



Regulation of Agricultural Biotechnology in Canada

A Post-Secondary Educator's Resource



Canadian Food
Inspection Agency

Agence canadienne
d'inspection des aliments

Canada 

About this Educators' Resource

This resource provides a description of the regulatory system overseen by the Canadian Food Inspection Agency (CFIA). This Agency, under the Government of Canada, assesses the safety of novel agricultural products in Canada. It is intended for post-secondary educators to facilitate learning about the CFIA and its regulatory role in the area of biotechnology.

The resource introduces biotechnology terms and describes the current regulatory system in Canada. Although there are several types of novel agricultural products, this educators' resource describes the CFIA's safety assessments for plants with novel traits (PNTs) and/or novel livestock feeds derived from plants to illustrate the CFIA's role in the regulatory system. The CFIA also has a role in the labelling of novel foods. Finally, the resource looks at how Canada's regulatory system is evolving to better serve the public interest and to address new developments and emerging issues in biotechnology.

To ensure the completeness of each section of this resource, some concepts are repeated.

Additional suggestions for reading and discussion are included throughout, including references to the CFIA website. An updated list of links is maintained on the CFIA site.

Disclaimer

Educators who use this resource are advised that it has been prepared as a convenient reference only and has no official sanction. Although the topic of agricultural biotechnology is multi-faceted, this resource is limited to providing an overview of the Canadian regulatory system.

Where applicable we have identified the sources of the materials used in the preparation of the resource and have obtained permission of the originating institutions for use of their materials. The resource as protected by copyright should not be copied without the permission of the CFIA and the other institutions from which copyright permission was obtained.

Educators are responsible for their own interpretation and presentation of the material. The CFIA is responsible for the provided text. Information in this resource is intended to facilitate learning about the CFIA and its regulatory role in the area of biotechnology.

© Her Majesty the Queen in Right of Canada, 2007

For more information, or to order additional copies, contact:

Office of Biotechnology

Canadian Food Inspection Agency

59 Camelot Drive

Ottawa, ON K1A 0Y9

Telephone: (613) 225-2342

Toll-Free: 1-800-442-2342

Facsimile: (613) 228-6604

Email: ob@inspection.gc.ca

www.inspection.gc.ca



Regulation of Agricultural Biotechnology in Canada

A Post-Secondary Educator's Resource

| | |
|---|----|
| Preface | 4 |
| What is the Canadian Food Inspection Agency (CFIA)? | 4 |
| Biotechnology and the CFIA | 5 |
| 1. Introduction to Biotechnology and Its Use in Agriculture | 6 |
| What is Biotechnology? | 6 |
| Biotechnology Uses in Agriculture | 8 |
| Why Regulate Novel Agricultural Products? | 8 |
| Suggestions for Reading and Discussion | 9 |
| 2. Canada's Regulatory System | 10 |
| Who Regulates Novel Agricultural Products in Canada? | 10 |
| A Brief History of Regulating Novel Agricultural Products | 11 |
| 1993 Federal Regulatory Framework for Biotechnology | 13 |
| Regulatory Concepts | 13 |
| Suggestions for Reading and Discussion | 15 |
| 3. Regulating Plants with Novel Traits (PNTs) and/or Novel Livestock Feeds Derived from Plants | 16 |
| The CFIA's Safety Assessments: from the Laboratory to the Field | 16 |
| Data Requirements for the CFIA's Safety Assessments | 20 |
| After the CFIA's Safety Assessments | 21 |
| Imported PNTs and Novel Livestock Feeds Derived from Plants | 22 |
| Management Plans for Insect Resistant and Herbicide-Tolerant PNTs | 22 |
| Gene Flow and Herbicide-Tolerant Crops | 24 |
| Plant Molecular Farming (PMF) | 24 |
| Suggestions for Reading and Discussion | 25 |
| 4. The CFIA's Role in Labelling of Novel Foods | 26 |
| 5. An Evolving Regulatory System | 28 |
| Seeking Expert Advice | 28 |
| Enhancing Consumers' Understanding of Regulation of Novel Agricultural Products | 30 |
| Regulatory Transparency | 30 |
| Researching Public Opinion | 31 |
| Public Consultation | 32 |
| Suggestions for Reading and Discussion | 33 |
| 6. Additional References | 34 |
| Publications | 34 |
| Careers at the CFIA | 34 |

Preface

What is the Canadian Food Inspection Agency (CFIA)?

The CFIA began operations on April 1, 1997, as Canada's largest science-based regulatory agency. The creation of the CFIA brought together inspection and related services previously provided through the activities of four federal government departments into a consolidated, single food-inspection agency. It serves as the main agency responsible for animal health, plant protection, and food safety. The CFIA is headed by a President who reports to the Minister of Agriculture and Agri-Food who, in turn, reports to Parliament. In all, the CFIA employs more than 5000 people across Canada.

Animal Health

The CFIA works to prevent animal diseases from entering Canada and to control the spread of animal diseases within Canada. When a disease outbreak occurs, the CFIA acts to eradicate it. To keep the food chain secure, the CFIA regulates livestock feeds and veterinary biologics (e.g. vaccines, diagnostic kits, veterinary biologics derived through biotechnology, etc.). The CFIA conducts regular animal disease monitoring programs that have been designed to head off serious threats to livestock health. In addition, the CFIA certifies the health of Canada's animal exports, evaluates the safety of imports, and regulates the humane transportation of animals.

Plant Protection

The CFIA works to prevent foreign plant pests from becoming established in Canada and to control the spread of quarantine pests within Canada. The CFIA verifies that seeds and fertilizers and supplements, both domestically produced and imported, meet federal requirements. CFIA plant health officials certify that plants, plant material, and other related matter intended for export from Canada meet the import requirements of foreign countries.

The CFIA Mandate:

To enhance the effectiveness and efficiency of federal inspection and related services for food and animal and plant health.

The CFIA Mission:

The CFIA is committed to enhancing the safety of federally regulated food and contributing to the protection of the health of animals and the plant resource base.



Food Safety

The CFIA delivers federal inspection and enforcement services related to food. The Canada Border Services Agency also plays a role in accordance with its mandate for initial inspection services at airports and other border points (including border points other than import service centres).

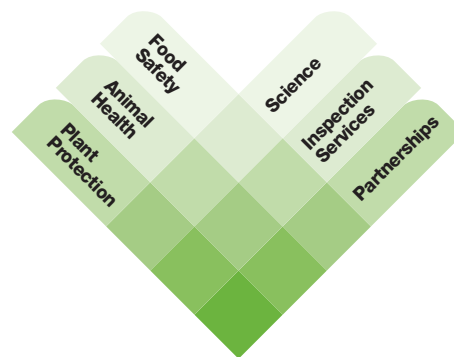
Primarily, this involves verifying that manufacturers, importers, distributors, and producers meet Government of Canada regulations and standards for safety, quality, quantity, composition, handling, identity, processing, packaging, and labelling. The CFIA works closely with Health Canada, the department responsible for setting food safety policy and standards.

Biotechnology and the CFIA

The CFIA regulates novel agricultural products, including plants, livestock feeds, fertilizers and supplements, and veterinary biologics. Depending on their intended use, novel agricultural products are assessed in terms of environmental safety, animal health, and human health through the CFIA's safety assessments. The CFIA also has a role in the labelling of novel foods.

Other departments, such as Health Canada and Environment Canada also have roles in the safety assessment process related to novel agricultural products; however, the focus of this resource is the CFIA's role in the process.

In addition to its domestic responsibilities, the CFIA leads or participates in the development of a number of international agreements, arrangements, and standards, such as the Codex Alimentarius and the Cartagena Protocol on Biosafety.



**Canadian Food
Inspection Agency**

1. Introduction to Biotechnology and Its Use in Agriculture

What is Biotechnology?

Biotechnology has long been used to make everyday products (e.g. the use of micro-organisms, such as bacteria or fungi, to manufacture cheese, wine, and antibiotics). The scope of this term has changed over time as new technologies have been invented. The term “biotechnology” came into widespread use in the 1970s following the development of genetic engineering. In looking back, however, it is evident that humans have used “biotechnology” in its simpler forms for thousands of years. For example, civilizations have actively developed and selected superior plants and livestock animals. The Government of Canada broadly defines biotechnology as: *the application of science and engineering to the direct or indirect use of living organisms or parts or products of living organisms in their natural and modified forms.*

The term biotechnology is defined in the *Seeds Regulations*, *Feeds Regulations*, *Fertilizers Regulations*, *Health of Animals Regulations*, and the *Canadian Environmental Protection Act, 1999 (CEPA 1999)*.

Canada has a unique regulatory approach for biotechnology products that considers the novelty of a product, not its method of production, as the trigger for regulatory review. For example, a new agricultural product may be considered novel if it has one or more new traits or one or more changed traits, or if it has a new use. The criteria for novelty are specific to the product (e.g. novel livestock feeds, novel fertilizers and supplements, and plants with novel traits are all defined in the appropriate Acts and Regulations). Novel agricultural products can be developed through various genetic modification techniques (traditional breeding, genetic engineering, mutagenesis, cell fusion, etc). For example, herbicide-tolerant canola developed through mutagenesis and herbicide-tolerant canola developed through genetic engineering are both subject to the CFIA’s safety assessments. Consequently, in Canada, most agricultural products developed through genetic engineering are, by definition, novel agricultural products, but not all novel agricultural products are developed through genetic engineering as other genetic modification techniques are also able to introduce novel traits into organisms.

