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Report Highlights:

In September 2023, the government of Canada published a draft guidance document for plant breeders and feed manufacturers that reinforces Canada's product-based approach and provides guidance on how Canada's Feeds Act and Feeds Regulations are applied to products of plant breeding. These documents follow the publication of similar guidance documents on human consumption and environmental release of novel products derived from plant sources, including plants with novel traits. Canada planted 11.7 million hectares of genetically engineered (GE) crops in 2023, mainly canola, soybeans, and corn. This is an increase of four percent from the previous year, on increased area planted to canola.

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 traits not previously observed in that plant, animal, or microorganism are referred to as plants with novel traits (PNTs) or novel foods. They are subject to an approval process from the Canadian Food Inspection Agency (CFIA) and Health Canada and in some cases Environment and Climate Change Canada (ECCC).

In September, 2023, the CFIA launched consultations on proposed guidance that reinforces this approach and clarifies which plant-derived feed ingredients require a premarket assessment, as per the Feeds Act and Feeds Regulations, including how to make a novelty determination of ingredients derived through plant breeding destined to be used in livestock feeds. Novel feeds consist of organisms or parts of products thereof that have never before been evaluated and approved for use as livestock feed in Canada, regardless of how they were developed. Novel feeds may be from plant sources, including plants with novel traits (PNTs).

These consultations follow the revision and final publication of two other guidance documents on PNTs, both of which support the introduction of gene-edited products in the Canadian market. Guidelines for the Safety Assessment of Novel Foods, published in July 2023, reinforce Canada's product-based approach and provide guidance on how Canada's Novel Food Regulations are applied to products of plant breeding.

Secondly, on May 3, 2023, Canada published updated guidance for determining whether a plant is regulated under Part V of the Seeds Regulations.

Analysis is currently being 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. The Canadian government has not posted a timeline but has stated that a public consultation will occur.

Since the publication of FAS Ottawa's last annual Agricultural Biotechnology report, Health Canada and the CFIA have approved two products with novel traits: borage for cultivation and rice for human consumption and animal feed. These varieties are further detailed in Part B: Policy, section (b), of this report.

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 11.7 million hectares of genetically engineered (GE) crops in 2023, mainly canola, soybeans, and corn. This is an increase of four percent from the previous year, on increased area planted to canola.

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.

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PART A: PRODUCTION AND TRADE

a) RESEARCH AND PRODUCT DEVELOPMENT

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.

PNTs 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.

This section outlines PNTs that have been approved for unconfined release and/or human food or feed consumption. PNTs approved in Canada are posted in the Canada Food Inspection Agency (CFIA) PNT database; however, these varieties are not necessarily intended for commercial production.

The CFIA's database entitled, "PNT and novel feeds from plant sources approved in Canada" indicates that since FAS Ottawa's 2022 Agricultural Biotechnology report, Health Canada and the CFIA have approved two events with novel traits. They are listed in Part B: Policy, section (b), of this report.

In addition to the CFIA's PNT database, other databases provide information on the novelty specific to plant products in Canada. Only one of these databases, on corn, indicates GM events.

"Varieties of Crop Kinds Registered in Canada" is a CFIA database that shares the registration date, status, expiry date, and further information related to registered crop varieties in Canada.

Seeds Canada's Corn Hybrid Database is a comprehensive compilation of corn hybrids available in Canada. The database lists GM events present (if any) and whether the hybrid is approved in the European Union, among other information.

Health Canada's list of non-novel products of plant breeding for food use identifies varieties that do not have a novel trait, regardless of whether the trait is genetically engineered.

Seeds Canada's Canadian Variety Transparency Database identifies any variety that been

"developed using gene editing technology and does not meet the definition of a novel food."

Three proponents have requested safety assessments since FAS Ottawa's 2022 Agricultural Biotechnology Report, and seen those assessments completed, according to information from the CFIA. The assessments are to determine the safety for human consumption.

Table 1: Completed safety assessments of novel foods, including genetically modified (GM) foods

No.	Decision Date	Product	Proponent
1	2023/02/08	ROXY rice expressing an oxyfluorfen herbicide tolerance characteristic	California Cooperative Rice Research Foundation (CCRRF)
2	2023/01/20	Fy Protein – A nutritional fungi protein from Fusarium sp. Strain flavolapis	The Fynder Group, Inc. DBA: Nature's Fynd
3	2022/10/11	Canola Protein Isolate and Cruciferin-rich Canola Protein Isolate	Merit Functional Foods Corporation

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.

