

The Centre for Safe Food (CSF) is a virtual research institute, involving scientists, economists and social scientists, based at the University of Guelph, but with strong collaborations to academic, government and industry research associations throughout Canada and internationally. CSF works closely with the Canadian Research Institute for Food Safety.

The CSF is composed of a multi-disciplinary team which uses electronic networks, extensive databases and rigorous field research to:



Centre  
For  
Safe Food

Identify, develop, implement and assess appropriate food safety interventions from farm-to-fork;

Incorporate public perceptions and cost benefit analyses into policy development without abdicating the leadership role of science;

Evaluate policy alternatives such as voluntary, regulatory and market interventions to achieve optimal levels of food safety;

Design scientific and publicly credible food safety risk management programs; and

Actively engage the Canadian public in debate about food safety options, alternatives and efficiencies.

The CSF works closely with national and international collaborators to put science into action — to develop and implement scientific and publicly credible policies and programs to enhance the safety of the food supply.



COUNCIL FOR  
BIOTECHNOLOGY  
INFORMATION

The Council for Biotechnology Information is committed to providing objective, balanced information to help people better understand and appreciate the benefits biotechnology offers, as well as to encourage informed debate about the issues it raises.



**CROP PROTECTION  
INSTITUTE**  
**INSTITUT POUR LA  
PROTECTION DES CULTURES**

Supporting sustainable agriculture in Canada, in co-operation with others, by building trust and appreciation for plant life science technologies.

For more information, please contact

**CROP PROTECTION INSTITUTE OF CANADA**

21 Four Seasons Place, Suite 627, Etobicoke, Ontario M9B 6J8

Telephone: (416) 622-9771 Fax: (416) 622-6764

Website: [www.cropro.org](http://www.cropro.org)



Plant biotechnology  
in Canada

1	OVERVIEW Plant biotechnology industry in Canada Historical perspective Human health & safety; environmental care
2	GOVERNMENT REGULATORY SYSTEM Product-based approach
3	REGULATIONS GOVERNING PLANT BIOTECHNOLOGY Canada's regulatory agencies
4	NOVEL FOOD REGULATIONS ARE PRODUCT-BASED Environmental safety Food and feed safety
6	Sample criteria
7	THE REGULATORY PROCESS...IN BRIEF Six steps to safety
9	COMPREHENSIVE REGULATIONS FOR A SAFE FOOD SUPPLY The Canadian perspective International standards emphasize food safety
12	ASSURING SAFETY; MINIMIZING RISK
14	POTENTIAL BENEFITS OF PLANT BIOTECHNOLOGY Benefits to consumers, agricultural producers, the environment
18	APPENDIX A: THE REGULATORY PROCESS...IN DETAIL Government Acts; Safety requirements
22	APPENDIX B: BIBLIOGRAPHY & RESOURCES
24	APPENDIX C: GLOSSARY OF TERMS

The Crop Protection Institute of Canada is the non-profit trade association representing manufacturers, developers and distributors of plant life science solutions for agriculture, forestry and pest management.



## Canada is a world leader in producing a safe, healthy and abundant food supply.

Our producers are able to provide our food supply and meet the needs of a growing world population by using a range of production tools. Among the important new tools available to producers are crop varieties derived through techniques in plant biotechnology.

The use of plant biotechnology and genetic engineering represents the next stage of evolution in our continuing efforts to improve plants used for the production of food and fibre. This powerful technique offers great potential for agricultural sustainability and the safe production of foods with increased nutritive value, improved flavour, prolonged freshness and even disease-fighting properties.

Scientists, producers and our regulatory officials understand the inherent benefits and power of what this technology represents. As a result, the plant biotechnology industry is regulated by our government to ensure that this technology is used ethically and in a way that safeguards our population and the environment.



*While the tools of this technology are highly specialized and state-of-the-art, the technology itself is a familiar one from a historical perspective:*

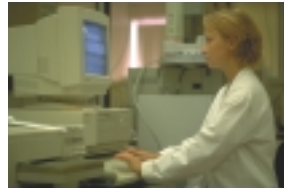
**biotechnology** dates back to pre-Christian times when **yeast** was used in the making of bread and wine; by the 1500s, **fermentation** was applied to make sauerkraut and yogurt; the mid-1800s saw the advent of **pasteurization**; and in the early 1900s, **plant cross-breeding** resulted in hybrid seed corn for expanding agricultural production.

In Canada, plant biotechnology is stringently regulated by the federal government. Our rigorous regulatory system, with its checks and balances, ensures the protection of human health and safety as well as protection of the environment.

In addition, on-going consultation with regulatory officials in other countries around the world ensures that this important science will continue to evolve to help meet the global need for a safe, healthy and abundant food supply while taking great care to protect the environment.

## Government regulatory system

Canada's federal government has guided the application of biotechnology in this country for almost a quarter of a century. This began in 1977, when the Medical Research Council of Canada (now the Canadian Institute for Health Research, CIHR) established *Guidelines for the Handling of Recombinant DNA Molecules and Animal Viruses and Cells*.



