

**Required Report:** Required - Public Distribution

**Date:** December 18, 2024

**Report Number:** CA2024-0059

## **Report Name:** Agricultural Biotechnology Annual

**Country:** Canada

**Post:** Ottawa

**Report Category:** Biotechnology and Other New Production Technologies

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### **Report Highlights:**

In May 2024, Health Canada published guidance that clarifies which plant-derived feed ingredients require a premarket assessment, as per the Feeds Act and Feeds Regulations. With this third and final guidance now complete, conventional herbicide-tolerant products are now unlikely to trigger novel feeds/foods review. Canada planted 11.8 million hectares of genetically engineered (GE) crops in 2024, mainly canola, soybeans, and corn. In 2023, imports of corn totaled 2.98 million metric tons (MMT), 8% less than the previous year, and 439.4 thousand metric tons (TMT) of soybeans (42% y/y). More than 90 percent of GE crops imported into Canada are sourced from the United States.

## ***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 May 2024, the CFIA [finalized 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 2022, reinforce Canada's product-based approach and provide guidance on how Canada's Novel Food Regulations are applied to products of plant breeding. Updated [guidance](#) for determining whether a plant is regulated under Part V of the Seeds Regulations was published on May 3, 2023.

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 is an importer of GE crops and products, including grains and oilseeds, such as corn and soybeans. In 2023, imports of corn totaled 2.98 million metric tons (MMT), 8% less than the previous year, and 439.4 thousand metric tons (TMT) of soybeans (42% y/y). More than 90 percent of GE crops imported into Canada are sourced from the United States.

Canada planted 11.8 million hectares of genetically engineered (GE) crops in 2024, mainly canola, soybeans, and corn. This represents a marginal increase from the previous year, on increased area planted to GE soybeans.

## ***CHAPTER1: PLANT BIOTECHNOLOGY***

### ***PART A: PRODUCTION AND TRADE***

#### **a. RESEARCH AND PRODUCT DEVELOPMENT**

Research and development on plants with novel traits (PNTs) 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.

#### **b. COMMERCIAL PRODUCTION**

In 2024, GE varieties of grains and oilseeds occupied an estimated 31 percent of total area planted for grains and oilseeds in Canada, unchanged from 2032 (based on revised 2023 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.

**Table 1. Area planted to genetically engineered crops in Canada**

<b>Area Seeded (1,000 hectares)</b>	<b>2019</b>	<b>2020</b>	<b>2021</b>	<b>2022</b>	<b>2023</b>	<b>2024</b>
Canola	8,572	8,410	9,012	8,659	8,857	8,846
GE canola	8,143	7,990	8,561	8,226	8,414	8,404
GE canola, % of total	95%	95%	95%	95%	95%	95%
Soybeans	2,313	2,052	2,087	2,135	2,279	2,310
GE soybeans	1,822	1,607	16,156	1,679	1,849	2,034
GE soybeans, % of total	79%	78%	77%	79%	81%	88%
Corn for Grain	1,496	1,440	1,488	1,466	1,548	1,478
GE corn	1,346	1,280	1,342	1,317	1,365	1,320
GE corn, % of total	90%	90%	90%	90%	88%	89%
<b>Area seeded to GE crops</b>	<b>11,311</b>	<b>10,877</b>	<b>26,059</b>	<b>11,222</b>	<b>11,628</b>	<b>11,758</b>

*Source: 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. Canada also produces less than 20,000 hectares of GE sugar beets.*

## **Canola**

Approximately 95 percent of total canola area planted was of GE varieties in 2024, consistent with the last several years. Eleven new hybrid varieties are available for planting in 2024, and another 19 new releases will be available in 2025.

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.

Canada's Clean Fuel Regulation (CFR) is spurring investment into renewable diesel, and canola oil will be the main feedstock. See [GAIN report CA202400057](#) for more information on the CFR and the current landscape for renewable fuel.

## **Soybeans**

Eighty-eight 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. The national rate has risen each year since 2021, when 77% of soybeans planted were GE varieties.

## **Corn**

In 2024, GE corn accounted for 89 percent of all area planted to corn in Canada, up from 88 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 GE 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 area for 2024 to be up 40% percent (to 18,800 MT) compared to 2022.

## **Apples**

Four varieties of GE apples are currently approved for commercial planting purposes and food use in Canada: Arctic® Golden Delicious, Arctic® Granny Smith, Arctic® Fuji, and Arctic® Gala, which received approval in 2024. Currently, there is no commercial production of any of these 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 on 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 GE wheat in Canada. Industry contacts state that one of the largest barriers to market is the low yield outcomes in trials, relative to non-GE wheat, in addition to lack of acceptance in some foreign markets.