Soybeans

Industry contacts state that there is an opportunity for food-grade, non-GE crops to expand in Manitoba if profitability for farmers improves. In the early 2000s, nearly all soybeans grown in Manitoba were food grade. In 2005 and 2006, herbicide tolerant crops took over in part because buyers of food grade soybeans (primarily from Japan) preferred to ship from Ontario. However, Seveta and Prograin recently have introduced closed loop systems in Manitoba, where the company provides the seed to the farmer and purchases and ships the seed after harvest. This process has increased profitably for farmers in Manitoba, but further increases are necessary to entice Manitoba farmers to grow an increased market share.

Wheat

The genetically engineered HB4 wheat (IND-00412-7) is transgenic and has a trait for drought stress tolerance. It has been approved for food and feed in seven countries (US, Nigeria, NZ, Colombia, Brazil, Australia, Argentina) and cultivation in two (Argentina and Brazil). Industry contacts do not believe HB4 will make inroads into Canada soon because of farmer and consumer opposition within Canada and several of its export

markets. HB4 wheat was developed by Trigall Genetics, a Bioceres joint venture with the French company Florimond Desprez.

b) COMMERCIAL PRODUCTION

In 2023, GE varieties of grains and oilseeds occupied an estimated 41 percent of total area planted for grains and oilseeds in Canada, unchanged from 2022 (based on revised 2022 Statistics Canada estimates).

Statistics Canada is reporting a year-over-year increase in area planted for corn, soybeans, and canola (of both GE and non-GE varieties). USDA's official forecast currently sees a five percent production increase in corn on increased yield and seeded area; a five percent decrease in canola production on reduced yield due to drought and despite increased area; and a two percent increase in soybean production on increased area seeded and despite reduced yield.

Beginning in 2022, Statistics Canada provides GE area seeded data from corn and soybean surveys, retroactive to 2018, in Canada, Newfoundland and Labrador, Prince Edward Island, Nova Scotia, New Brunswick, Manitoba, Saskatchewan, Alberta, and British Columbia. Data was not available prior to 2018 for Canada and these provinces. Previously, Statistics Canada only published area seeded data for Ontario and Quebec, and FAS Ottawa collected data on corn area planted in the prairie provinces from sources at the Manitoba Department of Agriculture, the Alberta Ministry of Agriculture, and from industry.

Table 2. Area planted to genetically engineered crops in Canada

Area Seeded (1,000 hectares)	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**
Canola	8,411	9,313	9,232	8,572	8,410	9,012	8,659	8,936
GE canola	7,990	8,848	8,771	8,143	7,990	8,561	8,226	8,489
GE canola, % of total	95%	95%	95%	95%	95%	95%	95%	95%
Soybeans	2,269	2,947	2,558	2,313	2,052	2,087	2,134	2,279
GE soybeans	1,727	2,441	2,105	1,822	1,607	1,616	1,679	1,849
GE soybeans, % of total	76%	83%	82%	79%	78%	77%	79%	81%
Corn for Grain	1,452	1,447	1,468	1,496	1,440	1,413	1,466	1,548
GE corn	1,253	1,269	1,303	1,346	1,280	1,276	1,317	1,365
GE corn, % of total	86%	88%	89%	90%	90%	90%	90%	88%
Sugar Beets	12	11	19	17	17	18	18	13
GE sugar beets	12	11	19	17	17	18	18	13
GE sugar beets, % total	100%	100%	100%	100%	100%	100%	100%	100%
Area seeded to GE crops	**10,983**	**12,568**	**12,198**	**11,328**	**10,893**	**11,471**	**11,240**	**11,716**

Source: Statistics Canada and industry sources

Notes: Corn and soybean data for 2019 to 2023 are derived from Statistics Canada, which began publishing national data in July 2022. Corn and soybean data from 2016 to 2018 are derived from Statistics Canada (for Ontario and Quebec) and provincial and industry sources. 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 for the years 2016 to 2018. Percentages were calculated using unrounded estimates of hectares. GE canola area for the year 2023 is an estimate based on industry sources.

Canola

Approximately 95 percent of total canola area planted was of GE varieties in 2023, consistent with the last several years. There are reportedly seventeen new hybrid canola varieties available for planting in 2023. Eleven new hybrid varieties are available for planting in 2024.

