Agriculture and Agri-Food Canada | Agriculture et Agro-alimentaire Canada

Food Production and Inspection Branch | Direction générale de la production et de l'inspection des aliments
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Your file / Votre référence

Our file / Notre référence

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January 1997

Dear Sir/Madam:

Thank you for your interest in biotechnology. In response to numerous inquires received by the Biotechnology Strategies and Coordination Office of Agriculture and Agri-Food Canada, we have assembled the following general information package entitled *"Biotechnology in Agriculture"*.

In addition to providing readers with an introduction to biotechnology and the related terminology, we have also enclosed a brief description of the work of Agriculture and Agri-Food Canada in ensuring the safety and efficacy of the various agricultural products produced by biotechnology. Given the widespread use of biotechnology in agriculture, information specific to various products of biotechnology, namely plants with novel traits, biofertilizers, biofeeds, and veterinary biologics have also been provided.

We hope this information package will serve as an introductory guide to biotechnology in agriculture. Should you require further information, please contact the Biotechnology Strategies and Coordination Office. This office has been established to serve as a single-window for biotechnology information and related activities within the department. This involves responding to biotechnology-related issues, and the development of biotechnology regulations and policies.

You can contact the Biotechnology Strategies and Coordination Office by calling the **Biotechnology Information Line** by **phone** at (613)952-8000 ext. 4229, **fax** (613) 941-9421, **mail** at 59 Camelot Drive, Nepean, Ontario K1A 0Y9
http://www.agr.ca

Sincerely,

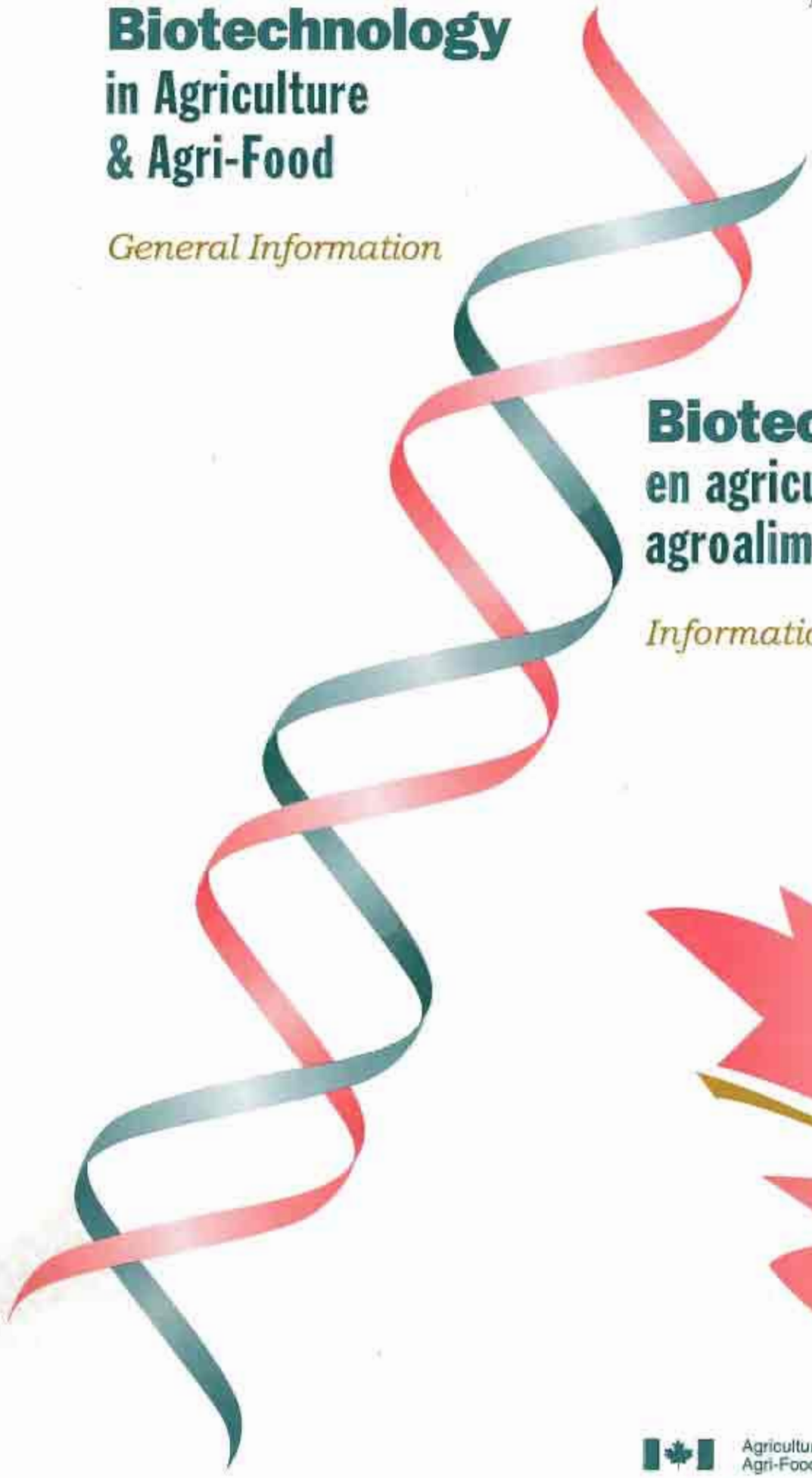
Margaret Kenny
Associate Director

Biotechnology in Agriculture & Agri-Food

General Information

Biotechnologie en agriculture et agroalimentaire

Informations générales



Agriculture and Agri-Food Canada
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BioInfo

Regulation of Agricultural Products • Réglementation des produits agricoles

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BioInfo

Regulation of Agricultural Products • Réglementation des produits agricoles

BIOTECHNOLOGY, AGRICULTURE AND REGULATION

Biotechnology is an umbrella term that covers a broad spectrum of scientific tools. Biotechnology takes advantage of living organisms, or their parts, to produce products. This discipline is not new, and describes traditional activities, such as making bread, yogurt and cheese, to more complex activities such as the production of antibiotics, vaccines and enzymes. What is new, is the refinement and precision that newer technologies such as genetic engineering provide to utilize certain aspects of biology. **Genetic engineering** involves the precise transfer of specific characteristics or genetic information from one organism to another. Using genetic engineering, scientists have learned how to remove or change the hereditary units (genes) of organisms, thus altering their characteristics. When these advanced technologies are combined with traditional methods, they provide a way to develop plants, animals and foods with novel attributes.

Some of the **benefits** of biotechnology to Canadians are the production of newer and better products that may be lower in price than their traditional counterparts. Biotechnology will also result in more rapid diagnosis and treatment of certain diseases. In the agricultural sector, there will be superior food products and healthier agricultural plants and animals. Agriculture and Agri-Food Canada is working with the public and industry to develop the best and safest ways of benefitting from biotechnology. The **purpose of this document** is to provide a brief description of the work of Agriculture and Agri-Food Canada in ensuring the safety and efficacy of the various agricultural products produced by biotechnology.

The **purpose of regulation** is to set standards for the safety and efficacy of new products for the protection of human, animal and environmental health. Regulations also maintain international quality and safety standards that facilitate trade. The role of the regulator is to evaluate products for safety and efficacy based on standards established under these regulations.

THE ROLE OF AGRICULTURE AND AGRI-FOOD CANADA

While Agriculture and Agri-Food Canada is the **lead agency** responsible for the regulation of agricultural products, it is not the only agency regulating agricultural products. **Health Canada** reviews novel products for food safety and sets data requirements for the assessment of the safety of all foods. It also identifies hazards, and specifies the standards that food inspectors observe. The **Pest Management Regulatory Agency, Health Canada** (PMRA), assumed responsibility for registration and regulation of all pest control products in April, 1995. It evaluates any product having pesticidal properties. **Environment Canada** works with regulatory agencies to help develop standards required for products that may affect the environment.

There are a wide range of products regulated under the authority of Agriculture and Agri-Food Canada. These include agri-food products, veterinary vaccines and biologics, plants and animals, fertilizers, livestock feeds and seeds. The regulatory authorities for these products are contained in Acts and Regulations. Whether the product has been produced by conventional methods or by advanced biotechnology, the general information requirements are the same. The Department strives to ensure that these regulatory requirements are consistent with those of recognized international scientific groups and with other national governments. This assists in the maintenance of quality and safety of agricultural products that are traded internationally.

GUIDELINES FOR EVALUATING PRODUCTS

Product evaluators at Agriculture and Agri-Food Canada are either in the process of developing **guidelines** or guidelines have been developed that are consistent with those used by international authorities. Some of the principles that are followed in Canada are:

1. To **build on current legislation** where possible, rather than creating new legislation to govern new products which are developed.

2. To focus on **product characteristics,** rather than the method of production. At the present time, all products developed through genetic engineering (recombinant products) are assessed for unintended effects that may result from the introduction of foreign genes or DNA sequences.

3. To conduct **evaluations for each product on the basis of its unique characteristics.** This becomes important with novel products that may be regulated for the first time. For these products, government evaluators may limit applications or uses of the product, until more experience is gained.

4. To establish **appropriate safety levels based on the best scientific information.** Safety is defined, not as the complete absence of risk, but rather as the level of

"acceptable risk". Scientific information is increasing continually and regulators must build their regulatory approach on this changing information base. This results in more efficient assessment as similar products are developed over time. This could also mean expanded uses and additional applications for a product as new information becomes available.