In 1990, the federal government created a regulatory framework for biotechnology, recognizing that the practical benefits of biotechnology-derived products must harmonize with the need for protection of the environment and human health and safety. That year, the Medical Research Council worked with the Laboratory Centre for Disease Control to develop *Laboratory Biosafety Guidelines*, the basis for Canada's biotechnology regulations.

### Regulations Based on Scientific Principles

Canada's regulations are thorough, comprehensive and based on objective scientific principles for evaluation.

### The Product-Based Approach

Federal officials use a **product-based approach** for evaluation. This approach places emphasis on the novel 'traits' or attributes introduced to a plant, a food or a food ingredient. This regulatory standard for evaluation is endorsed by experts in the scientific community\* world-wide.

### \* Validity of The Product-Based Approach

■ "The potential occurrence of unintended effects is not unique to the application of recombinant DNA techniques but is also a general phenomenon in conventional breeding."  
— *Report of the Food and Agriculture Organization of the United Nations, in joint expert consultation with the World Health Organization, May 29-June 2, 2000: Safety Aspects of Genetically Modified Foods of Plant Origin*

■ "No strict distinction exists between the health and environmental risks posed by plants genetically engineered through modern molecular techniques and those modified by conventional breeding practices."  
— *U.S. National Research Council press release, May 2000, following the report, Genetically Modified Pest-Protected Plants: Science and Regulation*

■ "I must emphasize that we believe it is the properties of a genetically modified plant, not the process by which it was produced, that should be the focus of risk assessments."  
— *Perry Adkisson, Committee Chair, U.S. National Research Council, Committee on Biotechnology*

■ "Risks associated with biotechnology-derived foods are not inherently different from the risks associated with conventional ones."

"There is no scientifically valid reason to treat possible gene transfer events involving GM organisms differently from those involving naturally occurring organisms...it is the gene and the trait it confers, and whether or not it brings a reproduction or selection advantage to the recipient organism, that are crucial concerns when possible impacts of potential gene transfer are being considered."  
— *Report of the task force for the safety of novel foods and feeds, Organization for Economic Co-operation and Development, May 17, 2000.*

## Regulations governing plant biotechnology

All products derived from plant biotechnology are subject to the same rigorous testing procedures as those produced by conventional methods — with utmost care for human health and safety and environmental protection — to ensure that Canadians receive the safest food supply possible.

Regulatory agencies responsible for products derived from plant biotechnology in Canada are:

- The Canadian Food Inspection Agency (CFIA)
- Health Canada (HC)
- Environment Canada (EC)

Together, these agencies monitor development of plants with novel traits, novel foods and all plants or products with new characteristics not previously used in agriculture and food production.

## REGULATORY AGENCIES: SPHERES OF RESPONSIBILITY

	CFIA	HC	EC		CFIA	HC	EC
<b>Human Health &amp; Food Safety</b> • Approval of novel foods • Allergens • Nutritional content • Potential presence of toxins		x		<b>Safety Assessments</b> (Humans, Animals & the Environment) • Fertilizers • Seeds • Plants • Animals • Animal vaccines • Animal feeds			
		x			x		
		x			x		
		x			x		
<b>Food Labeling Policies</b> • Nutritional content • Allergens • Special dietary needs • Fraud, misrepresentation protection		x		<b>Testing Standards</b> • Guidelines for Testing Effects on Environment			
		x			x		
		x			x		
	x						x

## Novel food regulations are product-based

When reviewing crop varieties or foods containing novel traits, the review is based on their traits, not the process or method used to produce those traits. In fact, several methods can be used to produce novel trait-containing crops or food products, including conventional breeding, mutagenesis and recombinant DNA techniques, also known as genetic engineering. The often-heard phrase 'genetically modified organism' or GMO refers to crop varieties or food products containing traits that were inserted using recombinant DNA technology.

### Environmental Safety

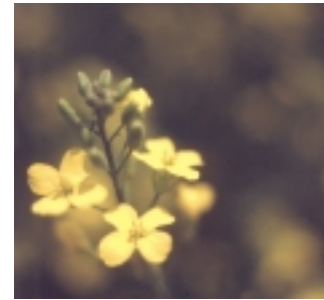
To protect our environment, Canadian scientists working in the laboratory with genetically modified organisms must by law adhere to Canadian Institute for Health Research (CIHR) directives. Also, the Canadian Food Inspection Agency monitors all field trials of novel crop varieties to ensure that the transfer of pollen to neighbouring fields is prevented and that trials comply with a thorough checklist for environmental safety.

### Food and Feed Safety

As part of the registration process, the Canadian Food Inspection Agency and Health Canada review all compiled data, from laboratory reports to production records, in order to evaluate novel crop safety to both humans and animals. This evaluation is based on the principle of **substantial equivalence**, which means that the novel trait-containing crop or food product is compared to the equivalent crop or product that has not been modified.

This process identifies any specific differences between the modified and non-modified versions. Using substantial equivalence\*, scientists determine which specific characteristics of the novel crop or food product require additional scientific risk assessment for potential allergenicity, toxicity and other unintended effects.