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

Canada's Clean Fuel Regulation (CFR) is spurring investment into renewable diesel, and canola oil will be the main feedstock. See GAIN report CA2023-0030 for more information on the CFR and the current landscape for renewable fuel.

Soybeans

Table 3: Area planted to genetically engineered soybeans by province

Area Seeded (hectares)		2019	2020	2021	2022	2023
Ontario	Soybeans	1,260,400	1,153,400	1,135,651	1,246,600	1,178,900
	GE soybeans	947,000	870,900	852,783	947,000	927,200
	GE soybeans, % total	**75%**	**76%**	**75%**	**76%**	**79%**
Manitoba	Soybeans	594,700	465,200	520,964	459,200	645,600
	GE soybeans	560,000	430,900	463,598	410,300	568,900
	GE soybeans, % total	**94%**	**93%**	**89%**	**89%**	**88%**
Quebec	Soybeans	366,700	358,300	380,879	386,800	405,300
	GE soybeans	247,700	245,100	256,903	286,300	310,700
	GE soybeans, % total	**68%**	**68%**	**67%**	**74%**	**77%**
Saskatchewan	Soybeans	60,700	51,300	30,100	18,400	27,500
	GE soybeans	52,600	41,900	26,415	16,500	24,400
	GE soybeans, % total	**87%**	**82%**	**88%**	**90%**	**89%**
Canada	**Soybeans**	**2,312,500**	**2,051,900**	**2,087,408**	**2,134,500**	**2,278,600**
	GE soybeans	**1,822,200**	**1,607,200**	**1,615,567**	**1,678,900**	**1,849,400**
	GE soybeans, % total	**79%**	**78%**	**77%**	**79%**	**81%**

SOURCES: Statistics Canada Table: 32-10-0042-01

NOTE: Beginning in 2022, Statistics Canada began publishing GE area planted for Canada and the provinces. The Ontario, Manitoba, Quebec, Saskatchewan total represents 99% of Canadian area planted.

Eighty-one percent of area planted to soybeans were GE varieties in 2023, with the rate being the highest in the Prairies due to the market share grown for human consumption

being lower than in Eastern Canada. Over the past five years, the national rate has varied by four percentage points, ebbing and flowing with provincial changes in total area of soybeans planted.

Pioneer P006A37X (RR2X) has been growing in market share in Manitoba, from 5.6 percent of soybean acres in 2022 to 7.2 percent in 2023 when it bumped Syngenta S007-Y4 (RT) from its first-place position held since 2017. At its peak market share in 2020, Syngenta S007-Y4 (RT) was grown on 17.1 percent of insured acres in Manitoba. It was first available to growers in the 2014 growing season. It has herbicide tolerance with trait RR2Y and phytophthora root rot field tolerance with the Rps1c gene.

Corn

Table 4: Area planted to genetically engineered corn by province

Area Seeded (hectares)		2019	2020	2021	2022	2023
Ontario	Corn	891,300	886,700	891,306	921,100	915,100
	GE corn	786,100	771,700	800,070	828,100	817,100
	GE corn, % total	**88%**	**87%**	**90%**	**90%**	**89%**
Manitoba	Corn	186,100	150,700	178,971	153,200	224,100
	GE corn	177,500	141,600	165,105	143,900	184,500
	GE corn, % total	**95%**	**94%**	**92%**	**94%**	**82%**
Quebec	Corn	382,500	360,500	371,700	361,100	363,500
	GE corn	350,900	331,200	339,432	317,200	330,000
	GE corn, % total	**92%**	**92%**	**91%**	**88%**	**91%**
Alberta	Corn	11,800	16,500	19,161	5,700	15,200
	GE corn	9,800	11,800	14,288	4,700	12,700
	GE corn, % total	**83%**	**72%**	**75%**	**82%**	**84%**
Canada	**Corn**	**1,495,500**	**1,440,400**	**1,487,853**	**1,466,300**	**1,547,700**
	GE corn	**1,346,000**	**1,279,500**	**1,342,103**	**1,316,500**	**1,364,800**
	GE corn, % total	**90%**	**89%**	**90%**	**90%**	**88%**

SOURCES: Statistics Canada Table: 32-10-0042-01

NOTE: The Ontario, Manitoba, Quebec, Alberta total represents 98% of national corn area planted. Sum does not equal national total, because the national total includes all provinces.

