 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 HC	*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 HC 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*. HC and CFIA carry joint responsibility according to these policies, with HC 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. HC 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 HC, 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 are covered 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 HC's activities with the Commission. Canada is also part of the Organization for Economic Co-operation and Development (OECD), and HC 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 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. 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

COMMERCIAL PRODUCTION:

Canada commercially produces several food ingredients derived from microbial biotechnology, including enzymes, coloring agents, flavoring, and sweeteners. HC 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:

Most of the trade in microbial biotech-derived products is from value-added products, although Canada may also export GE microbes themselves (referred to as "cells" or "seed stock").

Canada exports microbial biotech-derived food ingredients to the United States and other countries; however, export documentation does not necessarily declare such content, and there is no way to isolate products that utilize microbial biotech by HS code. 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.

FAS/Canada estimates that in 2020 Canada exported approximately $5.5 billion USD annually of processed products that use microbial biotech-derived ingredients at varying levels.[5] Ninety percent of this value represents products exported to the United States.

[5] This export value was derived from HS codes 0406 (cheese), 3507 (enzymes), 2203, 2204 (wine and beer), 2009 (fruit juice), 2106, 1905, 1904 (processed products), 2103 (condiments and sauces), and 190110 for (infant formula).

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.

It is estimated that Canada imported about $4.8 billion USD of processed products in 2020 that use microbial biotech-derived ingredients at varying levels. 58 percent of this value represents products imported from the United States, another 25 percent were imported from European countries, and the remainder of the value is imported from other various locations.

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. The regulations prohibit the advertisement or sale of a novel food before a notification is made to HC 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.

Division 28 of Part B of the FDRs (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's, 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 HC.

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.

When applicants submit a request to HC for a novelty determination, if the food is determined to be non-novel, HC publishes the non-novel determination on the List of Non-Novel Determinations for Food and Food Ingredients.

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 any 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:

Refer to Chapter 1, Part C.

Attachments:

No Attachments