METHODS OF CONTROL

There are a vast array of agricultural products that are being developed or imported into Canada. Depending on the type of product, where it comes from and the intended use, different control measures are used. All potentially hazardous **imported commodities** are controlled through measures that reduce the possibility of the introduction of agricultural pests and diseases. Examples of such controls include the use of permits, testing, quarantine or inspection. Products which may pose a hazard to the environment are subjected to an **environmental safety assessment.** All **new** products, whether produced by traditional means or derived through genetic engineering would be included in this category.

Government evaluators, in collaboration with industry and university experts, have already developed, or are in the process of developing guidelines for each class of product, which assist new product developers that are still in the research stage. These **guidelines** ensure that adequate and appropriate information will be presented by the product developer, so that potential hazards can be identified early in the process. Government regulators will use this information, and often will request additional data in order to be certain that new products meet acceptable safety standards.

Based on the product definition, specified protocols will be applied which govern the conditions of release into the environment. Frequently, field testing will be performed on a confined basis. In certain cases, such as for contract growing, certain confinement conditions may be either imposed or relaxed depending on the characteristics of a novel product. **Scientific information** is gathered during the development phase, and provided to evaluators as required. Information is produced during research trials conducted under laboratory conditions and field testing of new plants or animal testing in the case of veterinary biologics and livestock feeds.

Depending on the product, prior to commercial production, **approval, registration or licensing** might be required. This is done in the case of biofertilizers, certain plant species, livestock feeds and veterinary biologics. Once the product has been approved, **quality assurance monitoring** of the products, as in the case of veterinary biologics or **inspecting activities**, conducted to assure food safety, will be performed. All of these regulatory control measures are taken to ensure the quality, safety and efficacy of the product. **Labelling** is an important means to inform the consumer about product facts. Discussions are underway concerning the various ways to communicate information on products that are derived through genetic engineering.

SPECIFIC PRODUCT GROUPS

The existing legislation and the products that are regulated under it are outlined in Table I. This table gives examples of products derived from biotechnology for each of the main product groups. Some of the key control procedures that apply are also listed. Let's consider the classes of agricultural products that are derived from biotechnology, and look at some of the ways that Agriculture and Agri-Food Canada evaluates their safety:

1. **Plants with novel traits** are one of the more active areas of research using both conventional and genetic engineering (recombinant) methods. Crop and horticultural plants are included in this group and are regulated under the *Seeds Act* and the *Plant Protection Act*. Risk assessments are conducted on plants with novel traits, and consider plant biology, the new characteristics, the potential environmental impact and how the plant might affect human or animal safety. In evaluating the application, regulators may request data generated from controlled field trials.

2. **Biofertilizers** include rhizobia, other types of free-living nitrogen-fixing bacteria and some fungi. Recombinant products are not yet commercialized in Canada, and the research focus is on genetically improved rhizobia. The *Fertilizers Act* requires that products must be registered and specifies labelling requirements.

3. **Feeds** are defined as any substance or mixture of substances manufactured, sold, or represented for use for consumption by livestock, for providing the nutritional requirements of livestock, or for the purpose of preventing or correcting nutritional disorders of livestock. Biofeeds include microbial products (both viable and non-viable), plants with novel traits and fermentation products such as enzymes, biomass proteins, amino acids, vitamins and flavouring ingredients.

4. **Veterinary Biologics** include animal vaccines, toxins, antisera and diagnostic kits. Currently there are two classes of recombinant products: those inactivated products prepared from genetically engineered organisms; and those products containing live recombinant organisms. The *Health of Animals Act* requires extensive testing, limited field trials with target species, and ongoing quality assurance monitoring of the manufacturer. Licensing is also required. Some categories of veterinary biologics are regulated by Health Canada under the *Food and Drugs Act*, because these are prescribed substances, such as hormones e.g. somatotropin.

5. **Food inspection** is a broad area which covers meat, dairy products, eggs and egg products, fruits, vegetables, honey and maple products. Agriculture and Agri-Food Canada provides inspection programs that enforce safety standards, review labelling, and monitor the product quality and marketing. Genetically engineered foods will require a full risk assessment and Health Canada will establish safety standards and specify labelling requirements for safety under the *Food and Drugs Act*.

ADDITIONAL INFORMATION

This document provides an overview of how agricultural products are regulated. If you require more information, please contact the **Biotechnology Information Line at (613) 952-8000 (4229).** Additional bulletins are available on the following topics:

Science for Better Living provides information for the public concerning biotechnology-its benefits and the ways it is regulated.

Questions and Answers on Agriculture and Agri-Food Canada's Acts and Regulations provides answers to commonly asked questions concerning the regulation of agricultural products.

Glossary of Terms provides easy to understand definitions of terms used in regulation of agricultural products produced by biotechnology.

The Safety-Based Approach to Regulation of Agricultural Products assists product developers in determining when to submit their products for regulatory review. It also describes the steps that government evaluators follow when determining if hazards exist, and how to assess their effect.

Biotechnology, Agriculture and Regulation - provides an overview of how agricultural products are regulated. The various commodities are briefly discussed, and the acts are named.

This information is also available via the World Wide Web. Our **Internet** address is as follows: ***http://aceis.agr.ca/fpi/agbiotech/home.html/***

TABLE I: AGRICULTURAL PRODUCTS, LEGISLATION AND THE REGULATORY CONTROLS THAT ARE APPLIED, WITH PARTICULAR EMPHASIS ON PRODUCTS DERIVED FROM BIOTECHNOLOGY

PRODUCT	ACT	BIOTECH PRODUCTS	CONTACTS
Agri-food products (meat, dairy, eggs, fruits, vegetables, honey, maple products)	*Meat Inspection Act* *Canada Agricultural Products Act*	no biotech foods to date, but genetically engineered chymotrypsin, used to make cheese	Agriculture and Agri-Food Canada Food Production & Inspection Science & Technology Services Tel: 613-952-8000
Livestock feeds, additives	*Feeds Act*	biofeeds	Agriculture and Agri-Food Canada Food Production & Inspection Feeds Section, Plant Products Division Tel: 613-952-8000
Fertilizers, supplements	*Fertilizers Act*	biofertilizers	Agriculture and Agri-Food Canada Food Production & Inspection Fertilizer Section, Plant Products Division Tel: 613-952-8000
Plants	*Seeds Act* *Plant Protection Act*	plants with novel traits plants with novel traits and genetically engineered micro organisms	Agriculture and Agri-Food Canada Food Production & Inspection Plant Biotech Office, Plant Products Division Tel: 613-952-8000
Animals, veterinary biologics	*Health of Animals Act*	vaccines produced by or containing genetically engineered organisms	Agriculture and Agri-Food Canada Food Production & Inspection Veterinary Biologics & Biotechnology Section, Animal Health Division Tel: 613-952-8000

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Regulation of Agricultural Products • Réglementation des produits agricoles

BIOTECHNOLOGY IN AGRICULTURE AND AGRI-FOOD CANADA

WHAT IS BIOTECHNOLOGY?

The term "biotechnology" came into popular use in the 1970s after the development of genetic engineering techniques that allowed the modification of the genetic material in living cells. In simple terms, biotechnology involves using biological processes to produce substances beneficial to agriculture, the environment, industry and medicine. In fact, we have used biotechnology to make everyday products for thousands of years. The manufacture of antibiotics, cheese and wine, for example, relies on the activity of various fungi or bacteria.

Since the earliest days of agriculture, civilizations have tried to develop new plant and animal breeds that would be more useful or hardier. With new techniques of biotechnology, such as genetic engineering, scientists have more exact methods for breeding better livestock and crop varieties, as well as for improving foods, feeds, fertilizers, veterinary vaccines and pest control agents.

WHY USE BIOTECHNOLOGY?

Through new biotechnology techniques, scientists can modify the characteristics of organisms for our benefit in a more controlled way than with traditional practices. When using traditional breeding practices, it is often necessary to grow many generations of plants and animals to select for desired characteristics. It can take up to 12 years, for example, to breed disease-resistant plant varieties. With the new techniques of biotechnology, this time can be reduced considerably. These techniques allow the transfer of genes to be carried out in a very controlled way, so that only one or a few desirable traits are transferred at a time. Furthermore, these technologies can be used to introduce desirable traits from outside the species, something that is not possible with traditional breeding methods.

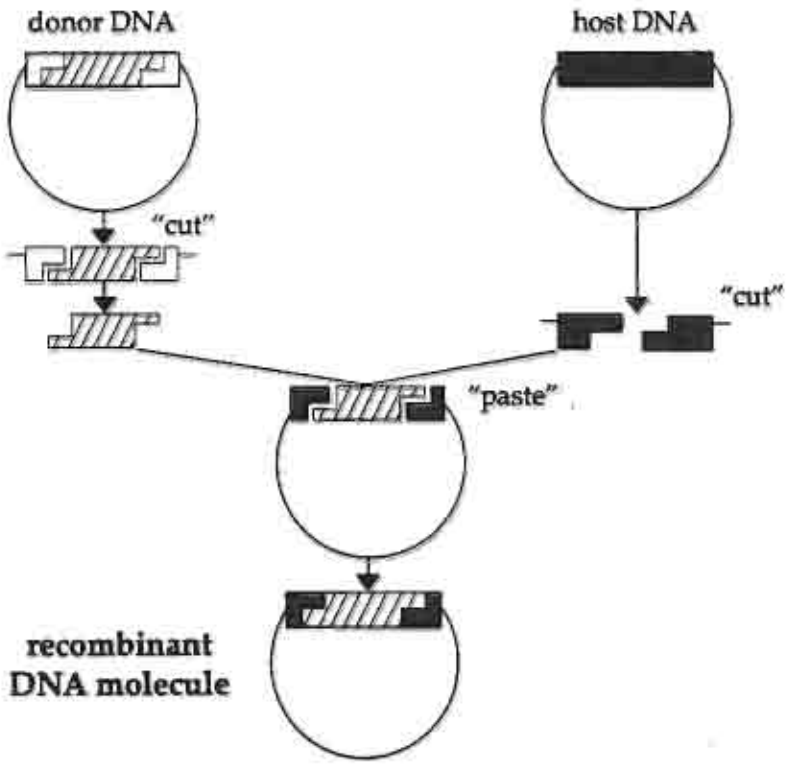
HOW DOES BIOTECHNOLOGY WORK?