Regulatory groups and policy makers around the world define biotechnology differently. The differences tend to centre on how broadly the term should be defined. For example, some countries may limit the definition of biotechnology to include modern biotechnology techniques, such as genetic engineering, while others’ definition includes other more traditional techniques.

Methods to Modify Plants through the Ages

- **use of natural reproductive methods** (e.g. making new crosses by transferring pollen)
- **mutagenesis**—use of chemicals or other processes to produce random mutations to then be used as sources of new traits in plants and other organisms
- **use of the gene gun** to insert new genetic material into a cell using gold pellets coated with the genetic material
- **agrobacterium-mediated transformation**—use of a bacterium as a tool to insert a gene of interest into a plant
- **somaclonal variation**—genetic changes resulting from in-vitro culture of higher plants
- **protoplast fusion** (somatic hybridization)
- **embryo culture and haploid plant production**



Biotechnology Terms

Biotechnology: The application of science and engineering to the direct or indirect use of living organisms or parts or products of living organisms in their natural and modified forms.

Modern Biotechnology: A term used to distinguish newer applications of biotechnology, such as genetic engineering and cell fusion from more conventional methods such as conventional selective breeding or fermentation. Most often the term “biotechnology” is used interchangeably with “modern biotechnology”.

Genetic Modification (GM): A method used to **alter** an organism’s genetic material through any method, including conventional selective breeding, genetic engineering, mutagenesis, etc. A GMO is a genetically modified organism. GMO is used by some people more narrowly to include only organisms modified through genetic engineering techniques.

- **Conventional Selective Breeding:** A method to propagate plants or animals sexually, selecting for certain traits (also referred to as selective breeding). Using selective cross-breeding, people can produce different varieties of plants and breeds of animals.

- **Genetic Engineering (GE):** A method by which the genetic material of an organism is changed in a way that does not occur naturally by multiplication and/or natural recombination. For example, a method used to directly **transfer** (or remove) a gene of interest from one organism to another (also referred to as recombinant DNA or rDNA technique).

- **Mutagenesis:** The use of methods to physically change or “mutate” the genetic sequence, without adding DNA from another organism. Various chemicals and ionizing radiation can be used to invoke these changes. “Site-directed mutagenesis” can also be used to invoke changes in specific genes. In plants, such agents are used to change a plant’s genetic sequence, and the plant can pass on these new characteristics to its offspring.

Transgenic Organism: An organism, such as a plant, animal or bacterium, is considered to be transgenic if one or more genes, genetic constructs, or traits have been introduced using genetic engineering. This includes the insertion of genetic material from the same or different species.

Novel Agricultural Product: An agricultural product may be considered novel if it has one or more:

- new genetic traits (or characteristics) or
- changed genetic traits (or characteristics) or
- new uses

Plants with Novel Traits (PNTs): A new variety of a species is subject to regulatory oversight when it possesses trait(s) novel to that species in Canada; that is:

- the new trait is not present in stable, cultivated populations of the plant species in Canada, or
- the trait in the plant species is present at a level significantly outside the range of that trait in stable, cultivated populations of that plant species in Canada

In Canada—because there are several genetic modification techniques available to introduce novel traits into plants—most GE plants are PNTs, but not all PNTs are GE plants.

Novel Livestock Feed: A feed composed of or derived from micro-organisms, plants or animal sources that:

- are not approved as livestock feed in Canada (not listed in *Schedule IV* or *V* of the *Feeds Regulations*)
- and/or contain a novel trait

A novel trait is an intentional genetic change that results in a feed that is not deemed equivalent in terms of use and safety to a similar feed set out in Schedules IV or V of the *Feeds Regulations*.

Living Modified Organism (LMO): Some international agreements, like the [Cartagena Protocol on Biosafety](#), use the term LMO. The Protocol defines a LMO as a micro-organism, plant, or animal that has been derived through modern biotechnology—using techniques such as recombinant DNA—that is capable of transferring or replicating its genetic material.

Novel Food:

a) a substance, including a micro-organism, that does not have a history of safe use as a food;

b) a food that has been manufactured, prepared, preserved or packaged by a process that:

- has not been previously applied to that food, and
- causes the food to undergo a major change;

c) a food that is derived from a plant, animal or micro-organism that has been genetically modified* such that:

- the plant, animal or micro-organism exhibits characteristics that were not previously observed in that plant, animal or micro-organism,
- the plant, animal or micro-organism no longer exhibits characteristics that were previously observed in that plant, animal or micro-organism, or
- one or more characteristics of the plant, animal or micro-organism no longer fall within the anticipated range for that plant, animal or micro-organism.

* To assist in the interpretation of the definition of novel food, the *Food and Drugs Act* provides a definition of “genetically modify”. “Genetically modify” means to change the heritable traits of a plant, animal or micro-organism by means of intentional manipulation.

Biotechnology Uses in Agriculture

Since the earliest days of agricultural production, people have developed new plant and animal breeds to suit their needs—perhaps to provide more food or to withstand particular environmental conditions. Micro-organisms have also played a role in food production. Today, the agriculture and agri-food sector has the same objectives, but many new tools are available to achieve them. Biotechnology has been used to produce novel agricultural products, for example:

- plants with novel traits or PNTs (e.g. horticultural plants, trees, and crops such as herbicide-tolerant canola and Bt corn)
- novel livestock feeds (e.g. where a plant variety has been determined to be a PNT, the feed derived therefrom will likely be considered novel)
- novel biopesticides (e.g. for insect, disease and pest control)
- novel fertilizers and supplements (e.g. microbial products)
- novel veterinary drugs and biologics (e.g. rabies vaccine)

Why Regulate Novel Agricultural Products?

Biotechnology is one of the many tools available to people working in the agriculture and agri-food sectors. For example, agricultural crops are at constant risk from insects, disease, and other environmental stresses that cause yield losses, and producers have indicated that PNTs may have the potential to address these issues. As such, producers have expressed to government the desire for continued access to safe products of biotechnology so that they may make their own decisions as to whether or not to use these PNTs. Techniques of biotechnology are combined with traditional agricultural methods to more quickly and accurately develop PNTs.

Depending on its intended use, CFIA evaluators must determine the following for each novel agricultural product:

- potential impact on human health (i.e. via occupational or bystander exposure)
- potential impact on livestock health
- potential impact on the environment

There is a wide range of expertise available within the CFIA to evaluate novel agricultural products of agricultural biotechnology. CFIA personnel include animal nutritionists, ecologists, entomologists, toxicologists, biochemists, veterinarians, and molecular and plant biologists—a combination of skills that contribute to a complete, rigorous safety assessment process.





Suggestions for Reading and Discussion

1. Research and discuss the impact of novel agricultural products on:

- farmers
- regulators
- food manufacturers
- scientists
- consumers
- retailers

2. Research and discuss agricultural biotechnology at the international level. Compare concepts and definitions used by international organizations, for example:

- World Health Organization (WHO)
- Food and Agriculture Organization (FAO)
- Cartagena Protocol on Biosafety
- International Plant Protection Convention (IPPC)
- Organisation for Economic Co-operation and Development (OECD)

3. Discuss the pros and cons of the use of novelty as a regulatory trigger. Consider the points of view of plant breeders, biotechnology industry, environmental groups, consumers, and importers and exporters.



2. Canada's Regulatory System

Who Regulates Novel Agricultural Products in Canada?

The paramount objective in regulating novel agricultural products is the health and safety of Canadians, animals and our environment. Several federal departments and agencies have responsibilities for the human health, animal health, and environmental risks of novel living organisms, including novel agricultural products (refer to [Table 1](#)). Most notably, the CFIA (e.g., under the [Feeds Act](#), [Fertilizers Act](#), [Seeds Act](#), and [Health of Animals Act](#)), and Health Canada (e.g., under the [Pest Control Products Act](#) and the [Food and Drugs Act](#)) have these responsibilities. The aforementioned Acts (excluding the [Food and Drugs Act](#)) are listed in [Schedule 4](#) to the [Canadian Environmental Protection Act, 1999](#) (CEPA 1999), which means that these products are not assessed under the regime set up under CEPA 1999. For novel living organisms not already falling within the purview of those Acts listed in Schedule 4 to the CEPA 1999, [Environment Canada](#) and Health Canada assess these organisms under the CEPA 1999. Micro-organisms used in bioremediation and industrial enzyme production serve as examples of such a situation.

CFIA

The CFIA regulates novel agricultural products including [plants](#), [livestock feeds](#), [fertilizers and supplements](#), and [veterinary biologics](#). Depending on their intended use, novel agricultural products are assessed in terms of environmental safety, animal health, and human health through the CFIA's safety assessments. The CFIA also has a role in the [labelling](#) of novel foods. The CFIA provides directives on its website that describe how the requirements in the various Acts and Regulations should be fulfilled. For PNTs and/or novel livestock feeds derived from plants these include:

- [Directive 2000-07: Conducting Confined Research Field Trials of Plants with Novel Traits in Canada](#)
- [Directive 94-08: Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits](#)
- [Directive 95-03: Guidelines for the Assessment of Novel Feeds: Plant Sources](#)
- [Directive D-96-13: Import Permit Requirements for Plants with Novel Traits and their Products](#)

Health Canada

The [Guidelines for the Safety Assessment of Novel Foods](#) outline the criteria Health Canada uses in assessing the human health safety of novel micro-organisms and plants for food use, as specified under the [Food and Drugs Act](#). Details concerning Health Canada's regulations of novel foods are not included in this document; however, information can be found on the Health Canada website at www.novelfoods.gc.ca.