In 2023, GE corn accounted for 88 percent of all area planted to corn in Canada, down from 90 percent in the previous four years. Corn in Canada goes into human food, feed, and ethanol channels. GE market share is highest in Ontario and Quebec, where a larger share of corn is grown for industrial purposes.

Seeds Canada's Corn Hybrid Database is a comprehensive compilation of corn hybrids available in Canada. The database lists GM events present (if any) and whether the hybrid is approved in the European Union, amongst other information.

Sugar Beets

Essentially, one hundred 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 planted acres for 2023 to be down 27 percent compared to 2022. In Alberta, the resolution of a contract between Rogers Sugar Inc. and Alberta growers came in late April. Some growers had elected to plant alternative crops, reducing Alberta acreage. Despite lower acreage, 2023 yields are expected to be improved over 2022, with production anticipated at a similar level. Ontario acreage estimates for 2023 are in alignment with 2021 planted acres, a decline of approximately 25 percent compared to the larger plantings in 2022.

Apples

Three varieties of GE apples 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 apple varieties in Canada, although 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.

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. 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. The Alberta Forage Industry Network continues reaffirming 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 the history of biotech wheat 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

Canola

Total canola seed exports rose six percent in marketing year (MY) 2022/2023 to 7.9 million metric tons on increased production after the severe drought in the Prairies in MY 2021/22.

Several factors will impact the growth of Canada's canola seed and oil exports. Bullish factors in the short and medium term include the U.S. Environmental Protection Agency's recent approval of canola as an official pathway for renewable diesel, which may lead to increased seed or oil exports to the United States. Difficult canola-growing conditions in the United States (e.g., due to persistent "heat blast") may also bolster Canada's export position unless solutions are developed to manage climate variables.

Factors that put downward pressure on seed and oil exports include the increase in domestic canola seed processing for domestic renewable diesel production, the extent to which hinges on forthcoming renewable fuel incentives which are expected to be published in Canada's Fall Economic Statement in October or November 2023. Further, if solutions are found to manage the climate challenges that U.S. farmers face growing canola (e.g., through the development of new varieties), more of it may be grown south of the border and compete with Canadian canola.

Table 5: Canola Seed Exports (MT, '000)

Partner	MY 2017/18	MY 2018/19	MY 2019/20	MY 2020/21	MY 2021/22	MY 2022/23
World	10,848	9,202	10,041	10,589	5,249	7,945
China	4,392	3,119	1,926	2,714	1,265	4,608
Mexico	1,474	1,266	1,155	1,374	1,035	1,209
Japan	2,584	2,137	2,140	2,323	1,383	1,101
United States	653	514	496	429	538	320
Pakistan	678	778	691	660	64	267
EU 27 Brexit	390	642	2,177	1,751	625	215
United Arab Emirates	637	457	989	997	307	169

Source: Trade Data Monitor, LLC

Table 6: Canola Oil Exports (MT, '000)

Partner	MY 2017/18	MY 2018/19	MY 2019/20	MY 2020/21	MY 2021/22	MY 2022/23
World	3,170	3,155	3,429	3,448	2,573	3,017
United States	1,872	1,731	1,852	1,793	1,920	2,601
China	871	1,004	970	1,192	246	145
Mexico	69	78	101	160	183	142
South Korea	133	136	143	154	95	79
Japan	11	18	46	14	20	17
Chile	109	103	150	94	71	15
Taiwan	9	10	10	8	10	8
Colombia	1	2	1	2	10	3
Hong Kong	39	22	33	17	10	2

Source: Trade Data Monitor, LLC

Soybeans and Soybean Product

In MY 2022/23, total soybean exports were 4.2 million MT, down one percent from the previous year. Thirty-three percent of Canada's soybean exports went to China, 20 percent to the EU, and ten percent to Iran.

Canada exported 139 thousand MT of soybean oil in MY 2022/23, down ten percent from the previous year. Ninety-four percent of soybean oil was exported to the United States.