Biotechnology, through genetic engineering, is carried out on the genetic material of a cell. If we examined a cell under a high-powered microscope, we would see long, thread-like structures called chromosomes. These chromosomes, composed of DNA (deoxyribonucleic acid), are organized into sections called genes. Genes control the production of particular proteins, and proteins, in turn, determine the characteristics of an organism. In some cases, a gene may govern one particular trait, such as an organism's resistance to disease, while in other cases, characteristics may be determined by many genes. It was the understanding of DNA that paved the way for genetic engineering. The knowledge gained has allowed researchers to transfer genes between the cells of different organisms.

CUT AND PASTE METHOD

The actual transfer of a gene is carried out in a complex "cut and paste" procedure. Specialized enzymes are used to "cut" or remove a specific gene from one organism's DNA, and then to "paste" or slice that gene back into the DNA of another organism. (See diagram below). The gene can be inserted into another organism through a variety of techniques, depending upon the characteristics and properties of the recipient organism, and whether it is animal, bacteria, or plant.

"Cut and Paste" Procedure



Some of the genetic engineering techniques used to modify organisms are:

In animals

A technique called micro-injection is the method often used to produce genetically engineered or transgenic animals. Through this technique, a very fine needle is used to inject a solution of DNA molecules containing genes that carry desired characteristics such as disease resistance into animal cells, usually at the embryo stage. The genes are incorporated into the animal cells' genetic material, and the cells begin to express the characteristic determined by the new gene. Several years ago, a widely publicized "super mouse" was produced by injecting the gene for growth hormone into mouse embryo cells. Mice containing this gene grew to be significantly larger than those without it. Applying this micro-injection technique could have potential benefits for agriculture as well.

In bacteria

In certain bacteria, small naturally occurring circular segments of DNA called plasmids are found, which can be used for genetic engineering. Plasmid DNA can easily be taken outside of the bacterial cell, modified with the addition of a new gene, and placed back into the cell. With the new gene, the bacterial cell can now manufacture the product of this gene as its own. Because bacteria reproduce very rapidly, large volumes of bacteria containing the modified plasmid can be used to produce commercially significant quantities of a gene product, such as a food additive or an animal vaccine, in short periods of time.

In plants

Plant cells have tough outer walls, making the delivery of genes into the plant cells a little more challenging than is the case for bacteria. There are two main techniques by which this process is carried out.

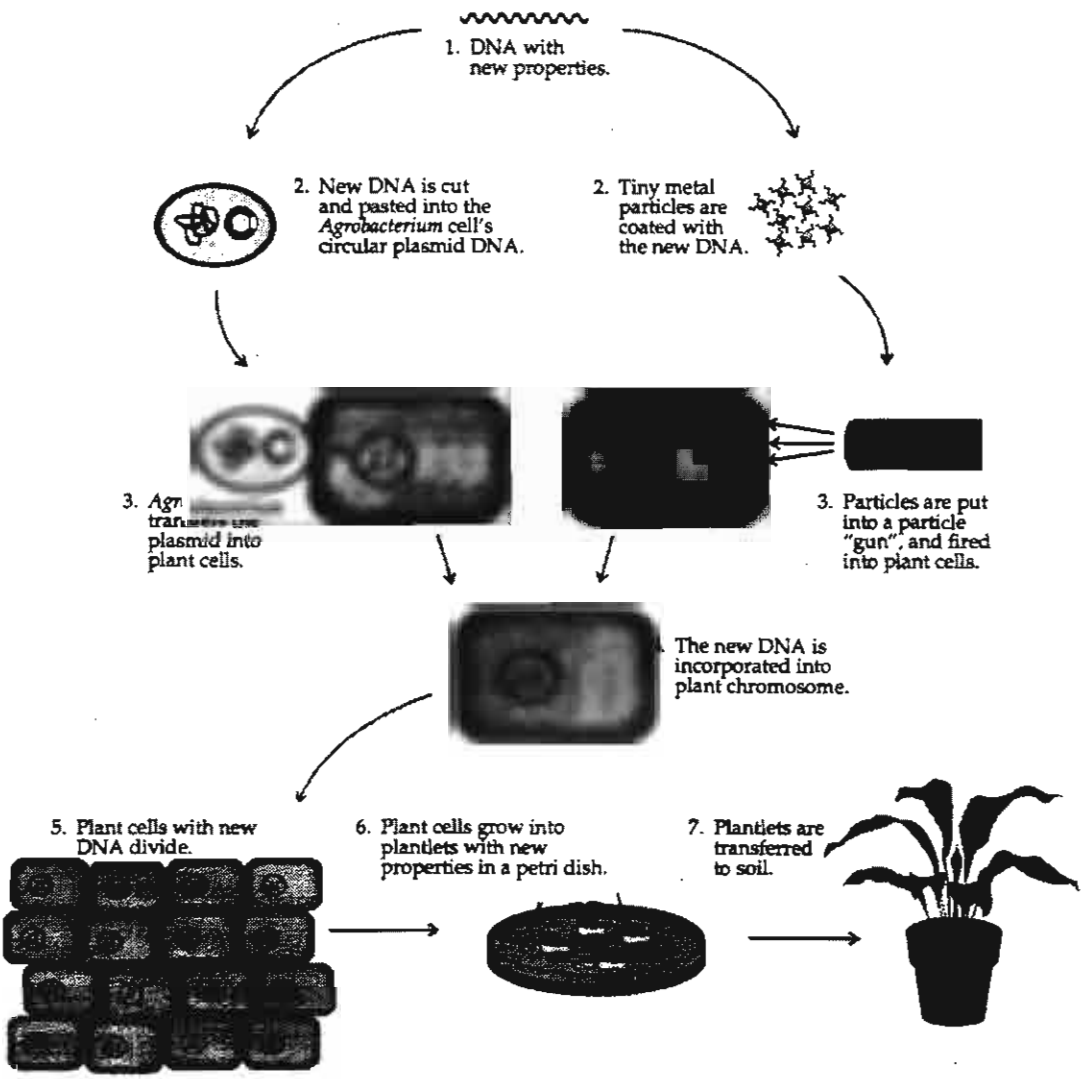
The first of these involves the use of a modified species of bacterium called *Agrobacterium*. In nature, the *Agrobacterium* invades a plant, then infects it with a segment of its own DNA that "codes" for the development of crown gall disease. This DNA is incorporated into the plant's DNA and the plant becomes diseased with crown gall. When using *Agrobacterium* to genetically modify plants, those disease-causing parts of the *Agrobacterium*'s DNA are removed. They are replaced with genes that carry desired characteristics (such as improved nutritional value) by the cut and paste procedure.

The *Agrobacterium* is then allowed to invade plant cells, and introduce the new gene. The full plants grown from these plant cells exhibit the newly incorporated characteristic conferred by the new gene. *Agrobacterium*, therefore, is a convenient delivery system by which new characteristics can be passed on to plants.

PARTICLE GUN METHOD

The second technique used to deliver genetically engineered DNA into plants is the DNA "particle gun" method. Tiny metal particles coated with genes of agronomic importance, such as improved nutritional value, are put into a particle gun and fired directly into plant cells. These genes are incorporated into the plant cells' DNA, and the cells are then grown into full plants. The new characteristic is thereafter present in the whole plant.

Two Methods for Delivering DNA into Plant Cells



NEW APPLICATIONS OF BIOTECHNOLOGY

Using new techniques of biotechnology, scientists will continue to build on current research to improve existing products and processes, and to generate many new ones. They will continue to take traditional agricultural practices and food production one step further.

Many applications of genetic engineering have concentrated on the transfer of valuable agricultural traits such as disease and pest resistance. One focus is on improving the natural pest resistance of broad-leaved crops such as soybeans and canola. Much work has also been done to improve consumer products and to increase the nutritional quality of food and feed grains. Here are several other examples of the new avenues opened by biotechnology:

Tomatoes which can ripen on the vine and then maintain their flavour and texture for several weeks with a reduced spoilage rate. This allows time for transport, retail display, and a longer storage period in the consumer's home.

Potato plants which are resistant to the Colorado Potato Beetle. This form of crop protection can provide an environmentally sound alternative to aerial spraying of chemical pesticides.

Micro-organisms and microbial products using recombinant DNA technology to develop animal vaccines e.g. prevention of shipping fever (pneumonia) in cattle; or diagnostic kits which can detect antibodies to or the presence of the actual disease organism in animals.

Other types of products could include:

- a potato developed, through genetic engineering, which will absorb less oil when cooked, or animals with leaner meat, thereby addressing the consumer's choice for reduced calorie foods.

- bacteria which take nitrogen from the air and convert it to a form usable by growing plants (legumes). These bacteria can be genetically engineered to improve the nitrogen fixation process and so help farmers to reduce the amount of nitrogen fertilizer they apply.