Environment Canada

Elements of the Environment Canada safety assessments are outlined within the [Guideline for Notification and Testing of New Substances Notification Regulations](#) and [Living Modified Organisms Regulations](#). Both documents are available on the Environment Canada website at www.ec.gc.ca.



TABLE 1

Agricultural Products, Legislation and Regulatory Controls, with Particular Emphasis on Novel Agricultural Products Grown Domestically

| Agency | Product | Act |
|---|--|--|
| CFIA | plants with novel traits (PNTs) | <i>Seeds Act</i> |
| | novel fertilizers and supplements | <i>Fertilizers Act</i> |
| | novel livestock feeds | <i>Feeds Act</i> |
| | veterinary biologics | <i>Health of Animals Act</i> |
| Pest Management Regulatory Agency (PMRA), Health Canada | pest control products | <i>Pest Control Products Act</i> |
| Environment Canada and Health Canada | all animate products of biotechnology for uses not covered under other federal legislation | <i>Canadian Environmental Protection Act, 1999</i> |
| Health Canada | novel foods | <i>Food and Drugs Act</i> |

Note: The *Plant Protection Act* also plays a role in protecting Canadian plant life (including agricultural and forestry products) from potential plant pests. A pest can be an insect, animal, virus, bacterium, disease-causing agent, or plants (including PNTs).

A Brief History of Regulating Novel Agricultural Products

The use of genetic engineering as a tool for product developers, advances in scientific knowledge, and growing public consciousness about environmental and food safety issues were the driving forces behind the requirement that novel agricultural products receive pre-market safety assessments. In the mid-1990s, the presence of novel traits in organisms was designated as a trigger for pre-market safety assessment. For plant breeders, this approach represented a significant shift in philosophy about the regulation governing the introduction of new plant varieties in Canada. Indeed, new varieties of familiar or conventional crops had been bred, sold, planted, and consumed in Canada for decades without such pre-market safety assessments.

Several events and factors led to this shift in philosophy. For example, in 1986, the Organisation for Economic Co-operation and Development (OECD) published *Recombinant DNA Safety Considerations*, which provided guidance in the form of a set of recommended requirements for GE products (refer to list of biotechnology terms). It proved to be an important document, used by many nations to develop their regulatory framework. The follow-up document, *Safety Considerations for Biotechnology* (OECD, 1992), outlined safety assessment requirements, especially related to environmental issues. As neither document prescribed a definition for biotechnology, OECD member countries defined the concept independently, and this led to the various definitions found worldwide today.

In 1988, Agriculture and Agri-Food Canada (AAFC) began accepting applications for the conduct of Canada's first confined research field trials for PNTs. At that time, AAFC was responsible for testing and registration of new plant cultivars and had been since 1923, under the *Seeds Act*. As such, AAFC had fostered the required expertise in agriculture, agronomy, and biology to evaluate PNTs.

On assuming this new regulatory responsibility, AAFC conducted a number of multi-stakeholder consultations to seek advice on the scope and approach of its regulatory work. For example, in 1988 the Canadian Agri-Food Research Council (CARC) held a workshop for respected Canadian scientists regarding the regulation of agricultural biotechnology. CARC is a not-for-profit consortium of researchers from industry, academia, and federal and provincial governments. As a result of this workshop, a product-based (i.e. genetic trait based), rather than process-based (i.e. technology used to develop the product), trigger for safety assessments of novel agricultural products was recommended to the Government of Canada.

Also in 1988, the *Canadian Environmental Protection Act* (CEPA 1988) was enacted with a requirement for regulatory review, adding a further level of guidance federally. CEPA 1988 identified that any person wanting to import, manufacture or sell a “new substance” must notify the appropriate Canadian regulatory authority so the product could be evaluated for potential effects on the environment and human health.

In 1993, the Government of Canada approved the *Federal Regulatory Framework for Biotechnology*. The framework set out that regulatory organizations should build on existing legislation and institutions, that is to say, rather than developing a new “*Gene Act*” or establishing a separate agency for biotechnology. The approach outlined in the framework was based on the use of science-based safety assessments and risk management with the goals of protecting human health, animal health, and the environment while contributing to the prosperity and well-being of Canadians. The establishment of this framework followed on the recommendation of the first *National Biotechnology Strategy* adopted by the Government of Canada in 1983.

The *Seeds Act*, *Feeds Act*, *Fertilizers Act*, and *Health of Animals Act* which govern the unconfined environmental release of novel agricultural products, were amended in 1996 following consultations with stakeholders. These new regulations incorporated the same definitions of “biotechnology” and “toxic” as provided for in CEPA 1988.

At its creation, in 1997, the CFIA took over regulatory responsibilities from AAFC in a number of areas, including the regulation of novel agricultural products under the *Seeds Act*, *Feeds Act*, *Fertilizers Act*, and *Health of Animals Act*. As mentioned above, AAFC had been responsible for regulating PNTs since 1988. The creation of the CFIA separated the agency from the parts of AAFC involved in research and development of novel agricultural products and market promotion. The Agency is separate from other arms of government responsible for economic development, market information and policy-related issues, such as farm income and rural development. The CFIA is not involved in the economic promotion of novel agricultural products.

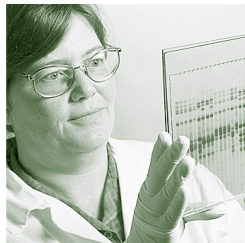
The Government of Canada renewed its commitment to the 1993 *Federal Regulatory Framework for Biotechnology* in the 1998 *Canadian Biotechnology Strategy* (CBS).

In 1999, CEPA 1988 was renewed thereby creating *CEPA 1999*. The latter further reinforced the key principles of environmental protection and created a means for other government departments to confirm their consistency with CEPA 1999. In 2001, the CFIA’s four biotechnology-related Acts and Regulations (i.e. *Seeds Act*, *Fertilizers Act*, *Feeds Act*, and *Health of Animals Act*) were listed on *Schedule 4* of CEPA 1999.



1993 Federal Regulatory Framework for Biotechnology

In 1993, the Government of Canada established the *Federal Regulatory Framework for Biotechnology*. This framework resulted from an agreement among federal regulatory departments on principles for an efficient, effective approach for regulating biotechnology. The following six principles were developed so that the practical benefits of biotechnology would be balanced with the need to protect human health, animal health, and the environment. The framework:



- maintains Canada's high standards for the protection of the health of workers, the general public, and the environment
 - uses existing legislation and regulatory institutions to clarify responsibilities and avoid duplication
 - continues to develop clear novel product evaluation guidelines that are harmonized with national priorities and international standards
 - provides a sound scientific database on which to assess risk and evaluate products
 - ensures transparent and consultative development and enforcement of Canadian biotechnology regulations
- contributes to the prosperity and well being of Canadians by fostering a favourable climate for investment, development, innovation, and adoption of sustainable Canadian biotechnology products and processes

Regulatory Concepts

Science-Based Approach

The CFIA's safety assessments of novel agricultural products are based on the review of information about the product, its effects on the environment and living organisms (including humans and livestock), and the technology used to create it. Evaluators are responsible for a critical review of the data collected from laboratory and confined research field trials submitted by the product developer.

Product-Based Approach

The CFIA regulates novel agricultural products based on their novelty, not on how they were produced. The decision to use a product-based approach was also based in part on the fact that the CFIA had several pre-existing product-based Acts (e.g. the *Feeds Act*, *Seeds Act*, and *Fertilizers Act*). Regulators saw new biotechnology methods (e.g. genetic engineering) as other means of producing new lines of the same family of products.

Case-by-Case

A case-by-case approach is used for the CFIA's safety assessments because each novel agricultural product may pose unique risks. PNTs, such as canola, that could outcross with wild relatives require environmental data different from that required for PNTs, such as corn, that have no wild relatives in Canada. Based on their biology and the amount they eat, livestock species can react differently to a novel protein expressed by a PNT, so species-specific data are required for each CFIA safety assessment.

Regulatory Transparency

Openness is key to an effective regulatory framework. As they develop new requirements, regulators consult with stakeholders from various areas including government, academia, industry, and the public. Regulators keep stakeholders informed by publishing decision documents that describe the CFIA's safety assessments. For more information, refer to the CFIA web links under [Decision Documents](#). Regulatory transparency is also discussed in Section 5, "[An Evolving Regulatory System](#)."

Harmonization

Canada works internationally to co-ordinate its domestic regulatory approach with those of other countries. Canadian regulators are seeking an integrated international regulatory framework for



biotechnology to address issues related to safety of humans, animals, and the environment. Increased international harmonization in regulatory approaches leads to mutual recognition of safety assessments, greater regulatory efficiency, and less duplication.

For example, Canada participates in the [OECD Working Group on Harmonization of Regulatory Oversight in Biotechnology](#) and the [Taskforce for the Safety of Novel Foods and Feeds](#). The main focus of the work done by these groups is to develop consistent regulations among member countries, while avoiding trade barriers.

Membership in international organizations helps to exchange expertise and facilitate access to current scientific and regulatory information regarding safety assessments of novel agricultural products at the international level.

Canada is also interested in bilateral initiatives with other countries. For example, Canada and the U.S. have harmonized their data requirements for molecular characterization data (the detailed information describing the genetic make up of an organism) of the regulatory review process for PNTs. For more information, see the "[Canada and United States Bilateral Agreement on Agricultural Biotechnology](#)," which is available on the CFIA website.