\* "In June 2000, an Expert Consultation on Food Derived from Biotechnology concluded that there are [currently] no alternative strategies that would provide a better assurance of safety for GM foods than the approach of applying...substantial equivalence."  
— Canadian Food Information Council, "What About Substantial Equivalence"



Following isolated development and study in scientific laboratories, novel plants that exhibit promising characteristics are transferred to the field for further testing under controlled conditions.

## PRODUCTS DERIVED FROM PLANT BIOTECHNOLOGY: ASSESSMENT RESPONSIBILITIES

	CANADIAN FOOD INSPECTION AGENCY	HEALTH CANADA
<b>Human Health: Safety</b> • Foods • Drugs • Cosmetics • Medical Devices • Pest Control Products		x x x x x
<b>Genetically Modified Crops: Risks</b> • Import Permits • Confined Trials • Unconfined Release • Variety Registration	x x x x	

Once regulatory approval is received, government guidelines stipulate that all novel foods derived through genetic engineering must be labelled to indicate any significantly different nutritional or compositional attributes as well as any possible allergenic components. The law stipulates that labels be accurate, clearly worded and not misleading. Voluntary labelling is also permitted with the same requirement for accuracy and clarity.

#### Sample criteria re: Environmental Safety Canadian Food Inspection Agency

- Is there potential for the GMO to become a weed of agriculture or be invasive of natural habitats?
- Is there potential for gene flows to wild relatives whose offspring may become more weedy or more invasive?
- Does the GMO alter the potential for plant pests?
- Is there potential for impact on non-target organisms?
- Is there potential for impact on biodiversity?

#### Sample criteria re: Human Consumption Health Canada

- How was the modified plant developed?
- Complete product information
- Description of dietary exposure
- Is there potential for nutritional impact on the quality of Canada's food supply?
- Are there any safety concerns related to the GMO?
- Is there potential for causing allergic reaction?



## The regulatory process...in brief: Six steps to safety

**Plants with novel traits (PNTs)** are subject to examination under a six-step regulatory process:

- 1 ■ Scientists working with genetically altered organisms, including the development of PNTs, adhere to Canadian Institute for Health Research directives, as well as the codes of practice of their own institutional biosafety committees. These guidelines protect the health and safety of laboratory staff and ensure environmental containment.
- 2 ■ The Canadian Food Inspection Agency monitors all PNT field trials to comply with guidelines for environmental safety and to ensure confinement, so that the transfer of pollen to neighbouring fields does not occur.
- 3 ■ The Canadian Food Inspection Agency scrutinizes the transportation of seed to and from trial sites as well as the movement of all harvested plant material; the CFIA also strictly controls the importation of all seeds, living plants and plant parts, which includes plants containing novel traits.
- 4 ■ Before any PNT is permitted to be grown outside of confined trials, CFIA scientists must complete an environmental safety assessment focusing on:
  - potential for movement of the novel trait to related plant species
  - impact on non-target organisms (including insects, birds and mammals)
  - impact on biodiversity
  - potential for weed infestations arising from the introduced trait(s)
  - potential for the novel plant to become a plant pest
- The Canadian Food Inspection Agency evaluates all livestock feeds for safety and efficacy, including nutritional value, toxicity and stability. Data submitted for novel feeds include a description of the organism and genetic modification, intended use, environmental fate and potential for the gene (or metabolic) products to reach the human food chain. Safety aspects cover the animal eating the feed, consumption of the animal product by humans, worker safety and any environmental impacts related to use of the feed.

- Health Canada is responsible for assessing food with no previous history of safe use; or food that is manufactured by a new process that causes a significant change in composition; or is derived from an organism genetically modified to possess novel trait(s).

Using *Guidelines for the Safety Assessment of Novel Foods*, Health Canada examines:

- How the food crop was developed, including molecular biological data
- Composition of the novel food, compared to non-modified counterparts
- Nutritional data for the novel food, compared to non-modified counterparts
- Potential for new toxins
- Potential for causing any allergic reaction
- Dietary exposure by the average consumer and population sub-groups (such as children)

**5** ■ Canada's system of registration for newly developed crop varieties ensures that only varieties with proven benefits to producers and consumers are sold. Once approved for use in field trials, varieties are evaluated in regional field trials. Plant varieties produced through biotechnology cannot be registered and sold in Canada until authorized for environmental, livestock feed and food safety.

**6** ■ Once environmental, feed and food safety authorizations are granted, the PNT and feed and food products derived from it can enter the marketplace — but they are still subject to the same regulatory scrutiny that applies to all conventional products in Canada. In addition, any new information arising about the safety of a PNT or its food products must be reported to government regulators who, upon further investigation, may amend or revoke authorization and/or immediately remove the product(s) from the marketplace.

## The regulatory process...in detail

Food, feed and environmental safety are assured in Canada through government regulations that monitor plant biotechnology well before a crop is seeded. *See Appendix A for detailed Safety Requirements*

## Comprehensive regulations for a safe food supply

### The Canadian Perspective

As noted previously, every effort is made through our regulatory system to ensure the safety of our population and the environment. Regulations and scientific protocols ensure that all data attained through registration trials are scrutinized by experts in all facets of plant science, including molecular biology, microbiology, chemistry, toxicology and nutritional science. In addition, several advisory committees have been formed to advise the government on current and future regulatory needs as well as non-scientific aspects of this technology.