Table 7: Soybean Exports (MT, '000)

Partner	MY 2017/18	MY 2018/19	MY 2019/20	MY 2020/21	MY 2021/22	MY 2022/23
World	4,925	5,239	3,909	4,554	4,289	4,235
China	1,725	3,157	173	527	481	1,378
Iran	191	202	780	863	469	413
Japan	365	376	323	294	288	377
Algeria	-	-	70	318	219	321
Italy	454	188	350	246	446	274
Indonesia	41	78	251	269	291	264
Belgium	52	134	315	150	171	136
Netherlands	236	41	229	273	193	128
Spain	306	35	108	146	121	109
United States	234	134	162	141	147	103

Source: Trade Data Monitor, LLC

Table 8: Soybean Oil Exports (MT, '000)

Partner	MY 2017/18	MY 2018/19	MY 2019/20	MY 2020/21	MY 2021/22	MY 2022/23
World	157	169	144	119	153	138
China	148	167	141	113	146	130
Iran	-	0	0	2	2	4
Japan	0	0	1	1	2	2
Algeria	0	1	1	0	1	1
Italy	-	-	-	1	1	1
Indonesia	-	-	-	1	0	0
Belgium	-	-	-	0	0	0
Netherlands	-	0	-	0	0	0
Spain	-	-	0	-	0	0
United States	0	0	0	0	0	0

Source: Trade Data Monitor, LLC

Corn

Canada's grain corn exports in MY 2022/23 were 2.9 million MT, up from 2.1 million MT the previous year. The top importers were the EU (63%) and the United States (22%).

Sugar Beets

Canada exports GE sugar beets from Ontario to Michigan for processing into sugar.

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.

Ethanol production and the livestock feed industry drive imports of corn and soybeans from the United States.

PNT imports require advanced approval from Health Canada and CFIA for use as human and animal consumption.

Canada has approvals to enable import of GE apples, GE potatoes, GE papaya, GE squash, GE pineapple, and GE plum.

Exports of Arctic® apples to Canada from the United States occur based on market demand. There is currently no target for quantity of exports to Canada. Arctic® Gala and Arctic® Honeycrisp varieties will be seeking regulatory approval in the future.

e) FOOD AID

Canada does not make in-kind food aid donations. All Canadian food assistance is provided in fully grant form. In 2008, Canada fully untied its food assistance budget, opening 100 percent of its food assistance budget to international procurement and supporting the purchase of food in developing countries.

Canada is not a food aid recipient and is unlikely to become one in the foreseeable future.

f) TRADE BARRIERS

U.S and Canadian industry have expressed concerns that the progress in which Canada is innovating has caused a deviation in alignment between biotechnology rules between Canada and the United States that could lead to trade disruptions.

PART B: POLICY

a) REGULATORY FRAMEWORK:

Canada's Regulatory System

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

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.

CFIA 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.

Health Canada defines "novel food" as:

- a substance, including a microorganism, that does not have a history of safe use as a food;
- a food that has been manufactured, prepared, preserved, or packaged by a process that:
  - has not been previously applied to that food, and
  - causes the food to undergo a major change; and
- a food that is derived from a plant, animal or microorganism that has been genetically modified so that the plant, animal or microorganism:
  - shows characteristics that it didn't before
  - doesn't show characteristics that it did before
  - has 1 or more characteristic that no longer falls within the expected range (aliment nouveau)

CFIA and Health Canada have authorities specifically applicable to PNTs and/or novel foods. The CFIA is responsible for regulating the importation, environmental release, and use of livestock feeds for PNTs. Health Canada is responsible for assessing the human health safety of foods and approving their use in commerce. PNT and novel food are also subject to the CFIA and Health Canada overall authorities relative to plants and foods.

Table 9: 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	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 10: 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 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.

In 2022, Canada had 93 PNT submissions and 271 field trials, primarily of canola and corn, but also barley, camelina, soybean, wheat, poplar, potato, and poppy. This is an increase of nearly 22 field trials over 2021. A summary of annual field trials by individual crop is typically available on the CFIA website at the end 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.

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 Health Canada 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 five to seven years of company research, two to three years of field trials, and one to three 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 genome-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.

New Guidance for Plant Breeders

On September 28, 2023, the CFIA launched consultations on proposed guidance that clarifies which plant-derived feed ingredients require a premarket assessment, as per the Feeds Act and Feeds Regulations, including how to make a novelty determination of ingredients derived through plant breeding destined to be used in livestock feeds. Novel feeds consist of organisms or parts of products thereof that have never before been evaluated and approved for use as livestock feed in Canada, regardless of how they were developed. Novel feeds may be from plant sources, including PNTs.

The proposed guidance will be of interest to plant breeders and feed manufacturers. For more information on how to comment, see GAIN report CA2023-0043.