Closer to home, the CFIA and Health Canada have adopted a policy of concurrent approvals (i.e. required assessments for all uses are completed at approximately the same time) to minimize the potential for unapproved PNTs, novel livestock feeds, and/or novel foods to enter into the Canadian environment, livestock feed and/or food supply.

Long-Term Considerations

A fundamental principle of the CFIA's safety assessments involves the scientific comparison of novel agricultural products with conventional products in order to determine whether they are as safe as the conventional products that are in use and generally considered safe in Canada. Given that the application of genetic modification does not necessarily introduce unique risks, the potential for long-term effects of these agricultural products is not necessarily different than that for conventional products. So far, many of the issues raised by products resulting from the application of biotechnology are equally applicable to agricultural products produced through conventional means. This being said, in order to continue strengthening the CFIA's safety assessment process, the Government of Canada is continuing to expand its database of knowledge through research.



Regulatory Research

The CFIA is primarily a regulatory body, so when conducting safety assessments it is not mandated to validate the research of novel agricultural products by testing them independently of the product developer. However, in support of its sound, science-based regulatory system, the CFIA regularly commissions studies to further build on its knowledge of biotechnology. These studies have focussed on potential impacts of novel agricultural products, regardless of the technique used to develop them. Various topics have been studied, for example:

- insect resistance and herbicide-tolerance management
- biodiversity and agricultural ecosystem management
- transgenic livestock safety assessments
- alternative selection markers for transgenic plants
- allergenicity for occupational and bystander exposure
- gene stacking
- plant molecular farming
- gene flow and fertility

Copies of several of these studies can be found on the CFIA website. For details on the studies, refer to the Progress Reports of the Government of Canada's Action Plan in response to the Royal Society of Canada Expert Panel Report. Specifically, refer to the Progress Reports of December 2002 (item 41), June 2003 (item 3), December 2003 (item 24), and August 2004 (item 36). The reports are posted on the CFIA and Health Canada websites.

Led by Environment Canada, the interdepartmental initiative known as Ecosystem Effects of Novel Living Organisms (EENLO) has been created to further develop a federal research strategy to generate knowledge related to the potential long-term ecosystem effects of novel living organisms. This initiative is in partnership with the CFIA, Natural Resources Canada, AAFC, Fisheries and Oceans Canada, the National Research Council, and Health Canada. The knowledge that is expected to be generated through this research will be considered in policy and regulatory decision-making processes in order to contribute to an environmentally sustainable future. For more information on the EENLO initiative, refer to the Environment Canada website.

Suggestions for Reading and Discussion

1. Research an influential figure in the history of genetics and/or biotechnology (e.g. Bruce Ames, Oswald Avery, Herbert Boyer, Stanley Cohen, Richard Keith Downey, Walter Gilbert, Barbara McClintock, Gregor Mendel, Sir Charles Edward Saunders, Michael Smith, James Watson and Francis Crick), and draw linkages on their impact on the regulation of novel agricultural products.
2. On April 7, 2004, a petition was filed under the Auditor General Act, which contained a series of questions relating to social, health, and environmental concerns about genetic engineering. Review and discuss the federal government's response to the petition. This petition, along with several others related to biotechnology, is available on the CFIA website.
3. Review one of the sets of Regulations and Guidelines/Directives for a novel agricultural product. Compare some of the unique regulations for novel agricultural products with those that apply to conventional agricultural products.

3. Regulating Plants with Novel Traits (PNTs) and/or Novel Livestock Feeds Derived from Plants

PNTs and/or novel livestock feeds derived from plants can be produced through conventional selective breeding, mutagenesis or recombinant DNA techniques such as genetic engineering. As of 2004, more than 50 PNTs and/or novel livestock feeds derived from plants have been approved for use in Canada (refer to Table 2). For the latest information and links to descriptions of approved PNTs and/or novel livestock feeds derived from plants, refer to the Status of Regulated Plants with Novel Traits Chart available on the CFIA website. Details regarding approved novel foods can be found on the Health Canada website at <www.novelfoods.gc.ca>.

The CFIA's Safety Assessments: from the Laboratory to the Field

The CFIA's pre-market safety assessments are mandatory and must be carried out before PNTs and/or novel livestock feeds derived from plants are made available for unconfined environmental release and/or use as a livestock feed (refer to *Figure 1*). In most cases, depending on their history and intended use, most are subjected to a step-wise process that involves contained use, confined research field trials, and then application for unconfined environmental release and/or use as a livestock feed (refer to *Figure 1*). The CFIA and Health Canada have adopted a policy of concurrent approvals (i.e. required assessments for all uses are completed at approximately the same time) to minimize the potential for unapproved PNTs, novel livestock feeds derived from plants, and/or novel foods to enter into the Canadian environment, livestock feed, and/or food supply.

Stage 1: Contained Use

Most PNTs and/or novel livestock feeds derived from plants are designed for unconfined environmental release and commercialization. However, some are designed strictly for research and are not intended for release into the environment (e.g. a specific gene is inserted into a plant to enable study of the gene's function). As well, other plants are designed for use only in contained facilities (e.g. plant molecular farming).

In the early stages of developing a PNT for unconfined environmental release and/or use as a livestock feed, the plants are grown in contained conditions, such as a laboratory growth chamber or greenhouse. When PNTs are grown in contained conditions, researchers operate under laboratory biosafety guidelines established by Health Canada and the Medical Research Council, as well as under codes of practice established by their own institutions. More information on Health Canada's laboratory biosafety guidelines is available on the Health Canada website.

Description of Requirements for Confined Research Field Trials

These trials are strictly regulated; for example, they are limited to one hectare in size and are allowed for research purposes only. Before allowing these trials, the CFIA requires information from the product developer including:

- detailed map of the field trial location, including surrounding crops and planting dates
- presence of endangered species at the field trial location
- size and number of field trial locations
- plan for the maintenance of reproductive isolation (e.g. isolated from other plants of the same or related species by specified minimum distances based on the known biology of the plant species)
- disposal of plant material (e.g. preventing spread of PNT material into wider environment through deep burial or complete incineration)
- post-harvest land use restrictions



TABLE 2

A Summary of PNTs and/or Novel Livestock Feeds Derived from Plants Approved for Use in Canada

| Plant | Trait(s) | Number of PNTs, novel livestock feeds derived from plants, and novel foods derived from plants |
|--------------------|---|--|
| Canola | herbicide tolerance | 7 |
| | male sterility/herbicide tolerance | 2 |
| | nutritional change | 1 |
| Corn | herbicide tolerance | 7 |
| | insect resistance/herbicide tolerance | 6 |
| | insect resistance | 2 |
| | male sterility/herbicide tolerance | 1 |
| Cotton Seed | herbicide tolerance | 2 ^a |
| | herbicide tolerance/insect resistance | 1 ^a |
| | insect resistance | 1 ^a |
| Flax | herbicide tolerance | 1 ^b |
| Potato | insect resistance | 2 |
| | insect resistance/virus resistance | 2 |
| | insect and virus resistance/herbicide tolerance | 1 |
| Rice | herbicide tolerance | 2 ^a |
| Soybean | herbicide tolerance | 2 |
| | nutritional change | 1 |
| Squash | virus resistance | 2 ^c |
| Sugar Beet | herbicide tolerance | 1 |
| Tomato | delayed ripening | 3 ^c |
| | insect resistance | 1 ^c |
| Wheat | herbicide tolerance | 2 ^d |

Note: the product developer is responsible for commercialization.

a – Not grown in Canada

b – Although approved, this flax variety was deregistered in 2001

c – Not grown in Canada and not intended for use as a livestock feed

d – Produced by mutagenesis; while considered a PNT and/or novel livestock feed derived from plants in Canada, it would not be reviewed for environmental safety by the EU, the U.S., Japan, and other countries.

Stage 2: Confined Research Field Trials

Product developers must submit an application to the CFIA before being authorized to conduct a confined research field trial in Canada. Confined research field trials provide developers an opportunity to evaluate the performance of their PNTs under highly controlled conditions that minimize the potential for environmental impact. Field trials also provide product developers the opportunity to generate data that they may submit as part of their application to the CFIA for unconfined environmental release and/or use as a livestock feed (stage 3). Typically, these field trials are conducted over a number of years in locations across Canada that are similar to where the plants are intended to be grown. The CFIA’s *Directive 2000-07: Conducting Confined Research Field Trials of Plants with Novel Traits in Canada* provides instructions to help applicants meet the regulatory requirements that must be met for confined research field trials.

Certain details concerning confined research field trials are available on the CFIA website. Details include crop species, breeding objective, general description of the novel trait(s), the organization conducting the field trial(s), and the province(s) in which the trials were, or are, being conducted. Provincial authorities are notified before a confined research field trial is authorized and are given a 30-day comment period. A [sample application form](#) for a confined research field trial, as well as [summaries of confined research field trials](#) conducted in Canada since 1988, can be found on the CFIA website.