- The Canadian Biotechnology Advisory Committee, formed in 1999, advises the government on ethical, social, scientific, economic, regulatory, environmental and health aspects.

- The Canadian General Standards Board was formed to develop standards on voluntary labelling of foods produced through biotechnology.

- Distinguished members from the Royal Society of Canada's expert panel of scientists have prepared a report to help strengthen Canada's regulatory system for future crops.

## International Standards Emphasize Food Safety

Canada's *Guidelines for the Safety Assessment of Novel Foods* is based upon scientific principles developed in consultation with experts in the global scientific community including:

- the Food and Agriculture Organization (FAO) of the United Nations,
- the World Health Organization (WHO), and
- the Organization for Economic Co-operation and Development (OECD).

Canada was among 138 countries to sign a global treaty, the *Cartagena Protocol on Biosafety*, on Jan. 29, 2000, in Montreal. Under this global treaty, procedural guidelines are provided, including those related to the shipment of genetically engineered commodities across international borders.

International standards have been established under the Codex Alimentarius Commission to fulfill the requirements of the Joint Food and Agriculture Organization / World Health Organization Food Standards Programme.



■ Currently, there are 43 plants with novel traits that have received food safety approval in Canada,\* since the first plantings of genetically engineered canola in 1995.

■ More than 5,000 field trials with genetically engineered crops have been conducted in Canada since 1988.

### GENETICALLY MODIFIED CROPS FOOD SAFETY-APPROVED (PARTIAL LIST)

GM CROP	INHERENT NOVEL TRAIT
Canola	- Herbicide tolerance - Hybridization system - Higher quantities of laurate and myristate - High oleic/low linolenic acid
Corn	- Herbicide tolerance - Insect resistance - Hybridization system
Cottonseed	- Herbicide tolerance - Insect resistance - Virus resistance
Potato	- Insect resistance - Virus resistance - Glyphosate selection system
Soybean	- Herbicide tolerance

\* For a complete list of approved genetically engineered products, see the Websites of —

Health Canada: [www.hc-sc.gc.ca/](http://www.hc-sc.gc.ca/)

Canadian Food Inspection Agency: [www.cfia-acia.agr.ca/](http://www.cfia-acia.agr.ca/)

## Assuring safety; minimizing risk

Plant biotechnology has become a familiar topic in the media and with members of the public. Much of the discussion is a result of plant biotechnology being a relatively unknown technology that is not well understood or accepted but is being developed and implemented at an accelerated pace in countries around the world.

As described earlier, scientists involved in developing this new technology must adhere to guidelines and regulations enforced by the federal government, with safety considered a priority every step of the way.

There are several concerns that have been expressed about genetically engineered organisms. The section below identifies some of these concerns and the steps taken to assure safety:

### ■ What is done to ensure that plants with novel traits are not released, in an unintended way, into the environment?

The Canadian Food Inspection Agency (CFIA) assesses plants with novel traits for effectiveness and safety to humans, animals and the environment. Every product is examined for:

- potential of plants to spread and transfer genetic material to other species,
- harm to non-target species,
- disruption of balance in natural ecosystems, and
- impact on biodiversity.

As an example, an environmental assessment is required prior to allowing confined field trials of plants with novel traits (trials that are very specifically designed, monitored and isolated from non-modified crops). A second assessment is also required prior to unconfined release, which is when producers can utilize varieties that include novel traits as part of their normal production program. If the crop is to be used either for food or for feed, a further safety assessment by Health Canada or the CFIA is required before it can be commercially produced.

### ■ What about the safety of novel foods compared to conventional foods?

Currently, novel foods have been evaluated using the principle of substantial equivalence and confirmed by Canadian regulators to be as safe as their conventional counterparts. Also, scientists are continually evolving procedures for the evaluation of novel crop and food products. This will help to ensure that any concerns relative to potential allergenicity are further addressed, even in addition to today's rigorous standards.

### ■ Is the meat from poultry and animals that have been fed grain from novel crops safe to eat?

Research indicates that animals fed crops containing novel traits are no different than those fed conventional feeds. Proteins from novel feeds have not been detected in milk, egg products or meat.

### ■ How safe is biotechnology as a new technique in food production?

Biotechnology has been used in crop and animal breeding for thousands of years, with the goal of producing improved food and health care products. Today, modern biotechnology enables us to develop products more safely and rapidly through genetic engineering. This technology speeds up the process of selecting and breeding desirable traits into plants and eliminates the trial-and-error approach of conventional breeding systems.

Scientific consensus is that the risks associated with food produced through biotechnology are fundamentally the same as with non-modified foods. They are safe to consume and safe for the environment.

To ensure that food produced in Canada is safe and nutritious, our country has one of the most rigorous and respected regulatory approval processes in the world. The Canadian Food Inspection Agency, Health Canada, provincial and municipal authorities all play a role in ensuring the safety of our food. Crops produced through techniques of modern biotechnology must meet the same safety standards as those created by traditional means.