CONCERNS AND ISSUES

Agricultural crops are at constant risk from insects, disease, and other environmental stresses that cause tremendous losses in yields and hardship to our farming communities. Current research in biotechnology is addressing these issues. Areas of biotechnology such as genetic engineering offer many benefits that could, for example, help to address concerns about pests and crop losses.

However, despite the potential benefits, biotechnology has raised questions and concerns. Some people have expressed concerns about the safety of these new technologies, especially the possibility of genetically modified organisms adversely affecting plants and other organisms outside the lab. To deal with these concerns, scientists and government regulators have taken steps to carefully assess all new products of biotechnology. Before a product can be released into the environment or made commercially available, it must be evaluated for safety and effectiveness, based on data collected from extensive testing.

SAFEGUARDS THROUGH REGULATION

In January 1993, federal regulatory departments agreed on principles for a more efficient and effective regulatory framework for Canadian biotechnology. Agriculture and Agri-Food Canada, along with other federal departments, including Environment Canada, Health Canada, Human Resources Canada, and Fisheries and Oceans, regulate products of biotechnology in order to protect human health, animal health, and the environment. Assessments are carried out to determine risk, if any, before products of biotechnology are tested in the environment, and before commercialization.

Agriculture and Agri-Food Canada assesses the traits of the final products rather than the actual processes of biotechnology. The approach taken under the regulatory framework is that genetically engineered organisms are not fundamentally different from traditionally bred organisms. This means that each new product is evaluated on its own merits and characteristics, and not on the method of its production. At the same time, however, the processes used are carefully considered. In fact, because of the precise nature of the new techniques of biotechnology, we may actually have more knowledge about genetically engineered organisms than those that occur naturally.

October 1996

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Regulation of Agricultural Products • Réglementation des produits agricoles

FOOD DERIVED FROM BIOTECHNOLOGY

FOOD AND BIOTECHNOLOGY

Biotechnology is not new. Cheese, bread and antibiotics are examples of traditional products produced from biotechnology. Biotechnology is the applied use of living organisms or their parts to produce new products.

What is new is the ability of scientists to work more directly with genes to shorten the process of conventional breeding. Genes are the basic unit of heredity and each gene is responsible for a particular characteristic. Using **genetic engineering** techniques, scientists can insert a specific gene into an organism, allowing it to display the new characteristic, with more precise control over the potential effects.

There are many benefits to products derived from biotechnology, but because these products are new, they will be subjected to scientific scrutiny in order to ensure that consumer and environmental safety is protected.

WHOSE RESPONSIBILITY IS IT?

- Three federal departments share the responsibility for food safety: **Health Canada, Agriculture and Agri-Food Canada and the Department of Fisheries and Oceans.**

Health Canada is the lead agency in ensuring food safety. This is done by:

- Establishing health, safety and quality standards for food processing establishments;
- Evaluating the safety of additives, pesticides, animal drugs, chemical residues and microbial pathogens;
- Inspecting, monitoring and testing to ensure adherence to safety standards; and
- Developing Novel Food Guidelines (September 1994), which will lay out the data requirements for companies wishing to have novel foods approved for safety.

Agriculture and Agri-Food Canada inspects and monitors the safety of imported food and that produced in registered establishments. Agri-food products include meat and meat products, dairy products, shell and processed eggs, fresh and processed fruits and vegetables, honey and maple products. The Department:

- Coordinates agri-food information requirements with other departments;
- Inspects and registers facilities, food animals, and licensed fruit and vegetable dealers;
- Monitors quality, grade packaging and labelling practices against national standards;
- Designs and conducts laboratory testing programs to ensure that agricultural products meet safety standards; and
- Certifies products for import or export trade.

Department of Fisheries and Oceans conducts similar activities for fish production, processing and trade as Agriculture & Agri-Food Canada does for agricultural products.

The **Pest Management Regulatory Agency, Health Canada**, has assumed in 1995, the responsibilities for registration of all pest control products in Canada.

FOOD PRODUCED FROM BIOTECHNOLOGY

- Is regulated in the same manner as that produced by conventional methods.
- Is approved for safety prior to reaching the food production system.

Foods with novel traits derived through genetic engineering are evaluated by **Health Canada**, under the **Novel Food Guidelines of the Food and Drugs Act**.

LABELLING OF GENETICALLY ENGINEERED FOOD

There is still considerable debate about the labelling of novel foods derived through genetic engineering. On one hand, producers argue that if food has passed the rigorous safety and quality reviews of the federal regulators, then it has been deemed safe, and there is no need to specifically label it. On the other hand, consumers might argue that it is their "right to know" in order to make informed choices on whether to consume such foods.

As the discussion concerning labelling continues, the federal departments will be weighing the pros and cons of whether to specifically require labelling of genetically engineered (novel) food.

Consultations on labelling of novel foods derived through genetic engineering is ongoing. In 1995, a document containing proposed guidelines was distributed for general comment. Further discussions on various options for providing relevant, factual and meaningful information to the consumer as well as labelling are planned. Many points of consensus have already been identified and supported by Government and consumers alike such as labelling for health and safety risks such as allergens.

RESPONSIBLE OFFICE

***Food inspection questions**

Science & Technology Services
Food Inspection Directorate,
Agriculture & Agri-Food Canada
Tel: 613-952-8000

***Food safety questions**

Food Directorate
Health Canada
Tel: 613-957-1821

May 1996

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Regulation of Agricultural Products • Réglementation des produits agricoles

THE SAFETY-BASED APPROACH TO REGULATION OF AGRICULTURAL PRODUCTS

If you are a researcher or a distributor of a new agricultural product, a question that will arise early in your development or commercialization efforts is **"When should new products be submitted to Agriculture and Agri-Food Canada for review?** The **purpose of this information bulletin** is to describe the principles that are used to develop product specific guidelines which will trigger a product safety assessment and/or efficacy review by the Department. This bulletin also provides an overview of the Canadian regulatory principles underlying the process of regulating agricultural products.

Agriculture & Agri-Food Canada is the **lead agency** responsible for the regulation of all **agricultural products**. This includes agri-food products that have been genetically engineered, veterinary biologics, plants and animals, fertilizers, livestock feeds and seeds. This authority comes through federal legislation and it is the role of the agency to ensure that the approach being used in Canada is fair and efficient and is consistent both nationally and internationally.

The **purpose of agricultural regulation** is to ensure consumers that new products are effective and safe to humans, animals and the environment. Another regulatory goal is to ensure that producers of new products make accurate performance claims. Regulations also assist Canadian companies in maintaining the quality and effectiveness of products that are traded internationally. This is why the Department makes every effort to ensure that Canadian regulatory methods are consistent with those of other recognized regulatory bodies, both nationally and internationally.

With the advent of **genetic engineering,** one of many tools of biotechnology, new regulatory requirements have been developed to specifically answer safety questions that these new technologies may raise. As a result, there has been increased interest from developers of new products to better understand the regulatory process. **Biotechnology** is defined by the federal government as "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." **Genetic engineering** is loosely described as the transfer of genetic material from one organism to another. Whether the product arises from biotechnology or conventional methods, the regulatory process is the same.

KEY ACTIVITIES IN REGULATION

There are **four activities** involved in the safety based approach to regulating agricultural products:

1. **When is a risk assessment required?** There are two steps involved in determining when a risk assessment is required: the product definition and the evaluation of the product using guidelines, which are being developed for the various commodities. Guidelines are being established, with advice from experts and expert organizations, to help proponents determine when their product needs to be reviewed by Agriculture & Agri-Food Canada. This decision depends on whether or not the product is familiar and substantially equivalent to other products that have been approved previously.

2. **Risk assessment** is performed by evaluators at Agriculture & Agri-Food Canada, and is the step in which potential risks are identified and assessed. Guidelines for the risk assessment provide guidance to the proponents regarding the type of information or data that is required. Once a potential risk has been identified, additional information may be required to assess the risk. This may include additional product testing in either laboratory or limited field trials.

3. **Risk management** minimizes identified risks by placing conditions on use. Examples of such measures include limitations on greenhouses or field testing, restricting the product use or modifying the product for its intended usage. In some cases, protocols are developed which clearly state the methods and limitations on the use of the novel product.

4. **Regulation** ensures that products meet the safety criteria. The purpose of regulation is also to ensure the quality, labelling, purity and potency of the product. The principles of regulation remain the same, whether the product is developed using newer tools of biotechnology or conventional production methods.

Meeting the requirements of more than one set of Acts and Regulations may be necessary for commercialization of products, depending on the commodity and proposed use. This may include inspection, labelling, certification, registration, licensing, food safety, environmental assessment or other regulatory requirements. It is suggested that the proponents refer to the information list on regulatory contacts and call the appropriate person early in the development process if there are any questions.

REQUIREMENTS FOR A RISK ASSESSMENT

1. **Criteria and guidelines** are under development to help the proponent of the agricultural product to determine when a submission for assessment of their product is required. A proponent could be the researcher who has developed the product, or commercial interests that want to manufacture or distribute the product. The product is first defined according to its traits, safety, usage, and its effect on the environment.

Three key questions are asked during the pre-regulatory review:

- Is this product familiar (similar) to other products that are already in the market?
- Is the product substantially equivalent to other products that have already been approved?
- For familiar and substantially equivalent products, does the product (or commodity) require regulation under existing legislation?

The concept of **familiarity** is the knowledge of similar products according to their traits and usage. The *principle of familiarity* may provide an accurate idea of the relevant risks in the novel product in the absence of direct experience with it. If the proponent identifies that the product is familiar according to the guidelines, an assessment for substantial equivalence is made. If not familiar, the product will undergo a safety assessment.