## **Flax**

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

### **c. EXPORTS**

Canada exports GE canola, corn, soybeans, sugar beets, and the products of these commodities (e.g. oil and meal, in the case of canola and soybeans) to the United States. Exports of GE commodities to foreign countries are not labeled as such unless requested by the importer. There are no specific laws in Canada about labelling GE foods differently.

In 2023, Canada exported 2.84 MMT of corn, up 28 percent from 2022; 7.1 MMT of canola seed, up 15.8 percent; and 4.5 MMT of soybeans, up 28.8 percent. Canada also exported 3.5 MMT of vegetable oils, up 4.23 percent, and 5.8 MMT of meal, up 2.4 percent.

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 2022 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 could put downward pressure on seed and oil export forecasts include the California Air Resource Board's (CARB) proposal to cap-biobased diesel from virgin soybean and canola oils at 20 percent on a companywide basis annually; any forthcoming regulatory guidance under the U.S. Inflation Reduction Act's 45Z that limits foreign feedstocks; and any Chinese tariffs that may arise out of [China's anti-dumping investigation](#) on Canadian canola. In November, industry sources stated that Chinese buyers are already reluctant to sign new deals, for fear that the duties will be imposed.

Canada continues to export small amounts of GE sugar beets from Ontario to Michigan for processing into sugar.

#### **d. IMPORTS**

Canada is an importer of GE crops and products, including grains and oilseeds, such as corn and soybeans. More than 90 percent of GE 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.

#### **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 advanced progress in which Canada's regulation is innovating has caused a deviation in alignment in biotechnology rules between Canada and the United States that could lead to trade disruptions.

## **PART B: POLICY**

### **a. REGULATORY FRAMEWORK**

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.

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 2: Table of Terms Used in Canada**

<b>Term</b>	<b>Definition</b>
Biotechnology	A general term used to describe the use of biological processes to make products, in contrast to purely chemical processes. Biotechnology has been in practice for centuries and includes such traditional applications as the use of yeast in making beer, as well as modern applications like recombinant DNA techniques to improve crops.



Genetic engineering	The technique of removing, modifying or adding genes to a DNA molecule to change the information it contains. By changing this information, genetic engineering changes the type or amount of proteins an organism is capable of producing. Genetic engineering allows scientists to isolate a specific gene for a particular trait - such as resistance to insect attack - in a plant or animal, and transfer it into another plant
Genetic modification	A general term which refers to any intentional change to the heritable traits of an organism. This includes both traditional breeding and recombinant DNA techniques.
Genetically modified organism (GMO)	An organism produced from genetic engineering techniques that allow the transfer of functional genes from one organism to another, including from one species to another. Bacteria, fungi, viruses, plants, insects, fish and mammals are some examples of organisms whose genetic material has been artificially modified to change some physical property or capability. Living modified organisms (LMOs) and transgenic organisms are other terms often used instead of GMOs.
Living modified organism (LMO)	Any living organism that possesses a novel combination of genetic material obtained through modern biotechnology. A living organism is a biological entity that can transfer or replicate genetic material.
Novel trait in a plant	A plant with characteristics not normally found in that species in which the new characteristic has been created through specific genetic manipulation, transformation, mutation, etc.
Novel food	<p>A substance, including a microorganism, that does not have a history of safe use as a food.</p> <p>A food that has been manufactured, prepared, preserved, or packaged by a process that:</p> <ul style="list-style-type: none"> <li>○ has not been previously applied to that food, and</li> <li>○ causes the food to undergo a major change; and</li> </ul>

	<p>A food that is derived from a plant, animal or microorganism that has been genetically modified so that the plant, animal or microorganism:</p> <ul style="list-style-type: none"> <li>○ shows characteristics that it didn't before</li> <li>○ doesn't show characteristics that it did before</li> <li>○ has one or more characteristic that no longer falls within the expected range</li> </ul>
Transgenics	<p>The insertion or splicing of specific genetic sequences from one species into the functioning genome of an unrelated species to transfer desired properties for human purposes. This may be viewed as a more precise form of hybridization or plant/animal breeding, with the added consideration that genetic material from species significantly different from one another is involved (for example, the insertion of genetic material from an animal into a plant or vice versa). Another possibility is the transfer of genetically controlled properties between different animal species, such as the breeding of goats whose milk yields spider silk for possible development of new structural materials.</p>

Source: [Health Canada](#)

**Table 3: Plant Biotechnology - Regulating Agencies and Relevant Legislation**

<b>Department/ Agency</b>	<b>Products Regulated</b>	<b>Relevant Legislation</b>	<b>Regulations</b>
<a href="#">Canadian Food Inspection Agency (CFIA)</a>	Plants and seeds, including those with novel traits	<i>Consumer Packaging and Labeling Act, Feeds Act, Food and Drugs Act, Seeds Act, Plant Protection Act</i>	<i>Feeds Regulations, Food and Drug Regulations</i>