### ■ Are there higher levels of toxins in foods derived from biotechnology?

No, in fact, improving the quality of the crop harvested is one of the benefits of the use of biotechnology in plants. For example, in Bt corn where insect feeding is virtually eliminated, one of the primary pathways for naturally-occurring fungal toxins to enter the grain is significantly reduced. In the future, biotechnology may also help to provide simpler and faster ways to locate naturally-occurring pathogens, toxins and microbial contaminants in our food, ensuring additional levels of safety in our food supply.

### ■ Are there any long-term effects to the environment from using biotechnology?

Current science shows that biotech products are safe for the environment. Every possible precaution is taken in assessing the safety of novel crops through the development and registration processes. Biotechnology is considered to be a key element in the future of agriculture. It will not only allow farmers to produce an abundant food supply for a growing population, but will also enable sustainable production practices to benefit the environment in the long term.

## Potential benefits of plant biotechnology

Within a historical context, plant biotechnology is simply one more method of food production, in much the same way that other, long accepted practices such as fermentation, pasteurization and hybridization have been used for generations.

Plant biotechnology offers many potential benefits. These include:

- The safe production of foods with increased nutritive value, improved flavour, prolonged freshness,
- Foods with disease-fighting properties,
- Enhanced agronomic performance from field to yield,
- Contribution to agricultural sustainability and environmental protection, and
- Improved efficiency at feeding an ever-expanding world population.

### Benefits to Consumers

*(A partial list of approved PNTs appears on page 11; current research is working toward improved traits in the food products as described below. Note that development of these new products is a time-consuming process that can take years between initial testing and final production. Scientific scrutiny and stringent regulatory requirements ensure that all safety and quality concerns are met to the highest degree.)*



■ **Improved nutritional content** — Bananas, peppers, raspberries, strawberries, sweet potatoes

■ **Enhanced flavour** — Tomatoes that soften more slowly and remain on the vine longer for better flavour and colour; sweeter-tasting peppers and peas; soybeans with better flavour

■ **Better quality produce** — Improved eating quality of corn; peppers and tomatoes that withstand shipping and handling

■ **Fresher foods, delayed spoiling** — Bananas and peppers with delayed ripening qualities; strawberries with improved freshness and texture

■ **Healthier processed foods** — Oils (soy, canola) lower in saturated fats, higher stearate content; potatoes less absorbent of cooking oils

■ **Reduced allergens** — Nuts and pulses with fewer allergenic proteins

■ **Disease-fighting properties** — Tomatoes with higher lycopene content, an antioxidant associated with reduced risk of prostate cancer; fruits and vegetables with higher vitamin content to aid disease prevention; garlic containing more allicin for lower cholesterol; oilseeds with higher vitamin E levels to strengthen the immune system; rice with higher vitamin A and iron to help fight anemia and blindness; nutraceuticals — foods that can deliver vaccines and medicines (such as for infants; also helpful in developing countries where medical staff, supplies and refrigeration are scarce)

■ **Economical food** — Tomatoes with a higher solids content mean less waste for food processors, lower prices for consumers

■ **Improved animal feed** — Reduced antinutritional factors; increased protein and amino acid content (canola, corn)



### Benefits to Agricultural Producers

■ **Higher yields with same land base** — Traits such as disease resistance, increased stalk strength and tolerance to environmental conditions such as cool or high pH soils enable farmers to grow more food on existing acres, retaining natural wilderness areas and biodiversity.

- **More options for pest management** — Planting novel crops gives growers more options for managing weed and insect infestations and disease. This is important not only to producing high yields and a quality crop, but also to the success of integrated pest management programs and sustainable agricultural practices.
- **Improved weed control** — Better yields and reduction of weed seeds in harvested crops limit the spread of weeds the following year.
- **Reduced pesticide resistance concerns** — Growing novel crops adds another tool, along with tillage methods, crop rotation and other control products, to managing pests and reducing concerns about pesticide resistance.
- **Greater harvesting flexibility** — Characteristics such as prolonged ripening time can favourably influence harvest timing, offering growers the convenience of spreading their workload and harvesting crops at optimal maturity.
- **Creating opportunities for production** — Biotechnology research into plant tolerance of drought, flood, heat, cold and mineral content in soils could enable crops to be grown in areas that are otherwise not currently suitable. Extending Canada's grape-growing region, for example, could increase crop output and offer opportunities for market growth. Cold-tolerant corn hybrids could provide growers in areas of the prairie provinces with an alternative crop for livestock feed production.

### Benefits to the Environment

- **Soil conservation** — Direct seeding into untilled fields reduces soil erosion. Used in tandem with longer crop rotations, the carbon content in the soil can be increased. At the same time, carbon levels in the air are reduced, which benefits the environment by not contributing to global warming.
- **Environmental protection** — Long-term research is being conducted to find (a) environmentally-friendly alternatives to fossil fuels, and (b) biodegradable plastics that will reduce waste currently disposed of in landfill sites. Through these and other research projects, biotechnology offers great potential for alternative fuels and consumer products that will help safeguard the environment globally.