Stage 3: The CFIA's Safety Assessments for Unconfined Environmental Release and/or Use as a Livestock Feed

The CFIA's evaluators address the following criteria during the safety assessments:



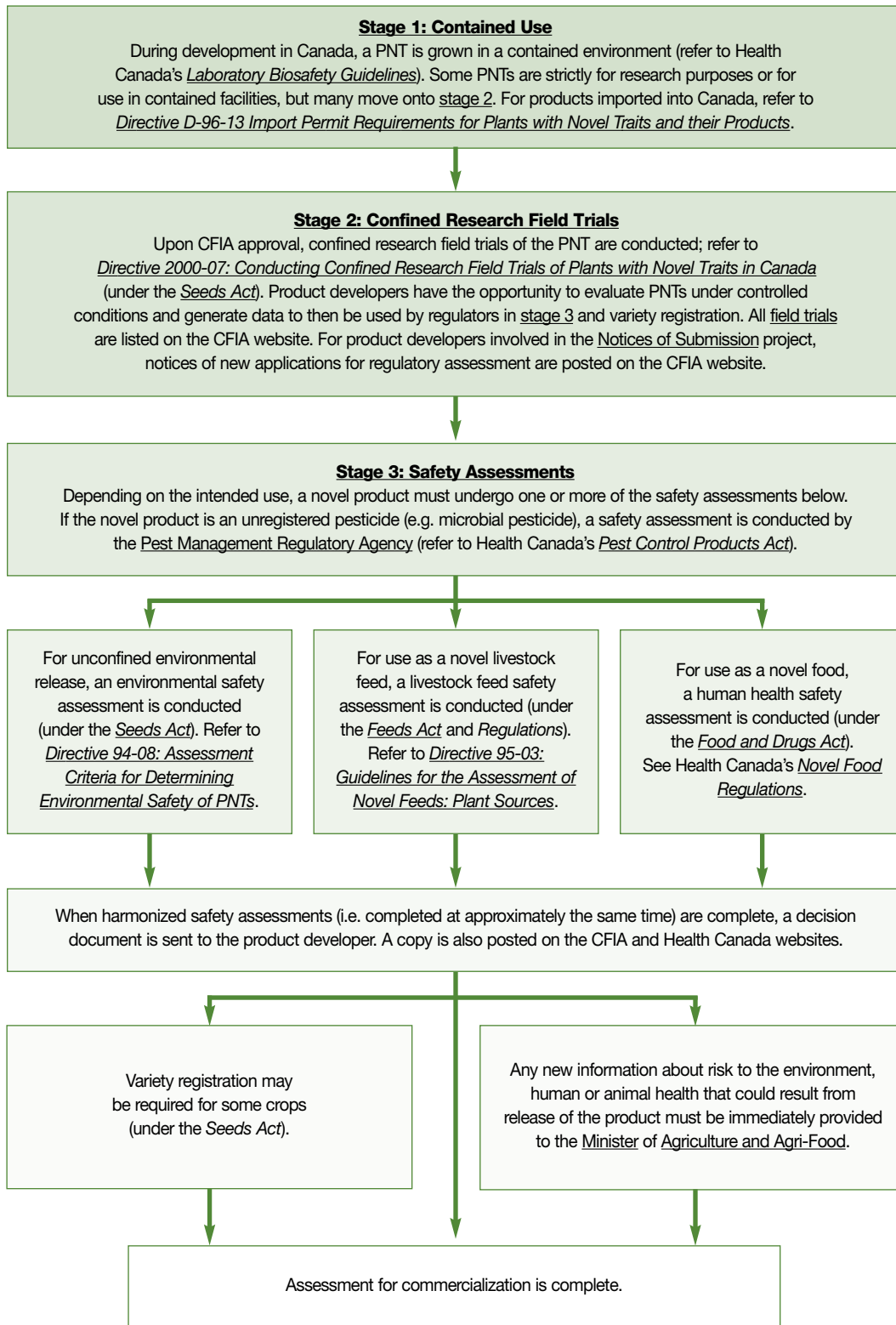
- Does the plant have the potential to become a weed of agriculture or to be invasive of natural habitats (i.e. become more competitive)?
- Is there potential for gene flow to wild relatives whose hybrid offspring may become more weedy or invasive (i.e. increased fitness of wild relatives, disturbance or loss of rare populations)?
- Does the plant have the potential to become a plant pest, or to have an impact on an existing plant pest?
- Is there a potential impact of the trait on non-target organisms?
- Are there other potential impacts on biodiversity?
- If the plant expresses an insecticidal property, is an insect resistance management plan in place?
- Does the plant, or its products, have the potential to affect livestock feed or food safety?
- Are there any possible concerns in relation to the detailed molecular characterization?

To address these questions, CFIA evaluators review volumes of scientific data submitted by the product developer (data generated in [stage 2](#)). They may also use pertinent information on the biology of the crop generated from the CFIA's own research (either conducted in-house or commissioned), or identified from other scientific sources (e.g. peer reviewed literature) on specific environmental concerns.

There are directives that dictate [what data must be submitted](#) and how CFIA evaluators must examine the data. *Directive 94-08: Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits* and *Directive 95-03: Guidelines for the Assessment of Novel Feeds: Plant Sources* guide applicants as to the information that they must provide in their applications. These directives are augmented by the *Reviewers' Checklist for Analytical Techniques*. Data must be of the same high quality as that required by scientific journals for publication and peer review. Documents such as the *Reviewers' Checklist for Analytical Techniques* and CFIA-specific Standard Operating Procedures provide consistency in the quality of the review. The data are thoroughly analyzed, as are the requirements used to verify the validity of results. If the data is scientifically unsound, incomplete or inadequate, government evaluators require that the product developer address the shortcomings of their submission before the assessment can continue. For more information on the data requirements for the CFIA's safety assessments for [unconfined environmental release](#) and/or [use as a livestock feed](#), visit the CFIA website.



Figure 1: Regulation of Plants with Novel Traits (PNTs) and/or Novel Livestock Feeds Derived from Plants in Canada



Government evaluators developed guidelines (e.g. *Directives 94-08* and *95-03*) related to applications for unconfined environmental release and/or use as a livestock feed, respectively, based upon principles developed through technical and extensive stakeholder consultations. These guidelines were influenced by expert consultations carried out by the OECD and the United Nations' WHO and FAO relative to the regulation of biotechnology products. The CFIA's directives are regularly updated to reflect new science and increased field experience.

Canada is not unique in conducting safety assessments with data generated by the product developer. This system is considered to be a standard scientific means of evaluation and is used by regulators around the world. Under this system, product developers are responsible for their product. In addition to the information product developers provide, government evaluators use available peer-reviewed scientific literature and expert advice from the scientific community. They are also able to commission studies or convene groups of experts to gain further advice and insights about specific types of products and research on their potential interaction with the environment.

Data Requirements for the CFIA's Safety Assessments

Identification and Classification

Fundamental information about each PNT and/or novel livestock feed derived from plants is needed for an understanding of the potential biological interactions of the plant in the ecosystem or its potential effects on livestock animals. Depending on the plant/trait combination, information requirements may include the following:

- name and taxonomy
- history or pedigree, or other information about the organism that defines its unique character
- how it will be used (the application)
- history of use as a livestock feed

Modification Methods

Many different genetic modification techniques can be used to develop PNTs and/or novel livestock feeds derived from plants. Data related to the modification methods must include the following elements:

- description of the genetic modification technique used
- identification of all genetic material potentially used to modify the host plant
- information about the DNA to be introduced (e.g. characterization, size, location, function, and orientation in the final vector/construct)

Description of the Novel Trait(s)

A PNT and/or novel livestock feed derived from plants can have several trait properties. For each novel trait, including any selectable marker genes used in the genetic engineering process, the following data are required:

- how the gene is expressed (e.g. expression levels, tissue-specific expression, stability, and transcriptional controls)
- description of by-products, if any
- known toxicity or interaction with other organisms



Environmental Data

PNTs intended for environmental release are examined for interactions with, and impact on, the ecosystems in which they are to be used. Data can be a combination of literature on the organism (e.g. flowering period and seed production) and test data from the laboratory or greenhouse and from field testing (e.g. potential to become a weed or plant pest).

Livestock Feed Data

Data must be submitted to assist CFIA evaluators in determining the impact of a novel livestock feed derived from plants on animal health and the environment as well as human health via occupational or bystander exposure who may come in contact with the novel livestock feed derived from plants.

• Nutritional Data

Data in this area include measurements of basic nutritional components—protein, fat, and fibre. The data may also contain compositional data on total lipids, the carbohydrate fraction, amino acids, fatty acids, and anti-nutrients such as trypsin inhibitors.

The dietary exposure to the novel livestock feed derived from plants is a key consideration in the CFIA's safety assessments. Novel livestock feeds derived from plants that are present in low levels in a complete diet may be of less concern than those feeds intended to be significant components of the diet.

• Toxicity and Allergenicity Data

Toxicity and allergenicity data for novel livestock feeds derived from plants are derived from product information and laboratory studies. The information required depends on the characteristics of the novel livestock feed derived from plants and the toxic or anti-nutritional compounds it may express. Information can include data on the following:

- concentration of toxins or anti-nutritional compounds in edible parts
- dietary exposure
- comparison of amino acid sequences and similarities to known toxins
- stability to heat or processing methods
- degradation in representative gastric and intestinal model systems
- allergenic potential of gene products

The potential for allergenic response in humans who would be exposed to the novel livestock feed derived from plants, in their work environment for instance, would be considered on the basis of the history of the host and donor organisms and the novel traits introduced.

After the CFIA's Safety Assessments

Once the CFIA's safety assessments are complete, a [decision document](#) is sent to the product developer. Following the product developer's receipt of the decision document, it is published on the CFIA website (and is also available in hard copy). Decision documents explain in detail what was reviewed to make the decision and why certain conclusions were reached.

Evaluators in regulatory departments and agencies in Canada and abroad acknowledge that because of the rapid pace of research advances, scientific knowledge is ever-expanding. Any authorization for a PNT and/or novel livestock feed derived from plants is subject to review if new information comes to light that indicates that an approved PNT and/or novel livestock feed derived from plants could pose an

unforeseen risk to the environment, human health, or animal health. As a result, any person who has provided notification or received authorization for release of a PNT and/or novel livestock feed derived from plants under either the *Feeds Regulations* (Section 4.4) or the *Seeds Regulations* (Section 112) is required to immediately provide any new information to the CFIA for a re-evaluation.