These consultations follow the revision and publication of two other guidance documents on PNTs, both of which support the introduction of gene-edited products in the Canadian market. Guidelines for the Safety Assessment of Novel Foods, published in July 2023, reinforce Canada's product-based approach and provide guidance on how Canada's Novel Food Regulations are applied to products of plant breeding.

Secondly, on May 3, 2023, Canada published updated guidance for determining whether a plant is regulated under Part V of the Seeds Regulations. Canada's Seeds Regulations, Part V – Release of Seed, came into force in 1996 and focus on the release of seed into the Canadian environment in terms of safety for the environment and human health. Revisions to "Directive 2009-09: Plants with novel traits regulated under Part V of the Seeds Regulations" clarify existing requirements for plant breeders and other stakeholders. The CFIA also published a rationale for updating this directive.

The first of the guidance documents on plants for human consumption, Health Canada's narrowed its definition of "novel foods," to provide clarity in their requirements for plants. This set a precedent for aspects of the remaining two guidance documents.

Specifically, Health Canada's position is that the following five categories of foods do 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 food derived from plants with genetic modifications:

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.

Health Canada's new guidance interprets 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. Health Canada has published on its website a list of non-novel determinations to improve transparency of the agency's decisions.

Separately, CFIA and Health Canada published revised regulatory guidance for cultivation (i.e. environmental release) in May 2023. Among other things, the guidance addresses concerns raised by the Standing Joint Committee for the Scrutiny of Regulations regarding lack of authority for the release of novel feeds and bilingual labelling.

The 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.

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.

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.Health Canada-sc.gc.ca/sr-sr/biotech/index-eng.php

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

b) APPROVALS/AUTHORIZATIONS

Since FAS Ottawa's last annual biotechnology report was published, CFIA and Health Canada have approved the following two submissions:

Table 11: Plants with novel traits (PNT) and novel feeds from plant sources approved in Canada Since Last Publication (Nov. 2022 – Oct. 2023)

PLANT	PRODUCT	LIVING MODIFIED ORGANISM	APPLICANT AT TME OF APPLICATION	NOVEL TRAITS	CFIA APPROVAL FOR UNCONFINED RELEASE	APPROVAL FOR LIVESTOCK FEED	HEALTH CANADA FOOD SAFETY APPROVAL
Borage	ST-1 and ST-2	Non-LMO	Bioriginal Food and Science Corp	Tolerance to imidizolinone herbicides	Yes (May 18th, 2023)	Not assessed for livestock feed	Not assessed for food
Rice	ROXY® ROX1.1	Non-LMO	California Cooperative Rice Research Foundation (CCRRF)	Tolerance to oxyfluorfen herbicide	Not grown in Canada	Yes (February 15th, 2023)	Yes (February 8th, 2023)

Source: *FAS/Ottawa, with data drawn from the Statistics Canada table entitled Plants with novel traits (PNT) and novel feeds from plant sources approved in Canada.*
Notes: **Living Modified Organism (LMO) is defined by the Cartegena Protocol on Biosafety to the Convention on biological Diversity as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.*
"Living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and vivroids.
"Modern biotechnology" means the application of:

- *In vitro nucleic techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or*
- *Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.*

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/AUTHORIZATIONS

Stacked products, defined in Canada as plant lines developed by conventional crossing of two or more authorized PNTs, do not require further environmental safety assessment. 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.*

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

d) FIELD TESTING

In 2022, Canada had 93 PNT submissions and 271 field trials, primarily of canola and corn, but also barley, camelina, soybean, wheat, poplar, potato, and poppy. This is an increase of nearly 22 field trials over 2021. A summary of annual field trials by individual crop is typically available on the CFIA website at the end of each year.

Field trial objectives were primarily to test herbicide tolerance and “selectable and/or screenable markers” (incl. antibiotic resistance).

e) INNOVATIVE BIOTECHNOLOGIES

Health Canada 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.

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 AND TRACEABILITY

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 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 reaffirmed 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 genome 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 FDRs, 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) POLICY

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) ADDITIONAL REGULATORY REQUIREMENTS

None

k) INTELLECTUAL PROPERTY RIGHTS (IPR)

The Patent Act and the Plant Breeders' Rights Act both afford breeders or owners of new varieties the ability to collect technology fees or royalties on their products. The Patent Act grants patents that cover the gene in the plant, or the process used to incorporate the gene but does not provide a patent on the plant itself. The protection of the plant would be covered by the Plant Breeders' Rights (PBR) Act. The 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.

l) 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 agricultural farm groups and businesses oppose ratification of the Protocol. 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.

m) INTERNATIONAL TREATIES AND FORUMS

Canada participated in the G20 Meeting of Agricultural Chief Scientists (April 17-19, 2023) where biotechnology was discussed related to the role of science, technology, and innovation for food security and nutrition.

