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Understanding Canadian Biotech Regulations

Research and innovation are driving the future of the agriculture and agri-food industry in Canada – an industry that contributes $150 billion per year and employs one in seven Canadians. By embracing a wide range of innovations like modern plant biotechnology, Canadian farmers are world-leaders in producing a safe, healthy and abundant food supply and achieving environmental sustainability.

Over eight million hectares of biotech crops including canola, corn and soybeans are being grown in Canada, contributing to over $2 billion (US) in farm income benefits from 1996-2008.[1]

The Canadian plant biotechnology industry is regulated by our federal government. Our stringent regulatory system, with its checks and balances, ensures that all products of biotechnology are safe for people, animals, plants and our environment before they are made available to the consumer. This includes an extensive safety review by both the Canadian Food Inspection Agency (CFIA) and Health Canada.

Canada's regulatory guidelines are based on scientific principles and were developed in conjunction with experts in the global scientific community including the United Nation's Food and Agriculture Organization (FAO) and the World Health Organization (WHO). Canada has one of the safest food supplies in the world which is evidence of how well this regulatory system is working.

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A scientific and product-based approach

Canada's federal government regulations ensure that the practical benefits of biotech products are realized in a way that protects health, safety and the environment. These regulations are based on a scientific and product-based approach:

Science-based – Canada's regulations are thorough, comprehensive and based on objective scientific principles for evaluation. Using science-based principles ensures that the safety assessment is reproducible – conclusions are determined by evidence rather than partisan interests.

Product-based – Canada uses a product-based approach for regulatory oversight. This approach places emphasis on the novel traits introduced to a plant, a food or a food ingredient, not the method used to produce those traits. All novel products, whether developed using conventional breeding or genetic engineering, are regulated.

How is plant biotechnology regulated in Canada?

In Canada, both Health Canada and the CFIA share responsibility for regulating novel agricultural products. The CFIA is responsible for regulating the safety of novel plants and novel livestock feeds. Health Canada is responsible for ensuring that all novel foods are as safe and nutritious for humans as foods already on the Canadian marketplace.

What are novel products?

In simple terms, novelty refers to something new. The novelty approach is used by the Canadian Food Inspection Agency (CFIA) in the regulation of plants and livestock feeds and by Health Canada in the regulation of novel foods. For example:

- CFIA defines a **plant with a novel trait** (PNT) as a plant that contains a trait which is both new to the Canadian environment and has the potential to affect the specific use and safety of the plant with respect to the environment, human and animal health.

- Health Canada defines **novel foods** as products that have never been used as a food; foods which result from a process that has not previously been used for food; or, foods that have been modified by genetic manipulation (often referred to as GM foods, genetically engineered foods or biotechnology-derived foods).

The Safety Assessment Process for Novel Products

Food, feed and environmental safety are assured in Canada through government regulations that require a full assessment before a biotech crop is seeded.

Innovation/Discovery – Innovation and discovery involves the growth and study of novel crops in the lab or confined greenhouses. Scientists working with novel crops adhere to federal agency guidelines, as well as the codes of practice established by their own institution.

Confined Field Trials – The next research step involves confined field trial evaluation where plants are grown in isolation from neighbouring crops. The CFIA regulates the confined field trial evaluation of all novel crops ensuring environmental safety and confinement.

Assessment – Before any novel product moves into the marketplace, CFIA and Health Canada scientists complete a critical review of the data collected from the lab and field experiments conducted by the developer. There are strict regulations that dictate what data has to be submitted, and how scientists must examine the data.

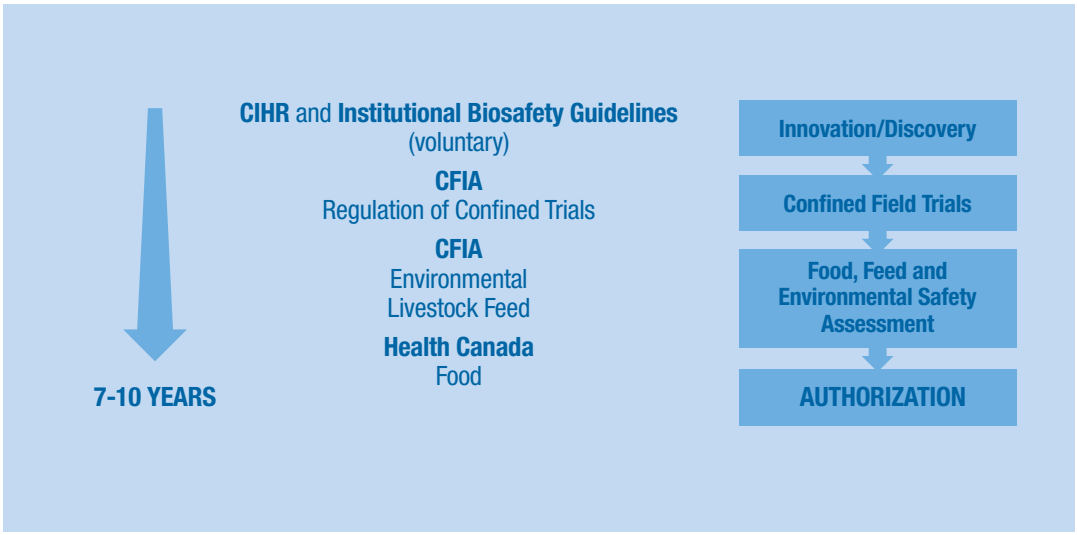
CFIA scientists focus on novel plant and livestock feed safety criteria, for example:

Is there potential for the plant to become a weed or invade natural habitats?
Is there potential for the plant to impact biodiversity?
Is the livestock feed safe for livestock, humans and the environment?

Health Canada scientists focus on human food safety criteria, for example:

Is the food and food product safe for human consumption?
What is the nutritional information?
Is there any potential for causing allergic reactions?

Decision documents describing these safety assessments and their results are published by the CFIA and Health Canada and are publicly available on their websites.



Did You Know?

Since **1994**, over **100** genetically modified products have been approved for sale in Canada. They range from insect-resistant corn and herbicide-tolerant canola to genetically modified yeasts that reduce levels of unwanted compounds in wine. A complete list of approved novel food products and decision documents containing background information is available on the Health Canada and CFIA websites.

Plant science companies invest between **$100 million** and **$150 million**, and up to **10 years** of research and testing for human health and environmental safety to bring a new plant biotechnology product to market.

Beyond government regulations, the plant science industry develops training and educational materials such as the CropLife Canada Compliance Management for Confined Field Trials Program which has trained over **300** Canadian researchers on how to properly conduct research trials.

In Canada, more than **7,000** field trials for environmental safety of biotech crop varieties have been conducted.

Plant biotechnology, the use of living organisms to give plants new beneficial traits, has been in practice for centuries. The term is very broad and includes traditional applications such as selective breeding and modern techniques like genetic modification or genetic engineering.

Genetic modification (GM) or **genetic engineering (GE)** involves altering the genetic material of a plant to create a crop with specific beneficial traits.

For more information on plant biotechnology regulations, please visit:

CFIA
www.cfia-acia.agr.ca

Health Canada
www.hc-sc.gc.ca

THE COUNCIL FOR BIOTECHNOLOGY INFORMATION

The Council for Biotechnology Information is a non-profit association whose mandate is to communicate science-based information about the benefits and safety of agricultural and food biotechnology. CBI members are the leading agricultural companies.

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1 Brookes, G., and P. Barfoot. (April 2010) GM Crops: global socio-economic and environmental impacts 1996-2008.