There have been occasions when new information has become available; however, based on this new information, as yet, there have been no changes in the outcome of the CFIA's safety assessments of any approved PNTs and/or novel livestock feeds derived from plants that have resulted in amendments to the regulatory requirements specific to the original authorizations. This has been the case, to date, regardless of the method used to produce the change to the molecular make-up of the PNT and/or novel livestock feed derived from plants (e.g. whether it is a product of modern recombinant DNA techniques or mutagenesis).

Post-Approval Monitoring and Inspection Programs

In addition to responsibilities related to the safety assessments of PNTs and/or novel livestock feeds derived from plants, the CFIA has a range of inspection and monitoring programs designed for different agricultural products. Approved PNTs and/or novel livestock feeds derived from plants are also subject to these programs, which involve post-approval inspections and monitoring to verify that all registered products continue to meet quality and safety standards.

Imported PNTs and/or Novel Livestock Feeds Derived from Plants

A permit is required to import unapproved PNTs and/or novel livestock feeds derived from plants into Canada. The CFIA issues import permits only after it has conducted a safety assessment, under the authority of the *Plant Protection Act*. Typically, permits are issued with specific conditions to limit the movement or use of the PNTs and/or novel livestock feeds derived from plants upon entry into Canada.

Management Plans for Insect-Resistant and Herbicide-Tolerant PNTs

Herbicide Tolerance Management Plans

The CFIA requires that product developers of herbicide-tolerant PNTs include management plans when they submit an application for unconfined environmental release. CFIA evaluators would not authorize a PNT if it could produce herbicide-tolerant (HT) hybrids that do not have effective or sustainable control options. As such, these management plans are designed to address:

- control of volunteer HT plants (e.g. if HT crops are planted one year, a farmer can expect a certain number of plants to re-grow the next year as a result of seed shattering or seed spillage before or during the previous harvest)
- the selection of herbicide tolerance in weeds resulting from the potential continued application of the same herbicide in subsequent years
- crop management during the growing season, particularly where tolerance to multiple herbicides could arise from cross-pollination between related crops
- an efficient mechanism to allow farmers to report problems to the product developer

Options for Controlling HT and Volunteer HT Plants

- use a different herbicide or rotate the herbicide used
- till the land immediately before seeding
- rotate the crops planted in a field each season
- use non-chemical weed control methods (e.g. silage or green manure)



Why do people discuss monarch butterflies and Bt corn?

In 1999, researchers at Cornell University did a preliminary laboratory study on the effects of Bt corn pollen on monarch caterpillars. The lead researcher, Dr. John Losey, sent a description of the study to the editors of the science journal *Nature* (Volume 399, 20 May 1999, page 214).

In Dr. Losey's study, monarch caterpillars were fed milkweed leaves that had been dusted with pollen from Bt corn in a laboratory. This was done because wind-borne corn pollen can settle on the leaves of milkweed plants, and milkweed is all that monarch caterpillars eat. Milkweed often grows in meadows or untilled fields and can be found in or near corn fields. Dr. Losey wanted to determine whether pollen from Bt corn would affect monarch caterpillars. His study found that: "... larvae of the monarch butterfly on milkweed leaves dusted with transgenic Bt-corn pollen ate less, grew more slowly, and suffered higher mortality than those fed leaves dusted with untransformed corn pollen or leaves without pollen."

Some people understood the results of the study to mean that Bt corn harms monarch caterpillars, but other scientists pointed out that the study may not accurately reflect what would happen in a field of Bt corn. They noted that:

- there were higher amounts of Bt pollen on the milkweed leaves in the laboratory than would be found in a field
- in the laboratory, caterpillars were limited to eating only leaves covered in corn pollen, whereas in a field, caterpillars may be able to avoid pollen-coated leaves

As a result of Dr. Losey's findings, some scientists decided to combine their research on this topic and produced a large body of peer-reviewed work on monarch butterflies and Bt corn, which was published in the *Proceedings of the National Academy of Sciences (PNAS)*. These studies concluded that monarch butterflies exposed to Bt corn in the environment are not subjected to any significant risk. More information on these studies can be found on the [U.S. Department of Agriculture, Agriculture Research Service website](#).

The CFIA, in co-operation with Environment Canada, commissioned a study that became part of that body of work entitled *Final Report on the Ecological Impact of Bt Corn Pollen on the Monarch Butterfly in Ontario*. In addressing risk posed by Bt corn pollen, two factors were considered: 1) the likelihood of exposure of larval stages to Bt corn pollen and 2) the dose of pollen at which a measurable effect can be determined to larvae or subsequent stages of the monarch. The study data indicated that the likelihood of exposure was 1% while the likelihood of encountering a toxic dose was less than 1%. Therefore, risk to monarchs from Bt corn pollen was determined to be less than 1/100 of 1%. For more information, visit the CFIA website.

Insect Resistance Management Plans

Bt crops provide another example of the need for management plans. Bt pest control products have long been used as foliar sprays in both conventional and organic production. As with other types of insecticides, there is the potential for insect pests to become resistant to these PNTs. Scientists across North America agree that through natural selection, target insect populations (e.g. European corn borer) could develop resistance to Bt proteins expressed in Bt crops. For this reason, the CFIA's authorizations of Bt corn are conditional on the implementation of insect resistance management (IRM) plans and have been since 1999. IRM plans are designed to control the pest population from becoming resistant to the Bt proteins.

Before 1998 companies marketed Bt corn in Canada with different IRM plans. At that time, an effort was made to establish a consistent single IRM plan that could be used as an industry standard to avoid any confusion or ineffectiveness that may have arisen (e.g. if a grower purchased Bt corn seed from two different companies with two different IRM plans). This effort was led by the Canadian Corn Pest Coalition, an advisory group of academics, provincial extension staff, representatives from the biotechnology industry, and government scientists.

The Canadian Corn Pest Coalition studied this question in depth and provided recommendations to the CFIA. The end result was a standard IRM plan for the European corn borer involving a lethal dose/refuge strategy. This strategy exposes one portion of the pest population to Bt plants expressing the lethal dose of Bt protein while maintaining another part of the population in a refuge area made up of non-Bt corn (covering at least 20% of the total corn area). Genetic mixing of any resistant insects from the Bt corn area with susceptible insects from the refuge area helps maintain a low frequency of resistance in the overall insect population.

Gene Flow and Herbicide-Tolerant (HT) Crops

Gene flow is defined as the transfer of genetic material by interbreeding from one population of a species to another population (same or related species), thereby changing the composition of the gene pool of the receiving population. In other words, gene flow occurs when plants of the same species pollinate one another or, in rare cases, pollinate a closely related plant of another species. Just as this can happen between non GE plants, it can also happen between GE plants and non GE plants (refer to the list of [biotechnology terms](#)).

Canola plants of any variety, including HT canola plants, can outcross with their same species relatives and with a few related plants of other species, such as rapeseed. If a trait for herbicide tolerance were passed onto a weed, it does not mean that the weed would become a more difficult pest, it means that the weed would be tolerant to a specific herbicide (i.e. it would become a HT volunteer plant). There have been claims that the transfer of HT traits from PNTs to wild relatives could create invasive “superweeds” that are harder to control. As well, there have been claims that gene flow from HT varieties to non HT varieties could create superweeds. The CFIA requires developers of HT varieties to implement stewardship plans to improve long-term sustainability of the product. To date, the CFIA’s safety assessments have concluded that while gene flow is possible, it does not result in increased weediness or invasive wild relatives.

Plant Molecular Farming (PMF)

PMF involves growing of plants in agriculture to produce pharmaceutical or industrial compounds instead of food, feed, or fibre. The possibilities range from the manufacture of medical products, such as pharmaceuticals (drugs) and vaccines, to the production of products such as biodegradable plastics and industrial chemicals. Tobacco is a non-food plant with a high growth rate that can be used in the ways mentioned. Tobacco has been experimentally modified to produce antibiotics, a dental treatment, and anti-cancer drugs. For example, tobacco lines have been modified to produce pharmaceutical compounds such as interleukin (a potential treatment for Crohn’s disease). These PNTs have been tested in confined research field trials in Canada.

Other examples of PMF products at the research development stage:

- edible vaccines
- medical treatments for animals
- an enzyme used in the treatment of cystic fibrosis
- food processing enzymes
- bioplastics made from simple, biodegradable molecules produced in plants
- antibodies for diagnostic, preventative, and therapeutic applications (such as preventing tooth decay, reducing kidney transplant rejection, and helping in cancer treatment)



To date, there is no commercial PMF activity in Canada, but confined research field trials have been conducted under the authority of legislation administered and enforced by the CFIA. These confined research field trials are allowed for research activity only. Until the Government of Canada completes a review of its policy on PMF, authorizations for confined research field trials are granted according to the interim amendments to *Directive 2000-07: Conducting Confined Research Field Trials of Plants with Novel Traits in Canada*. These amendments are available on the CFIA website.



In addition to reviewing applications for confined research field trials of PNTs intended for PMF, the CFIA has also been developing directives specific to confined research field trials and commercial cultivation of these PNTs. As part of this activity, in the fall of 2001, the CFIA hosted a broad, multi-stakeholder consultation and a public forum focusing on the particular concerns associated with PMF. Participants in the multi-stakeholder consultation included representatives from public interest groups, agriculture and agribusiness, industry, academia, and various government departments. The CFIA also invited comments from interested Canadians on the issues discussed during the multi-stakeholder consultation through a questionnaire posted on the Agency's website.