The designation of **substantial equivalence** can be made if the product traits, use, safety and effect on the environment are known to be equivalent to those of products that have already been approved by Agriculture & Agri-Food Canada or are generally regarded as safe for that use. It is possible that the majority of qualities of the novel product will be familiar, but that there is some aspect of novelty or a new potential risk that needs to be evaluated. In that case, the product will undergo risk assessment as it cannot be considered substantially equivalent.

Questions to ask on familiarity and substantial equivalence:

Whether or not the product is familiar may be answered by determining whether the product has a history of safe use in Canada, whether the new characteristic is similar to those already accepted as safe in the product, and whether the new characteristic was derived using a technique with a history of safe use. This would mean:

- identity - at the species level, has the species a history of safe use in Canada?
- new characteristic - for a species with a history of safe use in Canada, is this similar to those already introduced into that species?
- development technology - for a species with a specific characteristic with a history of safe use in Canada, was the characteristic introduced using a technique with a history of safety?

For a new product determined to be familiar, if it is known that it will not result in altered environmental interactions when compared to safe counterparts, then the new product can be considered substantially equivalent to existing safe products. The same is true for biotechnology products derived through recombinant DNA techniques where the specific genetic elements inserted are the same as those already approved in that specific product.

PLANT CASE STUDY

As an example, in the case of plants, for a new canola line, this would mean:

- altered environmental interactions - scientific rationale should show that, compared to similar plants of that species, the new plant product:
  - is not more weedy;
  - will not pass genes conferring its new characteristics onto relatives that might become more weedy;
  - will not display greater potential as a pest;
  - will not show a negative impact on biodiversity.

- if introduced through recombinant DNA technology, information is needed to determine if the specific genetic elements and methods of introduction are the same as those previously introduced into that same species and if they have been approved for use in Canada.

Depending on the information, there are several possible outcomes, which are depicted in Figure I:

a. Familiarity:

i) If the product is **not familiar** (NO), it will be referred to Agriculture and Agri-Food Canada for risk assessment. Either a novel trait or new usage would require risk assessment. This step can be thought of as a coarse trigger. For example, a new plant species to be grown as a crop in Canada that has not been previously seen would be considered unfamiliar.

ii) If the product **is familiar** (YES), it will be considered for substantial equivalence to its traditional counterpart. The new canola line example above would be considered familiar if developed using traditional plant breeding techniques that have a long history of safety.

b. Substantial equivalence:

i) If the product is **not substantially equivalent** (NO), it will be submitted to Agriculture and Agri-Food Canada for risk assessment. Using the 'familiar' canola example above, if the improved characteristics of the new line were derived using recombinant technology, the new product would not be considered substantially equivalent unless the specific genes construct in that same plant species has been previously assessed and evaluated as safe by Agriculture and Agri-Food Canada. For new products derived using recombinant technology which are not substantially equivalent, the risk assessment would focus on the specificity of the inserted DNA sequences and any potential changes in environmental interactions.

ii) **If the product is substantially equivalent** (YES), it will not be considered for risk assessment and will proceed to further regulation under existing legislation, where appropriate. For the new canola line above, this would mean variety registration and perhaps a food safety assessment by Health Canada.

c. Regulation:

i) If the familiar and substantially equivalent product release **is not governed** by federal legislation (NO), it can be commercialized without further consideration.

ii) If the product **requires approval** under existing legislation (YES), the appropriate group would be contacted.

2. **Risk assessment**, conducted by evaluators at Agriculture & Agri-Food Canada, is the process in which each risk is identified and reviewed in the light of the scientific information available. "Safety" does not imply the absence of risk, but rather a level of acceptable risk. Risk is further reduced through the application of risk management procedures. The level of risk is determined to be acceptable if the new product is as safe as its traditional counterpart. If the risks exceed the acceptable limits, the product will not be approved for use in Canada.

3. **Risk management** involves taking actions to reduce the risk. Examples of risk management measures include the limited release of the product through imposing confinement conditions, or the use of protective equipment.

4. **Regulation** is the final step in the regulatory process where a decision is made to release a product for a specific purpose. Several Acts exist in Canada to maintain standards, avoid fraud, identify quality or enforce conditions resulting from the risk management requirements.

As with any scientific discipline, the methods in regulatory science are evolving as new technical information becomes available. With each step described above, and with each new product that is produced, experience with the product and its risks is achieved.

This **information feedback** results in continual refinement of the risk management measures and the familiarity guidelines contained in the commodity-based guidelines. As a result, restrictions which are applied to a product may be modified as new information becomes evident.

REMAINING QUESTIONS

Now that we have looked at the process of regulation, there are still questions that remain, such as:

How do I know whether a product is familiar and/or substantially equivalent to one that is currently approved?

Advisory committees have been established for most commodities. These committees are composed of industry representatives, scientists, government and academic members. **Commodity-based guidelines** are being established to assist proponents in determining if their novel product is familiar to those that have previously been approved.

When should a new agricultural product be reviewed by Agriculture & Agri-Food Canada?

The government is required to review a new agricultural product if:

1. There is **potential risk** to human, animal or environmental safety. For example, a new fertilizer would require review. A totally new active ingredient will require a full assessment, while a new use for an existing active ingredient would require assessment of the efficacy and safety of the new use.

2. The product contains **novel traits** and the risk is not known. An example of such a trait would be the addition of a trait for herbicide tolerance not previously seen in a well known (familiar) plant. Regardless of whether this product is produced using recombinant technology or conventional breeding techniques, the new trait would have to be evaluated for risk to the environment.

3. The **method of production** has created intrinsic novelty, even though the traits of the product are the same as those already commercially available. Currently, an example of this class of products would include recombinant (genetically-engineered) products. For example, if a tomato variety was developed with a gene from an unrelated plant species or a fruit was produced with a higher solids content using genetic engineering, it would be assessed. Both the tomato variety, and the solids content trait are familiar, but the engineered gene in the tomato plant species would be novel. The new gene would produce proteins that would not normally exist in the conventionally bred tomato or pre-existing proteins expressed at different levels. As data become available on higher solids content produced in this manner, the need for risk assessment would diminish.

OTHER SOURCES OF INFORMATION

This document provides an overview of the safety-based approach to regulation of agricultural products. If you require more information, please contact the **Biotechnology Information Line at (613) 952-8000 (4229).** Additional bulletins are available on the following topics:

Questions and Answers on Agriculture & Agri-Food Canada's Acts and Regulations provides answers to commonly asked questions concerning the regulation of agricultural products.

Glossary of Terms provides easy-to-understand definitions of terms used in the regulation of agricultural products produced by biotechnology.

Biotechnology, Agriculture and Regulation provides an overview of how agricultural products are regulated. The various commodities are briefly discussed, and the eight Acts are named.

Agricultural Biotechnology Regulatory Information Manual (ABRIM) contains all the acts, regulations and guidelines as pertains to agricultural products.

RESPONSIBLE OFFICE

Biotechnology Strategies and Coordination Office
Food Inspection Directorate,
Agriculture & Agri-Food Canada
59 Camelot Drive
Nepean, Ontario
K1A 0Y9
Tel: 613-952-8000
Fax: 613-941-9421 Internet: http://aceis.agr.ca/fpi/agbiotec/home.html/

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GENERAL QUESTIONS AND ANSWERS ON BIOTECHNOLOGY

Q. What are the benefits of using biotechnology to improve domestic animals?

A. Biotechnology can be used to improve animal health and nutrition. The possibilities offered by genetic engineering are especially important in developing countries, in as much as improving the milk, meat, egg and wool production of livestock brings economic benefits and increases the food supply.

Using biotechnology, scientists can produce safer, more effective, less expensive vaccines to combat animal and human disease. By applying genetic engineering in animal husbandry, it may be possible to breed for livestock with specific traits such as greater resistance to disease. Genetically engineered animals may also yield improved human food products, such as leaner meat, for example.

Animal fodder is generally scarce and of poor quality in developing countries. Biotechnology techniques can modify bacteria that help certain animals, such as cattle, digest their food.

Q. Are genetically engineered plants more likely to "run wild" in the environment?

A. Most agricultural crops do not survive outside of the agricultural environment designed for them, and there is no evidence to suggest that genetically engineered crops have a better chance of becoming weeds. In a European study, genetically engineered canola that was deliberately introduced into various natural habitats did not live long enough to set seed.

Q. When genetically engineered plants are being field tested, can the new gene in the test plant be transferred to other plants?

A. In nature, genetic material can only be transferred to other sexually compatible plants by cross-pollination. In Canadian field trials, new genes are prevented from spreading by natural means because the plants used for research are confined or isolated from other sexually compatible plants. Additional preventative procedures are often incorporated into the field trial, such as using pollination cages or bags, removing plant flowers, or using male plants that cannot produce viable pollen.

Q. Are plants grown in field trials used in human or animal food?

A. Plants grown during field trials are prevented from entering the human or animal food chains. All such plant material is destroyed at the end of the field test or is retained for the purpose of future test plantings. However, if for any reason a request is made to allow plant material to enter the food chain, the material must be evaluated by the Food Directorate of Health Canada for food safety.

Q. What is a marker gene?

A. Marker genes are unique pieces of DNA that are inserted into genetically modified organisms so that the organisms can be identified or selected during development in the lab, or after release into the environment. Frequently, marker genes "code" for antibiotic resistance, allowing the recipient organism to be grown in the presence of certain antibiotics, unlike the unmodified organism. Recently, other marker traits have been used. They include markers for varying degrees of ability to use sugar, and those that cause colour changes in the organism for easy identification.