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.

Canada is a member of the Like-Minded Group (LMG) for Innovative Agricultural Biotechnologies, the Global Low-Level Presence Initiative (GLI), and the "Ag5" group of Western Hemisphere Agriculture Leaders.

n) RELATED ISSUES

High fertilizer costs, environmental concerns, and a national target of 30 percent reduction in nitrogen-based fertilizer emissions has triggered interest in the development of nitrogen-fixing cereals, although such products are likely years away from commercialization.

Secondly, Canada's new Clean Fuel Regulation limits carbon intensity of fossil fuels and is a catalyst for the development of new low-carbon fuel feedstocks developed using biotechnology. Proponents argue that new innovations may not only lower the carbon intensity of fuel but also leave more land available for food production.

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS

Canada's revised guidance documents, with reference to food and cultivation of plants with novel traits, were welcomed by industry groups for facilitating innovation and development of improved plant varieties. However, some environmental groups, the Quebec government, the Union des producteurs agricoles, the Conseil de la

transformation alimentaire du Québec, and Filière biologique, have reportedly voiced their concerns about product traceability.

b) MARKET ACCEPTANCE/STUDIES

Canadian Consumers' Perceptions of Sustainability of Food Innovations (R. Lassoued, J. Music, S. Charlebois, and **S. J. Smyth**. 2023) presents data on what Canadian consumers are interested in with respect to the food they purchase and consume. The authors found that surveyed consumers "were not at all or slightly familiar with […] gene editing including CRISPR (77%). The authors also outline that "a significant knowledge gap about gene editing has been underlined in recent studies on Canadian consumer perceptions of the technology."

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 how 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.

Canada has indicated that modernization of regulations for products of animal biotechnology will be occurring but, at present, exact timelines have not been published.

PART D: PRODUCTION AND TRADE

a) **RESEARCH AND PRODUCT DEVELOPMENT:**

Projects are being proposed but there is no indication that there are any new GE animals pending approval in Canada in the short term.

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. At this time, there is not a grow-out facility for production of finished product in Canada.

c) **EXPORTS:**
AquaBounty GE salmon eggs are exported from Prince Edward Island, Canada to a grow-out facility in the United States. FDA approved the import of these salmon eggs with USDA overseeing the bioengineered food standards requirements.

d) **IMPORTS:**
Imports of GE salmon (produced by AquaBounty) into Canada are approved and based on market demand. Imports of finished GE salmon entering Canada are currently sourced from the United States.

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

PART E: POLICY

a) **REGULATORY FRAMEWORK:**
In Canada, products of animal biotechnology may be defined and regulated as novel foods. According to the Food and Drug Regulations, a novel food is defined as:

- a substance, including a microorganism, that does not have a history of safe use as a food;
- a food that has been manufactured, prepared, preserved or packaged by a process that
  i) has not been previously applied to that food, and
  ii) causes the food to undergo a major change; and
- a food that is derived from a plant, animal or microorganism that has been genetically modified such that
  i) the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism,
  ii) the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or

iii) one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for the plant, animal or microorganism [B.28.001, FDR].

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

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. In February 2022, CEPA Bill S-5,

Strengthening Environmental Protection for a Healthier Canada Act, was introduced to the Senate proposing amendments to CEPA and the Food and Drugs Act. On June 13, 2023, the Bill received Royal Assent and passed into law. An implementation framework will be developed. The amendments will require notice that a product of animal biotechnology is under review rather and require that all interested persons be consulted on the toxicity of a new, vertebrate animal, prescribed living organism, or group of living organisms of biotechnology. It is not yet clear how the consultation of interested persons will function. Currently, CEPA does not apply to products of animal biotechnology which are subject to regulation under the *Pest Control Products Act, Fertilizers Act, Feeds Act, Seeds Act,* or *Health of Animals Act*.