Input from consultations has been incorporated in the previously mentioned interim amendments. More information is available on the CFIA website.

An important step in developing directives for the CFIA's safety assessments of PNTs intended for PMF involves examining whether these products and by products can be adequately segregated from other commodities, specifically, those intended for the food and livestock feed chains. To discuss this, the CFIA hosted a technical workshop in March 2004. Participants included representatives from industry, federal government departments (including Health Canada), agricultural and agribusiness associations, and experts in grain handling and identity preservation. As a result of the workshop, the CFIA, in collaboration with the U.S. Department of Agriculture's Animal and Plant Health Inspection Service, solicited advice on how best to expand the table of contents for a code of best agricultural practices for PMF. As well, the CFIA continues to work with Health Canada to develop an appropriate regulatory pathway, leading to the development of directives.

Suggestions for Reading and Discussion

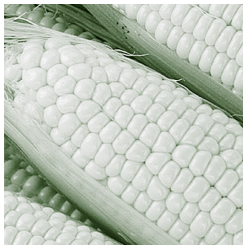
1. Review a CFIA regulatory decision document for any PNT and/or novel livestock feed derived from plants. Identify how each of the requirements contained within the appropriate CFIA Directives were met by the product developer during the safety assessment.
2. Review a CFIA regulatory decision document for a herbicide-tolerant PNT. Compare the stewardship plan provided by the product developer and the requirements contained within the appropriate CFIA Directives.

4. The CFIA's Role in Labelling Novel Foods

Health Canada sets food labelling policies regarding health and safety matters for all food, including novel foods. The CFIA has a role in the labelling of novel foods and is responsible for administration and enforcement of the *Food and Drugs Act* and the *Consumer Packaging and Labelling Act* and their regulations with respect to food labelling and advertising for non-health and safety matters.

Health Canada has responsibility for assessing the safety of novel foods that are part of Canada's food production system. Health Canada reviews all novel foods, including PNTs intended for food use, before they can be sold to consumers. This rigorous, science-based review process is applied to conventionally developed products with new characteristics and GE products alike.

Health Canada has the authority to require mandatory labelling if a food has undergone a significant change in nutrition or composition which may present a health risk that could be mitigated through labelling. This is done in consultation with the CFIA. The objective of this labelling is to provide the consumer with information about the significant change. The significant change is, usually, expressed in a modified common name of the food. For example, for novel foods where there is a significant change in composition, the common name is modified to highlight the change (e.g. mid-oleic sunflower oil).



The Government carefully considers requests by consumers for a mandatory labelling regime for GE foods. In considering such requests, the Government must take into account the objectives of mandatory labelling and the means available to achieve these objectives, whether regulatory or non-regulatory.

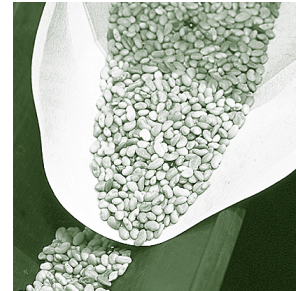
Existing legislation protects consumers from labelling that is misleading or untruthful, while allowing manufacturers to voluntarily use labels that tell consumers how a food has been produced, that is, its method of production. In permitting such labelling, the Government is recognizing that consumers want information that is not related to the safety of the product—such as whether or not a product has been derived through biotechnology. The Canadian Food Inspection Agency's role includes investigating complaints, providing advice and explanations about labelling in a regulatory context, and taking appropriate enforcement action under the authority of relevant Acts.



The new *National Standard for the Voluntary Labelling and Advertising of Foods That Are and Are Not Products of Genetic Engineering* assists manufacturers in making claims about their products and provides guidance to help them comply with regulatory requirements. Claims that follow provisions set out in the National Standard are considered to be in compliance with regulations under the *Food and Drugs Act* and the *Consumer Packaging and Labelling Act*. It is the responsibility of manufacturers to ensure that their claims are not false, misleading or deceptive and that they are not likely to create an erroneous impression regarding the food's character, value, quantity, composition, merit or safety.

The National Standard provides guidance to help consumers in making informed food choices, while allowing the agri-food industry the flexibility to make appropriate business decisions in response to market demands. In addition, for consumers who want additional details about a specific food product, the Standard requires that labels provide a toll-free telephone number or internet address from which information can be obtained. The Standard is available to the public on the Canadian General Standards Board's (CGSB) website at www.pwgsc.gc.ca/cgsb and is available, without charge, in hard-copy format. You can request a copy from the CGSB Sales Centre (Sales Centre, Canadian General Standards Board, Gatineau, Quebec K1A 1G6).

Canada's combination of legislative and standards-based approaches, along with the information provided through other sources—such as the internet or toll-free information lines—has the potential to provide Canadian consumers with more information than is available to consumers in countries that have simply adopted mandatory labelling policies for GE foods.



5. An Evolving Regulatory System

Through research and consultation with national and international experts, Canadian regulators are improving the science and methods used in the assessment and regulation of novel products. The federal government also routinely consults with Canadians to solicit expert advice, review issues of concern, and convey information about developments in the biotechnology industry.

Seeking Expert Advice

Royal Society of Canada Report

The Royal Society of Canada Expert Panel on the Future of Food Biotechnology, an expert panel established to examine future scientific developments in food biotechnology and their resulting impact on regulation, serves as an example of the federal government's commitment to consultation. In 2001, the Royal Society published the expert panel's report, entitled *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada*. The report provided recommendations for the regulatory system and outlined the scientific capacity the government needs to continue to verify that novel products are safe for use in Canada. The report's 53 recommendations can be categorized under the following themes:

- potential human health impacts
- considerations in the use of biotechnology in animal production systems
- environmental risks
- substantial equivalence as a regulatory concept
- precautionary principle and the regulation of food biotechnology
- issues in the science-based regulations of biotechnology

In response, the Government of Canada published an [action plan](#) and accompanying [progress reports](#). As required by the action plan, the government continues to:

- revise relevant documents and create new information materials explaining the regulatory system to the public
- update and refine protocols for the CFIA's safety assessment as science progresses and more advanced methods become available
- participate in international efforts and seek contributions from experts to develop and validate testing protocols and other tools to address biotechnology issues
- increase scientific and regulatory capacity with scientists trained in molecular biology, entomology, ecology, and other sciences related to plants, animals, and the environment
- support research projects relevant to biotechnology issues

The Government of Canada regularly posted progress reports on its action plan to address issues raised by the Royal Society of Canada expert panel report. These documents have been posted on [Health Canada's](#) website, and links are available from the CFIA website.



Canadian Biotechnology Advisory Committee (CBAC) Report

The CBAC is an arm's-length expert advisory body created by the federal government to assist in the formulation of public policy on a range of biotechnology issues. In 1999, the Government of Canada established CBAC to study social, economic, scientific, regulatory, and health aspects of biotechnology and to advise federal Ministers accordingly. The creation of CBAC was driven by the 1998 *Canadian Biotechnology Strategy (CBS)*. The 21-member committee was drawn from the scientific, business, general public, ethics, and environmental communities. In the spring of 2001, CBAC held five consultations across Canada with industry stakeholders, academia, and civil society to discuss the regulation of novel foods. CFIA officials participated in each workshop to provide technical and regulatory information as required. CBAC released an interim report in August 2001, and CFIA officials met with CBAC members to comment on the report. Canadians were given until January 2002 to provide comments. CBAC's full report was released in August 2002 and is accessible through the CBAC website at www.cbac-cccb.ca. The CBAC report, entitled *Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada*, provided 44 recommendations for improving the regulation of novel foods that can be categorized under eight areas:



- structure, organization and operation of the federal food regulatory system
- transparency and public involvement
- precautionary elements
- evaluation and monitoring of long-term health impacts
- environmental stewardship
- improved information to support consumer choice
- labelling
- other social and ethical considerations related to GM foods

The federal government has responded to the recommendations made in the report. Links to the CBAC report can be found on the CFIA website.

Enhancing Consumers' Understanding of Regulation of Novel Agricultural Products

The Government of Canada strongly supports providing consumers with meaningful information to help them make informed choices. Specifically, the CFIA is actively seeking opportunities to provide the public with information on the safety of the Canadian regulatory system and the safety of novel agricultural products on the marketplace. This can be achieved through many means, including brochures, websites, information kits, education and awareness programs, and toll-free lines.

For example, the CFIA website contains comprehensive information in plain language [fact sheets](#) that discuss the regulation of novel agricultural products and in [simplified decision documents](#) that describe the CFIA's safety assessments for certain PNTs ([complete versions](#) are also available). Directives containing information on topics, such as import permit requirements, confined research field trials, and authorizations for unconfined environmental release and/or use as a livestock feed are also available. Information on the [PNTs and/or novel livestock feeds derived from plants that have been approved in Canada](#) is available on the website. The CFIA continues to evaluate its website, as well as its various other communications products, always with the intention of improving public accessibility, readability, and content.

Regulatory Transparency

The Government of Canada is committed to increasing transparency and openness in the Canadian regulatory system, specifically related to product information and the CFIA's safety assessments. Some of the initiatives described below aim to achieve these goals.