Q. If I eat plants carrying marker genes that are resistant to antibiotics, will medical antibiotics be ineffective if I have an infection?

A. There is no evidence to suggest that this would occur. Bacteria in our bodies are already resistant to the antibiotics associated with these marker genes, and such antibiotics are not clinically important. Furthermore, these antibiotic-resistant markers are used less frequently because there are now other means to do the same job.

Q. Why are some field trials conducted in Canada and not in the United States?

A. The types of agricultural crops grown in Canada and the United States are often different, or economically significant to one country but not to the other. For example, testing of genetically engineered cotton has not been conducted in Canada since cotton is not an economically important Canadian crop.

Q. How is the public kept informed of field trials?

A. Agriculture and Agri-Food Canada provides the public with information on approved field testing of genetically engineered material, and supplies information for publication to the Canadian Environmental Assessment Agency (CEAA) on a biannual basis. A list of these Canadian field trials, is available through CEAA.

Q. What are the advantages of using genetically engineered bacteria over naturally occurring bacteria?

A. Genetic engineering allows existing traits to be enhanced, or new, beneficial traits that might not normally be found in bacteria to be developed. For example, *Rhizobium*, a bacterium used as a biofertilizer, can be engineered to fix nitrogen more efficiently. *Rhizobium* may also be developed to have pesticidal properties, thus further reducing the need to use chemicals on agricultural land.

Q. Are there disadvantages to using genetically engineered bacteria over naturally occurring bacteria?

A. Some people are concerned about the possible environmental and health risks. However, before field testing is carried out, Agriculture and Agri-Food Canada ensures that these risks are thoroughly assessed.

Q. Which plant species have been or are currently the subject of genetic engineering research?

A. *Worldwide* scientific research in biotechnology has focused on the following plant species:

Alfalfa	Cucumber	Potato
Apple	Eggplant	Raspberry
Asparagus	Flax	Rice
Barley	Grape	Rye
Birch	Horseradish	Soybean
Broccoli	Kiwi	Spruce
Canola	Lettuce	Squash
Cantaloupe	Muskmelon	Strawberry
Carrot	Oats	Sugar beet
Cauliflower	Papaya	Sugarcane
Celery	Pea	Sunflower
Chicory	Peanut	Sweet Potato
Chrysanthemum	Pepper	Tobacco
Corn	Petunia	Tomato
Cotton	Plum	Turf Grass
Cranberry	Poplar	Walnut

Some of these species are the subject of genetic engineering research in Canada.

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PLANTS WITH NOVEL TRAITS

PRODUCTS REGULATED

Plants with novel traits require an import permit from the **Plant Protection Division** prior to import into Canada, and authorization from the Plant Products Division prior to release into the Canadian environment. This is achieved through written notification to the relevant Division and a safety assessment by that Division before authorization.

RELEVANT LEGISLATION and GUIDELINES

The **Plant Protection Act and Regulations** (Plant Quarantine Regulations), Section 4(1); the **Canada Seeds Act and Regulations**, Section 3 and proposed **Regulations**, Part V are relevent to plants with novel traits. For **confined field testing**, please refer to **Regulatory Directive Dir95-01** Field Testing Plants with Novel Traits in Canada.

For unconfined release, refer to **Regulatory Directive Dir94-08** - Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits and the species-specific companion documents (**Dir94-09** - The Biology of Brassica napus L., **Dir 94-10** - The Biology of Linum usitatissium L. and **Dir94-11** - The Biology of Zea mays L. - The Biology of Solanum tuberosum L, **Dir T-1-09-96**). Further companion documents are under development for, canola (Brassica rapa), alfalfa and soybean.

KEY REQUIREMENTS

1. Safety assessment of plants with novel traits is made on a case-by-case basis. As knowledge of specific new product types is gained, information requirements for the safety assessment of similar product types may decrease. Information requirements include descriptions of the host species, of the novel trait, and any donor organisms (with special emphasis on the introduction methodology in the case of novel plants derived through recombinant DNA technology). Requirements also include the stability of the novel plant material with a comparison to its non-modified counterparts. The safety evaluation will include potential toxicity, biochemical changes and allergenicity.

2. **Import** information is required for safety assessment with special emphasis on potential plant pest characteristics, including the geographic origin of the novel plant material, and how it will be used and stored. Applicants are encouraged to identify the species and provide a general description of the novel traits or genes, the quantity of material they wish to import, and the purpose of the importation. If used in a contained facility that prevents dissemination of any genetic material from the facility into the environment, no further notification is required. Applicants should use Form AGR 1274 Application for Permit to Import for importing plants with novel traits into Canada. The permit must accompany the shipment.

3. **Confined release** is the release into the environment with conditions of confinement used to minimize gene escape, either in the form of pollen, seed or vegetative plant parts. Early testing of plants with novel traits is always conducted in this manner and some agronomic testing and seed increase has taken place under conditions of confinement. The safety assessment in addition to a full description of the novel plant material concentrates on the proposed release protocol and on the release site. In particular, an understanding of the potential sexual mates of the novel plant material that may be present at the trial site is required so any outcrossing is minimized. Applicants should use Field Testing Plants with Novel Traits in Canada Dir 95-01 to make a submission for authorization to conduct a confined release.

4. **Unconfined release** is the release into the environment without conditions of confinement. The safety assessment, in addition to a full description of the novel plant material, concentrates on potential changes in environmental impact when compared to unmodified plants of the same species. This will include a consideration of human and animal safety (non-target effects) and the potential negative impact that an unconfined release into the environment may have on either the natural or agricultural environment. Applicants should use Assessment Criteria for Determining the Environmental Safety of Plants with Novel Traits Dir 94-08, and the relevant species-specific companion document to make a submission for authorization for unconfined release of a plant with a novel trait. Following approval, no further notification for unconfined release of the specific plant line or its progeny is required, providing that no other novel trait is introduced into the approved plant line.

5. **Other regulatory requirements** may need to be met prior to commercialization, even if a plant with a novel trait has been authorized for unconfined release:

Health Canada will require information to make a food safety assessment if the novel plant material is used as food and is subject to Novel Food regulations;

Feed Section of Agriculture & Agri-Food Canada will require information to show that any animal feed from a plant with a novel trait is substantially equivalent to feed from its unmodified progenitors; and

Variety Registration is required if the species is subject to variety registration, as are the majority of field-scale crops grown in Canada.

RESPONSIBLE OFFICE

***Import permit**

Import Section
Plant Protection Division
Tel: 613-952-8000
Fax: 613-943-1252

***Confined/Unconfined release authorization**

Plant Biotechnology Office
Plant Products Division
Tel: 613-952-8000
Fax: 613-992-5219

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VETERINARY BIOLOGICS

PRODUCTS REGULATED

Veterinary biologics are used for the prevention, treatment or diagnosis of infectious diseases of animals. This includes vaccines, bacterins, toxins, toxoids, antisera and diagnostic kits. Products produced conventionally and those derived from biotechnology are reviewed in the same manner; however, this fact sheet will emphasize products derived from biotechnology.

The **role of the Veterinary Biologics and Biotechnology Section, Animal Health Division, Animal & Plant Health Directorate,** is to ensure that veterinary biologics are safe pure, potent and efficacious. The risk assessment assures safety of the products for animals, man and the environment. The review and evaluation of conventionally produced veterinary biologics are similar to that for products derived from biotechnology. These products are classified according to the level of risk and the classification can be seen in the Guidelines mentioned below.

RELEVANT LEGISLATION/GUIDELINES

Section 64(s) of the ***Health of Animals Act*** and Part 11 of the ***Regulations*** are relevant to this topic. The ***Summary of Requirements and Guidelines for Veterinary Biologics in Canada***, dated May 18,1995, explain the forms, facilities, personnel, manufacturing, data, and labelling requirements. It also provides guidance on the regulatory controls exerted in the testing, quality assurance, and licensing of commercial veterinary biologics manufactured or imported into Canada.

The May 1994 ***Guidelines for the Regulation of Veterinary Biologics Produced by Biotechnology*** explain the process and documentation required for the approval of biotechnology-derived veterinary biologics by Agriculture and Agri-Food Canada. As well, the 1996 ***Laboratory Biosafety Guidelines*** from Health Canada are relevant.

KEY REQUIREMENTS

The regulation of veterinary biologics involves:

1. **Inspection of manufacturers' and importers' facilities** - Both Canadian and international manufacturing facilities are inspected. Those facilities that meet the standards are granted an Establishment License. This entitles the licencee to manufacture veterinary biologics.

2. **Licensing of veterinary biologics** - Data on purity, potency, safety and efficacy of products submitted for licensing or registration, is evaluated by Veterinary Biologics and Biotechnology Section. Permission is required to conduct trials on products outside of containment facilities. An environment assessment is conducted. Laboratory testing may also be conducted by federal laboratories to monitor quality assurance. On fulfilment of the licensing requirements, the product is allowed for distribution and sale. Details are given in the guidelines.

3. **Importation** - Products that are produced by foreign companies are allowed to be sold in Canada by means of designated importers. These products are subject to all aspects of the licensing procedure for Canadian products and, in addition, require an import permit, which is generally granted annually.

4. **Investigation of adverse reactions** - Adverse reactions to any licensed veterinary biologic must be reported by the attending veterinarian to Veterinary Biologics and Biotechnology Section for investigation. Manufacturers are instructed to address such reports and may be asked to conduct special investigations or even to withdraw the product from the market.

5. **Advertisements** - All manufacturers who want to promote or advertise their products must submit draft forms of the advertisements or promotional material for review and approval to the Veterinary Biologics and Biotechnology Section. The purpose of this requirement is to ensure that the claims made are not false or misleading.