# The regulatory process...in detail

## CANADIAN GOVERNMENT REGULATIONS GOVERNING REGISTRATION OF PLANTS WITH NOVEL TRAITS (PNTs)

### ■ Novel Food PNTs

Food and Drug Act, Evaluation Division, Health Canada's Food Directorate  
 - *Guidelines for the Assessment of Novel Foods, Volume II*

**INFORMATION REQUIRED:**

- Modification process
- Toxicology data
- Allergenicity data
- Nutritional data
- Laboratory & animal studies

### ■ Novel Feed PNTs

Feed Act Section, Plant Products Division, Canadian Food Inspection Agency  
 - *Guidelines for the Assessment of Livestock Feeds from PNTs (Dir95-03)*

**INFORMATION REQUIRED:**

- Details on novel traits
- Toxicology data
- Nutritional data
- Laboratory animal/livestock feeding trials

### ■ Environmental Safety of PNTs: Unconfined Release

Seed Act, Plant Biotechnology Office, Canadian Food Inspection Agency  
 - *Assessment Criteria for Determining Environmental Safety of PNTs (Dir94-08)*

**INFORMATION REQUIRED:**

- Potential of gene flow
- Potential to become a weed of agriculture
- Impact on biodiversity
- Potential to become invasive of natural habitats

### Other Regulatory Requirements for PNTs

Field-testing PNTs	CFIA Dir2000-07
Import Permits for PNTs	CFIA Dir96-13
Variety Registration	CFIA
Plant Breeders' Rights	CFIA

## Safety Requirements

### A) Common Requirements to Food, Feed & the Environment

#### Development and Production of the PNT

- Characterization of the PNT; compare to conventional or unmodified counterpart
- Of particular concern are PNTs whose parent or vector is from species known to produce toxins
- When possible, avoid markers which may generate safety concerns

#### Host and Donor Organisms

- Information on natural history of donor and host (known toxin production, relationship to toxin-producers, history of safe use)

#### Description of Modification Process

- Information on transformation method
- Information on source, purity and stability of all inserted material
- Identify all regulatory elements, their source and coding sequences
- Map of genetic construct

#### The Modified Host (Plant)

- Assess growth and genetic stability
- Assess potential secondary effects on biochemistry, physiology and secondary metabolism of the host
- For pesticidal properties: mechanism of action, consequences on final composition

#### The Novel Trait

- Characterize and describe activity of the gene product, breakdown products, by-products and metabolic pathways
- Expression level/orientation and location/number of copies
- Induced or constitutive
- Toxicity to humans, predators, parasites, etc.

#### Markers

- Identify
- Characterize any secondary effects
- Information on consequences to the final plant

#### Allergenicity

- Based on history of the host and donor organisms
- Consult agencies



## Safety Requirements

### B) Food Safety: Novel Food Requirements

#### Plants Used as Food

- Detail proposed use, processing, quality control
- Information comparing composition of the novel food to unmodified host (should demonstrate uniformity of the composition of the final product and include analysis/ characterization of gene products)

#### Dietary Exposure

- Detail amount of plant material and/or its products in the finished food
- Will be considered in combination with use pattern and dietary intake to develop overall dietary exposure

#### Nutritional Data: Nutrient Composition

- Proximate composition
- Protein content, amino acid profile
- Composition of total lipids, carbohydrate fraction and vitamins
- Presence of antinutrients
- Storage stability with regard to nutrient degradation



#### Nutrient Composition: Nutrient Bioavailability

- Compare chemical analysis of product and commodity
- Animal studies may be needed to assess nutritional adequacy

#### Toxicology Data

- Triggered by concerns with any of preceding requirements
- Studies on whole food, constituent or specific component
- Necessary when high diet exposure to new or altered component

#### Laboratory Animal Studies

- Address both nutritional and toxicological concerns
- Establish an Acceptable Daily Intake (ADI) for the compound(s)
- Potential to elicit short-term, chronic, carcinogenic, genotoxic, reproductive and teratogenic adverse effects
- Study protocols are defined by the Organization for Economic Co-operation and Development (OECD)



## Safety Requirements

### C) Feed Safety: Novel Feed Requirements

#### Nutrient Composition

- Analysis of feeds from PNTs: crude protein, crude fat and fibre, any crude fibre or Acid Detergent Fibre or Neutral Detergent Fibre
- Statistical comparison of these nutrients is *required*
- Proximate composition
- Protein content, amino acid profile
- Composition of total lipids, carbohydrate fraction and vitamins
- Presence of antinutrients
- Storage stability with regard to nutrient degradation

#### Dietary Exposure

- Detail amount of feed from the PNT in the complete feed

#### Toxicology Data

- Triggered by concerns with any of preceding requirements
- Studies on whole food, constituent or specific component
- Necessary when high diet exposure to new or altered component

#### Laboratory Animal/Livestock Feeding Trials

- May be needed as evidence of nutritional adequacy, including nutrient bioavailability

### D) Environmental Safety: Unconfined Release Requirements

#### Biology & Interactions of the PNT

- Data to determine if PNT could become an agricultural pest, invasive of natural habitats or otherwise harm the environment
- Reproduction and survival biology
- Adaptation to stress
- Compare agronomic characteristics to unmodified counterpart

#### Agricultural Practices

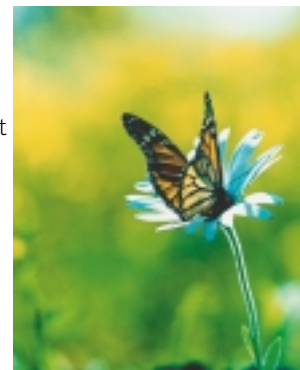
- Release site of PNT
- Will PNT be outside normal growing region or habitat?
- Will cultivation practices change? If yes, describe.
- Will volunteers of PNT cause altered cultivation practices?