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 10: 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/AUTHORIZATIONS:**

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) **ADDITIONAL REGULATORY REQUIREMENTS:**
None

f) **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.

g) **INTERNATIONAL TREATIES and FORUMS:**
Canada previously was part of the now dissolved Codex Alimentarius Commission Task Force on Foods Derived from Biotechnology through Health Canada's activities with the Commission. Canada is also part of the Organization for Economic Co-operation and Development (OECD), and Health Canada participates on the OECD Task Force for the Safety of Novel Foods and Feeds. Additionally, Canada is a member of the World Organisation for Animal Health (OIE). Canada allows for the importation, production, and sale of approved animal biotechnologies as well as engaging in research. Canada also supports the Joint Statement on Innovative Agricultural Production Technologies.

h) **RELATED ISSUES:**
None.

PART F: MARKETING

a) **PUBLIC/PRIVATE OPINIONS:**
Canada has groups lobbying the government against GE animals. Most notable is the Canadian Biotechnology Action Network, which has organic and ecological farming groups, environmental groups, and international anti-GE groups amongst its members. Popular press and social media indicate a wide spectrum of opinions from Canadian consumers surrounding GE products as well as varying levels of understanding of biotechnology.

Nature Canada, a national organization with an environmental focus, has been outspoken on the amendments to CEPA arguing that they do not go far enough to provide adequate transparency for new risk assessments and that they do not provide substantive protections to protect wild populations from perceived impacts of GE animals.

Certain First Nations/Indigenous groups have also been outspoken regarding assessment of GE animals and a lack of consultation with First Nations when assessing potential environmental impacts of approving GE animals.

b) **MARKET ACCEPTANCE/STUDIES:**

A 2022 study by Vasquez et al., 'Canadian Consumer Preferences Regarding Gene-Edited Food Products', reported that Canadian consumers have a moderate to high level of trust of the Canadian food system but less so of food products derived through innovative processes. Notably though, respondents reported a higher level of trust in genome-edited technology compared to "genetically modified" technology. The majority of respondents felt that genetically modified foods were tampering with nature and almost have identified them as "not natural".

More recently, a 2023 study by Lassoued et al., 'Canadian Consumers' Perceptions of Sustainability of Food Innovations', observed that Canadians ranked "free of GM" claims as the seventh most significant decision factors when purchasing food, ranking identically with sustainable production claims.

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 challenging to identify.

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 identify products that utilize microbial biotech by HS code.

FAS Ottawa estimates that in 2022 Canada exported $7.8 billion USD of processed products that use microbial biotech-derived ingredients, up from $6.6 billion USD the previous year.[1] Ninety-two percent of the total export value represents exports to the United States.

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.

Our best estimate is that in 2022 Canada imported $9.8 billion USD of processed products that use microbial biotech-derived ingredients at varying levels, up from $9 billion USD in 2021. Fifty-eight percent of this value represents products imported from the United States, and another 25 percent were imported from the EU.

d) TRADE BARRIERS

FAS Ottawa is not aware of any specific barriers to trade (TBT) issues pertaining to microbial biotech-derived food ingredients. Any barriers would apply more broadly and not be focused solely on these ingredients.

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 Health Canada by a petitioner.

A description of the pre-submission process specific to novel foods, novel feeds and plants with novel traits is available on the Health Canada website. The description of how to request a novelty determination for a food or food ingredient is available here. Health Canada strives to provide a written response on the novelty status of the food or food ingredient within 60 calendar days.

[1] 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).

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 Health Canada.

b) APPROVALS/AUTHORIZATIONS:

Health Canada 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, Health Canada 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 Health Canada for a novelty determination, if the food is determined to be non-novel, Health Canada 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) ADDITIONAL REGULATORY REQUIREMENTS:
None

f) 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.

g) RELATED ISSUES:
A national target of 30 percent reduction in nitrogen-based fertilizer emissions has triggered interest in the development, research, and good use of biotechnology in microbial plant stimulants and other products.

Secondly, Canada's new Clean Fuel Regulation limits carbon intensity of fuels and is a catalyst for research into the use of biotechnology to develop fuel feedstocks that have lower carbon intensities than field crops. Proponents argue that new innovations may not only lower the carbon intensity of fuel but also leave more land available for food production.

PART I: MARKETING

a) PUBLIC/PRIVATE OPINIONS:
Refer to Chapter 1, Part C.

b) MARKET ACCEPTANCE/STUDIES:
Refer to Chapter 1, Part C.

Attachments:

No Attachments