<a href="#">Health Canada</a>	Foods, Pest control products	<i>Food and Drugs Act, Canadian Environmental Protection Act, Pest Control Products Act</i>	<i>Novel Foods Regulations, New Substances Notification Regulations, Pest Control Products Regulation</i>
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Sources: Health Canada, Canadian Food Inspection Agency

**Table 4: Plant Biotechnology - Regulating Agencies' Responsibilities**

<b>Category</b>	<b>CFIA</b>	<b>HEALTH CANADA</b>
<b>Human Health &amp; Food Safety</b>		
Approval of novel foods		X
Allergens		X
Nutritional content		X
Potential presence of toxins		X
<b>Food Labeling Policies</b>		
Nutritional content		X
Allergens		X
Special dietary needs		X
Fraud and consumer protection	X	
<b>Safety Assessments</b>		
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

In May 2024, Health Canada published 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. With this final guidance complete, conventional herbicide-tolerant products are unlikely to trigger novel feeds/foods review. This guidance will be of interest to plant breeders and feed manufacturers. For more information, see GAIN report [CA2024-0019](#).

This revised guidance follows 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 2022, 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. This guidance states that “conventional” (non-GE) based herbicide tolerant plants now only require a 60-day review of an agronomic stewardship plan rather than the former, full application which had an average of 24 months.

In the 2022 guidance documents on plants for human consumption, Health Canada 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**

Refer to the [CFIA PNT database](#) for 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**

A summary of annual field trials by individual crop is typically available on the CFIA [website](#) at the end of each year.

In 2023, 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 regards to health and safety matters, while the CFIA is responsible for development of non-health and safety food labeling regulations and policies. It is the CFIA's responsibility to protect consumers from misrepresentation and fraud 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.

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 GE material mixed in with a non-GE product in international trade.

LLP may cause trade disruptions in cases in which the low-level GE 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](#) ( [May 15-17, 2024 in Brazil](#) ) where biotechnology was discussed related to the role of science, technology, and innovation for food security and nutrition. The meeting will next take place May 5 – May 7, 2025.

[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**

None of significance known to Post.

### ***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, have been produced at a land-based facility in Prince Edward Island. As of December 2024, AquaBounty has announced the closure of their Canadian facilities.

### **c. EXPORTS**

AquaBounty GE salmon eggs have historically been 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. With the closure of the Canadian egg production facility, these exports will no longer occur.

### **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 have been sourced from the United States. It is unclear if U.S. production and exports to Canada will continue given current operations changes at AquaBounty.

## 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 Spring 2024, Health Canada consulted on a [proposed policy update](#) that would see foods derived from SCNT cloned cattle and swine and their offspring no longer be considered as novel foods and therefore, no longer subject to the pre-market notification process. This would only apply to cattle and swine, not other species. Health Canada indicated a report from the consultation would be published with the intent to implement the revised policy in Fall 2024 if there was no new scientific evidence which would warrant a further review of the proposed revision.

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](#)**

<b>Product</b>	<b>Agency</b>	<b>Act</b>	<b>Regulation</b>
Foods and drugs derived through biotechnology	Health Canada	<i>Food and Drugs Act</i>	<i>Food and Drug Regulations (Novel Foods)</i>
Veterinary biologics	CFIA	<i>Health of Animals Act</i>	<i>Health of Animals Regulations</i>
Feeds	CFIA	<i>Feeds Act</i>	<i>Feeds Regulations</i>
Fish products of biotechnology	Environment Canada Health Canada Department of Fisheries and Oceans (via a memorandum of understanding)	<i>Canadian Environmental Protection Act, 1999</i>	<i>New Substances Notification Regulations (Organisms)</i>
All animal products not covered under other federal legislation	Environment Canada Health Canada	<i>Canadian Environmental Protection Act, 1999</i>	<i>New Substances Notification Regulations (Organisms)</i>

*\*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>

In December 2023, Health Canada approved head-on-gutted AquAdvantage salmon for food uses, which had not previously been part of the original submission. The additional approval was required as the original submission did not consider bone and brain, only muscle and skin from filets.

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

**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 2023 Canada exported \$8.3 billion USD of processed products that use microbial biotech-derived ingredients, up from \$7.8 billion USD the previous year.<sup>1</sup> Ninety-two percent of the total export value represents exports to the United States, the same share as in 2022.

#### **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 2023 Canada imported \$8.2 billion USD of processed products that use microbial biotech-derived ingredients at varying levels, down from \$9.9 billion USD in 2022. Fifty-nine percent of this value represents products imported from the United States, and another 23 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.

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. 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