The Biosafety Clearing-House

The [Biosafety Clearing-House \(BCH\)](#) was established under the [Cartagena Protocol on Biosafety \(the Protocol\)](#) as a Web-based tool that allows users to search domestic and international biosafety information. The Protocol is a supplementary agreement to the United Nations [Convention on Biological Diversity](#). Canada supports the objective of the Protocol—to protect and preserve biodiversity—and [signed](#) it in April 2001. The Government of Canada continues its efforts to contribute to the transparency of the Protocol, for example, through the development of the [Canadian portion](#), or node, of the BCH.

Cartagena Protocol on Biosafety

The United Nation's [Convention on Biological Diversity](#) is an international agreement aimed at conserving biological diversity and minimizing unintended impacts on the environment. In January 2000, the [Conference of the Parties to the Convention on Biological Diversity](#) adopted a supplementary agreement known as the [Cartagena Protocol on Biosafety \(the Protocol\)](#). The Government of Canada [signed](#) the Protocol in April 2001 and continues its efforts to contribute to the transparency of the Protocol, for example, through the development of the [Canadian portion](#), or node, of the [Biosafety Clearing-House \(BCH\)](#).

The Protocol sets the international standard for the safe transfer, handling and use of living modified organisms (LMOs). One specific component of the Protocol ([Article 20](#)) established the development of the BCH, a tool for exchanging biosafety information. Its purpose is to protect the environment and global diversity by ensuring that there is adequate protection for transferring, handling and the use of LMOs (refer to the list of [biotechnology terms](#)). The Protocol provides a regulatory framework to move LMOs safely between countries. If a country is a Party to the Protocol, the obligations outlined in the Protocol must be introduced into its domestic regulatory system, which will be the basis for decisions on the import of LMOs. Under its domestic regulatory system, Canada already regulates the import and production of LMOs.



In addition to providing public access to biosafety information, the BCH allows countries to exchange scientific, technical, environmental, and legislative information about living modified organisms (LMOs) produced through modern biotechnology (refer to list of [biotechnology terms](#)). CFIA, along with [Health Canada](#), is assisting [Environment Canada](#) in implementing the [Canadian Node of the Biosafety Clearing-House \(CNBCH\)](#). The CNBCH is a central portal to information on the Canadian regulatory system for LMOs and safety assessments conducted thereunder. The CNBCH is available on the internet at www.bch.gc.ca.

Notices of Submission

In October 2003, the CFIA and Health Canada launched a joint pilot *Notices of Submission Project*. With the launch of this project, the federal government is responding with a credible means of addressing the public's interest in a more transparent process of regulating PNTs and/or novel livestock feeds derived from plants. Previously, only lists of [approved PNTs and/or novel livestock feeds derived from plants](#), along with their accompanying [decision documents](#) and directives, were posted on the CFIA and Health Canada websites. To complement this practice, notices of new submissions are being posted on the CFIA site. These notices describe PNTs and/or novel livestock feeds derived from plants currently under review for approval and summarize the information being used in their safety assessments. As such, this new initiative allows for public input during the assessment process itself, rather than only after approval has been granted. Also, for the first time, the public has access to a list of safety-related scientific studies conducted on PNTs and/or novel livestock feeds derived from plants. For more information on this pilot project, or to receive [e-mail notification](#) of new submissions, visit the CFIA website.



Researching Public Opinion

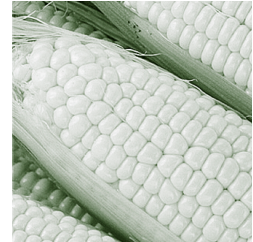
Since 1999, the Government of Canada's [Canadian Biotechnology Secretariat](#) and its partners have maintained a large scale tracking program of public opinion research (POR). During that time, it has commissioned 14 public opinion surveys and more than 90 focus groups. In all, there are more than 20,000 data points available in what is North America's largest and most comprehensive investigation into attitudes about biotechnology and the public policy that surrounds it. The program is designed to produce two waves of research each year, with a large tracking component and chapters of more intensive inquiry into specific topics. Results have been remarkably consistent since the inception of the research program. For a comprehensive list of POR into biotechnology and related topics, please visit the Government of Canada's BioPortal website, specifically [Public Opinion Research](#) in the index of topics at www.biportal.gc.ca.

Public Consultation

The CFIA frequently engages the public in consultations to help develop guidelines and regulations for novel agricultural products. The CFIA consultation process includes conducting workshops, convening multi-stakeholder meetings, and distributing draft documents for public review and comment. In addition, the CFIA uses information arising from citizens' conferences, which are also known as consensus conferences. These consultations include discussion of technical and scientific matters. Some of the topics discussed include:

- regulations and the CFIA's safety assessments
- labelling of novel foods
- insect resistance management strategies
- plant molecular farming

In addition to these consultations, a wide range of subject experts, representing academia, industry and non-government organizations, have participated in extensive commodity-specific consultations on technical and scientific matters.



Departments and agencies post information on the internet about their intentions to consult with the public on a topic and, in addition to providing "how to" information, often include discussion papers and other documents on the topic of concern. Public consultations are also advertised through newspaper ads and public service announcements. When technical consultations are held, invitations are sent out to various stakeholders. A list of CFIA consultations is available on the CFIA website.

Some examples of federally initiated consultations are provided below. New consultations are continually being held, including consultations regarding the EENLO initiative, import requirements for ornamental PNTs, and potential requirements for a commercial plant molecular farming inspection program (consultations were held in spring of 2005). Details concerning consultations are posted on the CFIA website as they become available.

Pest Resistance Management Strategies for Bt Potatoes

In 2000, the CFIA sponsored a meeting to discuss pest management strategies for Bt potatoes. More than 40 representatives from government, industry, and academic research communities, as well as U.S. and Canadian growers, shared their experiences and concerns. Key topics included management of insect resistance to Bt potatoes and mobility and survival of the Colorado potato beetle. The goal of the consultation was that the CFIA would be provided with sound information for developing recommendations and strategies for pest management and control.

Revisions to Directives

In 2002, the CFIA and Health Canada hosted a joint consultation that brought together a range of experts, stakeholders, and government regulators. Participants discussed revisions to directives and guidelines for the safety assessment of novel foods, PNTs, and novel livestock feeds derived from plants. Discussion focussed on several areas: the concept of novelty, molecular characterization data, environmental characterization data, safety and environmental assessment criteria, and detection and identification.



Management of Herbicide-Tolerant (HT) Crops

The CFIA held a technical workshop on the management of HT crops in September 2003. Invited attendees were representatives from industry, federal and provincial departments and agencies, agriculture and agribusiness associations, and academia. There were four objectives:

- gain a better understanding of current management practices as well as the benefits and problems experienced with the cultivation of HT crops
- identify potential solutions to further improve the management and stewardship of HT crops
- identify future challenges that industry and regulatory bodies alike may face with the cultivation of HT crops
- identify (i) any outstanding knowledge gaps regarding the management of HT crops and (ii) identify research priorities

Novelty as a Regulatory Trigger

Representatives from industry, academia and Agriculture and Agri-Food Canada research centres met with regulators from the CFIA and Health Canada at a workshop held in March 2004. The workshop was organized to discuss the application of novelty as the regulatory trigger for products of biotechnology. The influence of plant breeding methods on unanticipated effects of plant breeding was also discussed.

Suggestions for Reading and Discussion

1. Review and discuss an expert panel report or consultation proceeding, and discuss some of the related changes occurring in the regulatory system.
2. Research an emerging issue in agricultural biotechnology on the CFIA website. Some suggestions are provided below:

International Harmonization

Canada is involved in a number of international initiatives through the Convention on Biological Diversity, the OECD, and the North American Plant Protection Organization. The federal government has also signed the Canada and United States Bilateral Agreement on Agricultural Biotechnology, which is intended to harmonize the environmental and molecular characterization data required for the safety assessment of PNTs.

Detecting PNTs

The CFIA is building its biotechnology testing and detection capabilities by developing better methods, acquiring new expertise and staff, and using new technologies and equipment.

Plant Molecular Farming (PMF)

PMF is at the experimental stage and specific regulatory directives are under development. Refer to a PMF discussion document and an amendment to Directive 2000-07 on the CFIA website.

6

6. Additional References

Publications

- *Regulating Biotechnology, Safety Comes First* information kit includes (bilingual): fact sheets, brochures and posters related to the regulation of novel agricultural products
- *CFIA's Biotechnology Highlights Report 2001-2002*: the CFIA's report to the public
- *Regulation of Agriculture Biotechnology at a Glance*: Poster (bilingual)

Government of Canada's BioPortal <www.bioportal.gc.ca>

The Government of Canada's BioPortal is the online gateway to the latest government information on biotechnology for consumers, industry, scientists and educators. This easy to use and fully searchable site brings together resources from all federal departments and agencies, including:

- government policy and research activity
- business support programs and market intelligence
- a virtual library of educational resources
- regulations on biotechnology research and applications

Careers at the CFIA

The CFIA offers a wide range of career opportunities covering many disciplines, such as pure and applied science, communications, business, and financial services. For more information about career possibilities, visit the CFIA Human Resources website at:

www.inspection.gc.ca/english/hrrh/employmente.shtml

www.inspection.gc.ca/english/hrrh/poscare.shtml

For contact information please see:

www.inspection.gc.ca/english/hrrh/offbureaue.shtml



Co-op opportunities for university students are also available. Consult your university's co-op office for more information.

www.inspection.gc.ca

Office of Biotechnology

Canadian Food Inspection Agency

59 Camelot Drive, Ottawa, ON K1A 0Y9

Telephone: (613) 225-2342 • Toll-Free: 1-800-442-2342

Facsimile: (613) 228-6604