RESPONSIBLE OFFICE

Veterinary Biologics and Biotechnology Section
Animal Health Division
Tel: 613-952-8000
Fax: 613-952-8884

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LIVESTOCK FEEDS

PRODUCTS REGULATED

Feeds are defined as any substance or mixture of substances manufactured, sold or represented for use or consumption by livestock, for providing the nutritional requirements of livestock, or for the purpose of preventing or correcting nutritional disorders of livestock.

Biofeeds microbial products (both viable and non-viable) such as bacteria, yeast, fungi, microalgae or forage/silage inoculants; plants with novel traits; or fermentation products such as enzymes, biomass proteins, amino acids, vitamins, or flavouring ingredients.

RELEVANT LEGISLATION/MEMORANDA

The ***Feeds Act and Regulations*** specifies that all single ingredient feeds be evaluated prior to their use in livestock feeds. This applies to imported or domestically manufactured products. Standards and labelling requirements are specified in the legislation.

Trade memoranda describe the data requirements for registration of biofeed products. T-3-141 deals with single ingredient feeds; T-3-141 discusses supplemental data requirements for safety evaluation; T-3-142 discusses specialty feeds; T-3-122 discusses forage additive products; T-3-143 discusses viable microbial products; and T-3-153 discusses yeast products and T-3-148 discusses enzyme products.

A draft guideline for the assessment of plants with novel traits as livestock feed, was prepared in 1994 and provides detailed requirements for the registration of these plants.

KEY REQUIREMENTS

1. Registration of biofeeds - Imported and domestically manufactured product applications are reviewed for safety and efficacy. This includes human (occupational and food safety), animal and environmental safety. Labelling must conform to the legislated requirements.

Data requirements vary with the product, but may include a complete identification of all ingredients, certificates of analysis, laboratory methodology, Quality Assurance procedures and a product sample. Toxicity and stability data will be required for safety assessment.

Data submission for **biofeeds** should include a description of the organism and the genetic modification, the intended use, the environmental fate and a determination of whether the gene products, or their metabolic products, will reach the human food chain. **Refer to the appropriate Trade Memoranda and Guidelines for specific details.**

2. Import requirements - The importation of nonregistered biofeeds requires application for a Letter of Authorization prior to entry. These products may also be subject to animal and plant health importation requirements.

3. Field Testing - Novel biofeed products being developed or tested in field trials are subject to regulatory requirements. They are subject to a safety assessment and are regulated under the *Feed Regulations*.

INDUSTRY CONSULTATION

In consultation with the Feed Advisory Committee composed of government, industry and academic representatives, **Guidelines for the Assessment of Plants with Novel Traits as Livestock Feeds** were developed in September 1994. This was followed by general consultation with groups representing public, producer and industry interests. Similar consultations are being planned for **microbial products.** Guidelines which establish the safety and efficacy criteria for microbial products have been developed in consultation with industry, and will be made available to the public in 1996.

RESPONSIBLE OFFICE

***Registration, field testing, importation**
***Contact with other departments**

***Plants with novel traits**

Feeds Section Office
Plant Products Division
Tel: 613-952-8000

Plant Biotechnology Office
Plant Products Division
Tel: 613-952-8000

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BIOFERTILIZERS

PRODUCTS REGULATED

Microorganisms, either naturally occurring or genetically modified that improve the physical condition of soil, aid plant growth or increase crop yield. These may include **rhizobia**, such as *R.meliloti*, *B.japonicum*; **free living nitrogen fixing bacteria**, such as *Bacillus*, *Pseudomonas*; or **fungi**, such as *Penicillium*, *Glomus* spp.

RELEVANT LEGISLATION/MEMORANDA

Section 3(a) of the ***Fertilizers Act*** requires supplements be registered before sale in Canada; and applies to imported or domestic products. Standards and labelling requirements are specified in Sections 3(b) and 3(c).

The ***Plant Protection Act and Regulations*** indicate that import permits are required before a biofertilizer may be imported into Canada for experimental or commercial purposes. As well, ***Trade Memoranda*** T-4-107 explains registration requirements; T-4-103 explains research exemption requirements; and T-4-108 expliains the requirements for field testing supplements.

Draft guidelines for the identification and safety evaluation of microbial products intended for field application or registration under the *Fertilizers Act* are available. These guidelines detail the information requirements to be submitted for safety assessment of biofertilizers.

KEY REQUIREMENTS

1. **Imported microbial supplements for research** require an import permit. Application forms and information can be obtained from the addresses listed below. Permits are required to import a micro-organism for laboratory or greenhouse uses. If the product is imported for experimental release, a research exemption must also be obtained.

2. Research trials - Exemptions may be obtained by submitting an application package based on the information detailed in the guidelines for Identification and Safety Evaluation. An exemption from the Act and Regulations may be granted to researchers who are conducting experimental releases to generate data for registration. This exemption requires that the product be reviewed for safety and that the release is designed to generate statistically significant efficacy data. Information providing guidance for field releases is contained in T-4-108, while T-4-103 provides information for obtaining a research exemption. Copies of these memoranda are available through the Fertilizer Section.

3. Registration of supplements for sale - require that applications be submitted for review to the Fertilizer Section. Both domestic and imported product applications are reviewed to assure that products are safe, effective and in compliance with labelling and other standards (eg., quality and safety). Efficacy claims must be supported by data. Human health, environmental, plant and animal safety reviews are conducted by Agriculture and Agri-Food Canada. Environment Canada and Health Canada may be consulted during the evaluation process. See Trade Memorandum T-4-107.

4. Post registration surveillance - is conducted by regional inspectors to ensure that registered products continue to meet quality and safety standards after registration. This involves random sampling of the product with subsequent laboratory testing by Agriculture and Agri-Food Canada laboratories and research stations. The results of tests for rhizobial inoculants and pre-inoculated seed are published and distributed annually. Post-registration surveys are administered by the Fertilizer Section.

RESPONSIBLE OFFICE

***Registration or Research Exemption**

Fertilizer Section
Plant Products Division
Tel: 613-952-8000

***Import information**

Import Section
Plant Protection Division
Tel: 613-952-8000

General inquiries may also be directed to the regional office of Agriculture and Agri-Food Canada, Food Production and Inspection Branch in your local area. Please consult the blue pages of your telephone directory for the office nearest you.

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FIELD TRIALS AND REGISTERED PRODUCTS OF BIOTECHNOLOGY UNDER AGRICULTURE AND AGRI-FOOD CANADA'S ACTS

Fertilizers Act

Field Trials

The first trial of a genetically engineered fertilizer occurred in 1991. In this trial, a bacterium, *Rhizobium meliloti*, genetically engineered to contain a marker gene, was monitored in an environmental fate study under field conditions.

Registered Fertilizers

There have been no genetically engineered fertilizers registered for commercialization. There are currently 50 applications for field trials for microbial fertilizer suppments.

Feeds Act

Seven feeds from novel plants were approved in 1995.

Food Acts (*Canadian Agricultural Products Act, Meat Inspection Act*)

Two tomato strains have been approved for sale in Canada but have not yet entered the market place. The New Leaf™ potato was approved by Health Canada in September 1995 and is now on grocery store shelves.

Health of Animals Act

Field Trials

As required, field trials for veterinary biologics are evaluated and authorized.

Registered/Veterinary Biologics

Therapeutic/prophylatic use.

PRODUCT	MANUFACTURER
E. coli Bacterin	Solvay Animal Helath
E. coli Bacterin	Solvay Animal Health
E. coli Bacterin	Solvay Animal health
E. coli Bacterin	Smith Kline Beecham
E. coli Bacterin-Toxoid	Sanofi
E. coli Bacterin-Toxoid	Smith Kline Beecham
Feline leukemia virus vaccine (subunit)	Coopers Animal Health
P. hemolytica bacterial extract plus genetically-attenuated leukotoxin	Biostar

Diagnostic Kits

PRODUCT	MANUFACTURER
Avian Reovirus Antibody Kit	Kirkegaard & Perry
Canine Heartworm Antigen Kit	IDEXX
Canine Heartworm Antigen Kit	Synbiotics
Canine Heartworm Antigen Kit	Vineland
Canine Heartworm Antigen Kit	IDEXX
Canine Heartworm Antigen Kit	Synbiotics
Canine Heartworm Antigen Kit	Synbiotics
Canine Heartworm Antigen Kit	Agen Biomedical Ltd.
Canine Heartworm Antigen Kit	IDEXX
Canine Heartworm Antigen Test Kit	IDEXX
Feline Immunodeficiency Virus Antibody Test Kit	IDEXX
Feline Leukemia Virus Antigen Test Kit	IDEXX
Feline Leukemia Virus Antigen Test Kit	IDEXX
Feline Leukemia Virus Antigen-Feline Immunodeficiency Virus Antibody Test Kit	Synbiotics IDEXX
Feline Leukemia Virus Antibody Test Kit	Cambridge Bioscience
Feline Leukemia Virus Test Kit	IDEXX
Feline Leukemia Virus Test Kit	Synbiotics
Salmonella enteritidis Antibody Test Kit	IDEXX
Bovine Leukemia Antibody Test Kit	IDEXX
Feline Leukemia Antigen-Feline Immunodeficiency Virus Antibody Test Kit	IDEXX
Canine Parvovirus Test Kit	IDEXX
Feline Leukemia Virus Antigen Test Kit	IDEXX
Feline Leukemia Virus Antigen Test Kit	Synbiotics
Avian Leukosis Virus Antibody Test Kit	IDEX

1. FIELD TRIALS

•Summary of Submissions and Field Trials of Genetically Engineered Plant Material Proceeding under the Seeds Act, 1988-1995.