#### Potential Environmental Effects from Introgression

- Where potential for gene flow to related species exists, detail consequences of the novel gene introgression into those species and resulting expression

#### Efficacy & Resistance Management

- Where not regulated by another agency (i.e. insect resistance)



## APPENDIX B: Bibliography & Resources

Bilmer, Bart; *CFIA Role in Agricultural Biotechnology*, Canadian Food Inspection Agency, Office of Biotechnology

*Biotechnology and Food Safety*, Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, Rome, 1996.

[www.fao.org/waicent/faoinfo/economic/esn/biotechn/tabconts.htm](http://www.fao.org/waicent/faoinfo/economic/esn/biotechn/tabconts.htm)

*Biotechnology Training Workshop* manual, Crop Protection Institute of Canada, March 2000

Canadian Environmental Protection Act [www.ec.gc.ca/ccebl/eng/biohome.html](http://www.ec.gc.ca/ccebl/eng/biohome.html)

Canadian Food Information Council, three articles on *Agri-food biotechnology*:

(1) *What About Antibiotic Resistance Marker Genes?* (2) *What About Food Safety and Allergens?* (3) *What About Substantial Equivalence?*

Canadian Food Inspection Agency, Office of Biotechnology [www.cfia-acia-agr.ca/](http://www.cfia-acia-agr.ca/)

Environment Canada [www.ec.gc.ca/](http://www.ec.gc.ca/)

*Food Allergens*, Institute of Food Science & Technology, June 23, 1999.

[www.ifst.org/hotspot19.htm](http://www.ifst.org/hotspot19.htm)

*Food Allergy Myths and Realities*, International Food Information Council, Nov./Dec. 1997.

[www.ificinfo.health.org/insight/novdec97/foodallergy.htm](http://www.ificinfo.health.org/insight/novdec97/foodallergy.htm)

*GM Plants and Antibiotic Resistance Genes*, The Food Safety Network, Sept. 28, 1999.

[www.plant.uoguelph.ca/safefood](http://www.plant.uoguelph.ca/safefood)

Health Canada, Health Protection Branch, Office of Food Biotechnology [www.hc-sc.gc.ca](http://www.hc-sc.gc.ca)

Industry Canada, Canadian Biotechnology Strategy Secretariat [www.strategis.ic.gc.ca/cbs](http://www.strategis.ic.gc.ca/cbs)

International Food Biotechnology Council and ILSI Allergy and Immunology Institute, (1996). *Allergenicity of Foods Produced by Genetic Modification*, E. Clydesdale, (Ed.). *Critical Reviews in Food Science and Nutrition*, Vol. 36, CRC Press, N.Y., U.S.A.

McIntyre, Karen E.; *The Regulation of Biotechnology-Derived Foods in Canada*, Health Protection Branch, Health Canada

RABNA, *Overview of Canadian Regulations*, April 1999

The Royal Society of Canada [www.rsc.ca](http://www.rsc.ca)

*Safety Aspects of Genetically Modified Foods of Plant Origin*, Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, Geneva, 2000.

[www.who.int/fsf/gmfood/fao-who\\_consultation\\_report\\_2000.pdf](http://www.who.int/fsf/gmfood/fao-who_consultation_report_2000.pdf)

*Safety Evaluation of Foods Derived Through Modern Biotechnology: Concepts and Principles*, Organization for Economic Co-operation and Development (OECD), 1993.

[www.oecd.org/dsti/sti/s\\_t/biotech/prod/modern.htm](http://www.oecd.org/dsti/sti/s_t/biotech/prod/modern.htm)

### Additional Website Resources: Biotechnology Topics

AgBioS [www.agbios.com](http://www.agbios.com)

AgBioForum [www.agbioforum.org](http://www.agbioforum.org)

AgBioWorld [www.agbioworld.org](http://www.agbioworld.org)

AGCare (Agricultural Groups Concerned About Resources and the Environment) [www.agcare.org](http://www.agcare.org)

Agricultural Institute of Canada [www.aic.ca](http://www.aic.ca)

Agriculture and Agri-Food Canada Communications Branch [www.agr.ca](http://www.agr.ca)

Ag-West Biotech Inc. [www.agwest.sk.ca](http://www.agwest.sk.ca)

Alberta Research Council [www.arc.ab.ca](http://www.arc.ab.ca)

Alliance for Better Foods (U.S.A.) [www.betterfoods.org](http://www.betterfoods.org)

BioAtlantech [www.bioatlantech.nb.ca](http://www.bioatlantech.nb.ca)

BIOTECCanada [www.biotech.ca](http://www.biotech.ca)

Biotechnology Industry Organization [www.bio.org](http://www.bio.org)

Canadian Council of Grocery Distributors [www.cfta.ca/](http://www.cfta.ca/)

Canadian Federation of Agriculture [www.cfa-fca.ca](http://www.cfa-fca.ca)

Canadian Federation of Independent Grocers [www.cfig.ca/](http://www.cfig.ca/)

Canadian General Standards Board [www.pwgsc.gc.ca/cgsb/](http://www.pwgsc.gc.ca/cgsb/)

Canadian Produce Marketing Association [www.cpma.ca](http://www.cpma.ca)

Canola Council of Canada [www.canola-council.org](http://www.canola-council.org)

Consumers' Association of Canada [www.consumer.ca](http://www.consumer.ca)

Convention on Biological Diversity [www.biodiv.org](http://www.biodiv.org)

Council for Biotechnology Information [www.whybiotech.com](http://www.whybiotech.com)

Crop Protection Institute of Canada [www.cropro.org](http://www.cropro.org)

Dietitians of Canada [www.dietitians.ca](http://www.dietitians.ca)

Fisheries and Oceans Canada Communications Branch [www.dfo-mpo.gc.ca/](http://www.dfo-mpo.gc.ca/)

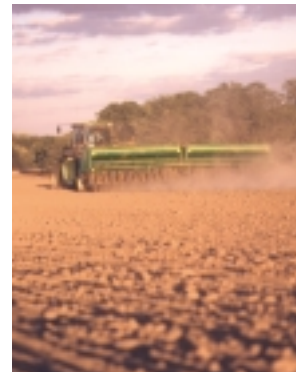
Food & Consumer Products Manufacturers of Canada [www.fcPMC.com](http://www.fcPMC.com)

Food Biotechnology Communications Network (FBCN) [www.foodbiotech.org](http://www.foodbiotech.org)

Genetic Engineering News [www.genengnews.com](http://www.genengnews.com)

Lumen Foods [www.lumenfds.com/bseries.htm](http://www.lumenfds.com/bseries.htm)

Ontario Agri-Food Technologies [www.oaft.org/](http://www.oaft.org/)



## Glossary of Terms

- biodiversity — The variety of life and its processes. Biodiversity includes all life forms, from one-celled fungi, protozoa and bacteria to complex organisms such as plants, insects, fish and mammals. It includes processes, pathways and cycles that link living organisms into populations, ecosystems and landscapes. This variety of life is dynamic and constantly changing and evolving. It is sensitive to perturbations that may result from human activity. Biodiversity is generally recognized on three levels:
  - genetic diversity — The variety of genetic building blocks found among individual representatives of a species;
  - species diversity — The variety of living organisms found in a particular place; and
  - ecosystem diversity — The variety of species and ecological functions and processes, both their kind and number, that occur in different physical settings.
- biotechnology — The application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms (*Canadian Environmental Protection Act*).
- confined trial — System of growing test plots of novel crops (e.g.) in a manner that prevents transfer of pollen to neighbouring fields and meets other regulatory requirements for experimentation under controlled conditions.
- DNA — Deoxyribonucleic acid: the molecule that contains genetic information and carries hereditary information from one generation to the next.
- genetic construct — As in 'transgene': A 'package' of genetic material (i.e. DNA) that is inserted into the genome of a cell via gene splicing techniques.
- genetic engineering — Inserting genes from one source into another using molecular techniques.
- genome — The genetic information particular to individuals.
- GMO — Genetically manipulated organism, or genetically modified organism
- introgression — The incorporation of transgenes (genes from transgenic organisms) into a wild type's genome.
- marker (genetic marker) — A trait that can be observed to occur or not to occur in an organism such as a bacterium or plant.
- mutagenesis — As in 'site-directed mutagenesis' (SDM): a technique that can be used to make a protein that differs slightly in its structure from the protein that is normally produced (by an organism or cell).
- novel trait — New characteristic or attribute scientifically introduced to a plant, a food or a food ingredient
- nutraceutical — Refers to either a food or portion of food (e.g. a vitamin, essential amino acid, etc.) that possesses medical or health benefits (to the organism that consumes the nutraceutical).
- PNT — Plant with novel trait
- recombinant DNA (rDNA) — Artificially splicing pieces of DNA together, usually using specialized enzymes. Synonymous with 'genetic engineering'.
- substantial equivalence — The comparison of a novel food product (e.g.) to an equivalent product with conventional characteristics. A system of evaluation applied to determine specific characteristics of a novel food (e.g.) that require scientific risk assessment of potential for allergenicity, toxicity and other unintended effects.
- transformation — The process in which free DNA is transferred directly into a competent recipient cell. The direct transfer of genetic material from donor to recipient. The acquisition (e.g. by bacteria cells) of new genetic markers (new traits coded for by the new DNA) via the process of transformation.
- transgenic organism — An organism whose gamete (sperm/egg) cells contain genetic material originally derived from an organism other than the parents or in addition to parental genetic material.
- unconfined release — The stage of growing newly developed crops (e.g. plant types) after all regulatory requirements have been met in confined trials (see *above*) and the seed, plant or crop is evaluated and confirmed as safe under all required aspects.
- wild type — The normal form of an organism as it is ordinarily encountered in nature.