YEAR	# OF SUBMISSIONS1	# OF FIELD TRIALS2	CROP KIND3	BREEDING OBJECTIVE4	PROVINCES WHERE FIELD TRIALS TOOK PLACE5
1988	10	14	8 Canola 2 Flax	10 Involv. Mark. Genes 5 Novel Herbicide Tol. 2 Nutritional Change 2 Marker Genes Only 1 Modified Oil Comp.	6 Saskatchewan 4 Alberta 3 Manitoba 1 Ontario
1989	28	44	21 Canola 4 Flax 1 Alfalfa 1 Tomato 1 Tobacco	24 Novel Herbicide Tol. 24 Involv. Mark. Genes 2 Nutritional Change 2 Marker Genes Only	29 Saskatchewan 9 Ontario 4 Manitoba 2 Alberta
1990	40	76	26 Canola 3 Potato 3 Tobacco 3 Flax 2 Corn 2 Alfalfa 1 Tomato	35 Involv. Mark. Genes 32 Novel Herbicide Tol. 6 Marker Genes Only 3 Virus Resistance 2 Nutritional Change	49 Saskatchewan 17 Ontario 4 Manitoba 3 Alberta 2 B.C. 1 N.B.
1991	39	174	29 Canola 4 Potato 2 Flax 2 Alfalfa 1 Tobacco 1 Corn	32 Involv. Mark. Genes 30 Novel Herbicide Tol. 4 Virus Resistance 4 Marker Genes Only 3 Male Steril./Restor. 1 Insect Resistance	107 Saskatchewan 28 Alberta 20 Manitoba 14 Ontario 2 B.C. 2 N.B. 1 P.E.I.
1992	40	298	23 Canola 6 Alfalfa 5 Potato 3 Flax 2 Tobacco 1 Soybean	32 Involv. Mark. Genes 25 Novel Herbicide Tol. 5 Stress Tolerance 3 Male Sterility 3 Insect Resistance 3 Virus Resistance 2 Marker Genes Only 1 Nutritional Change 1 Modified Oil Comp.	131 Saskatchewan 66 Alberta 56 Manitoba 30 Ontario 9 N.B. 4 P.E.I. 2 B.C.

YEAR	# OF SUBMISSIONS[1]	# OF FIELD TRIALS[2]	CROP KIND[3]	BREEDING OBJECTIVE[4]	PROVINCES WHERE FIELD TRIALS TOOK PLACE[5]
1993	88	489	58 Canola 7 Alfalfa 7 Potato 6 Corn 5 Tobacco 3 Soybean 2 Flax	58 Novel Herbicide Tol. 52 Involv. Mark. Genes 11 Nutritional Change 9 Modified Oil Comp. 9 Insect Resistance 7 Stress Tolerance 7 Male Sterility 5 Virus Resistance 2 Fungal Tolerance 1 Marker Genes Only	214 Saskatchewan 96 Manitoba 90 Alberta 75 Ontario 10 P.E.I. 4 N.B.
1994	111	774	74 Canola 12 Potato 8 Corn 4 Flax 4 Tobacco 2 Soyabean 2 Wheat 2 Japanese Tree Foil 2 Strawberries 1 Brown Mustard	66 Novel Herbicide Tol. 13 Male Steril./Restor. 9 Virus Resistance 9 Stress Tolerance 8 Modified Oil Comp. 2 Nutritional Change 2 Generation of Mutants 1 Pharmaceutical 1 Genetic Research	367 Saskatchewan 159 Alberta 145 Manitoba 73 Ontario 12 N.B. 9 B.C 9 P.E.I.
1995	127	529	70 Canola 18 Corn 14 Potato 8 Alfalfa 5 Other 4 Flax 4 Soybean 3 Wheat 1 Tobacco	63 Novel Herbicide Tol. 23 Modified Oil Comp. 21 Insect Resistance 13 Stress Tolerance 9 Male Steril./Restor. 9 Virus Resistance 7 Genetic Research 4 Fungal Resistance 3 Nutritional Change 2 Pharmaceutical 1 Other	67 Alberta 6 B.C. 80 Manitoba 38 N.B. 132 Ontario 14 P.E.I. 4 Quebec 188 Saskatoon

Novel Herbicide Tol. = Novel Herbicide ToleranceMale Steril./Restor. = Male Sterility/Restoration
Modified Oil Comp. = Modified Oil CompositionInvolv. Mark. Genes = Submissions Involving Marker Genes

[1]This category includes the number of submissions that were approved and for which field trials took place (not all field trials take place once approval is granted).

[2]Includes the number of field trials that were approved and that took place (not all field trials take place once approval is granted).

[3]Data is based on the number of submissions.

[4]Some submissions have more than one breeding objective, therefore the number of submissions listed under breeding objective may exceed the total number of submissions authorized.

[5]Data is based on the number of field trials.

1. Explanatory Notes Regarding the Attached Summary Information for 1988-95 Field Trials of Genetically Modified Plants in Canada

In 1993, in collaboration with the Biotechnology Strategies and Coordination Office (BSCO) and the Plant Health Risk Assessment Unit, the coding system for field trials and submissions has been modified to accommodate the review of every genetic construct (or groups of constructs considered similar) by the Plant Bitoechnology Office of the Variety Section and by the Plant Health Risk Assessment Unit. Numbers have also been modified to consistently account for individual experiments (which the applicant usually presents as individual trials).

The application of this new coding system has resulted in a dramatic increase over the previously reported 1988-92 field trial numbers. A consistent system of reporting field trials now exists, which is accurate, clear, and more closely aligned to the United States Department of Agriculture system of reporting permits and sites.

2. Plants Authorized for Unconfined Release and Feed Use

Description	Trait	Date Authorized	Company Name
Canola *(Brassica napus)*	Herbicide tolerance	March 10, 1996	AgrEvo Canada Inc.
Canola *(Brassica napus)*	Herbicide tolerance	March 24, 1996	Monsanto Canada
Canola *(Brassica napus)*	Herbicide tolerance	April 21, 1995	Pioneer Hi-Bred
Canola *(Brassica napus)*	Herbicide tolerance	April 28, 1995	Plant Genetic Systems
Soybean	Herbicide tolerance	November 20, 1995	Monsanto Canada
Potato	Insect resistance	December 27, 1995	Monsanto Canada
Corn	Insect resistance	January 29, 1996	Ciba Seeds
Corn	Insect resistance	February 2, 1996	Mycogen

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Regulation of Agricultural Products • Réglementation des produits agricoles

LEGISLATION AND AGRICULTURAL PRODUCTS

A COMPLEX INDUSTRY....

- **Agricultural products** include animals, plants, and seeds and their products, as well as products used to nurture and protect them from diseases. Such products include drugs and vaccines, feeds and additives, fertilizers and supplements.

- **"Agri-food"** refers simply to food that is either fresh or processed.

- **Federal departments** ensure that these products, including those derived from genetic engineering, are safe for human health and the environment, that compositional standards are met, and that label information claims are accurate and not misleading. Products derived from biotechnology are regulated in the same manner as those produced conventionally.

- To simplify a complex process, submissions should be sent to **Agriculture and Agri-Food Canada** for the regulation of agricultural products. Reviews with other agencies, if required, will be managed by the Department.

REGULATED VIA THE FOLLOWING ACTS

Several departments are involved in the regulation of agricultural products. The main departments are **Agriculture and Agri-Food Canada, Health Canada and Environment Canada.**

LEGISLATION	PRODUCTS/BIOTECH EXAMPLES	DEPARTMENTS
Feeds Act and Regulations	**livestock feeds**, e.g. yeasts, microbes, enzymes, single cell protein	Agriculture & Agri-Food Canada Food Production & Inspection Catherine Italiano Tel. 613-952-8000
Health of Animals Act and Regulations	**animals, their products and by-products**, e.g.vet biologics, animal pathogens & materials	Agriculture & Agri-Food Canada Food Production & Inspection B.S. Samagh Tel. 613-952-8000
Fertilizers Act and Regulations	**fertilizers/supplements**-e.g. rhizobial products, naturally occurring and genetically engineered microorganisms	Agriculture & Agri-Food Canada Food Production & Inspection Hans Yu Tel. 613-952-8000
Plant Protection Act and Regulations	products that are, or are likely to be, **plant pests - all** genetically modified plants will be evaluated	Agriculture & Agri-Food Canada Food Production & Inspection Stephen Yarrow Tel. 613-952-8000
Seeds Act and Regulations	**plant seeds/new plant varieties**	Agriculture & Agri-Food Canada Food Production & Inspection Simon Barber Tel. 613-952-8000
Pest Control Products Act and Regulations	**pesticidal products**, e.g. naturally occurring and genetically engineered microorganisms, invertebrates	Health Canada, Pest Management Regulatory Agency Jean Irvin Tel. 613-952-5330
Food and Drug Act and Novel Foods Regulations and Guidelines	**veterinary drugs**, hormones and growth factors, blood products, vaccines, antibodies, **novel foods**	Health Canada Bureau of Veterinary Drugs Tim Scott Tel. 613-957-3824 Paul Mayers Tel. 613-952-5137

MORE ABOUT PRODUCTS DERIVED FROM BIOTECHNOLOGY....

- **Biotechnology is not new.** Biotechnology is the applied use of living organisms or their parts to produce new products. Conventional plant and animal breeding has produced new genetic variations for decades. What is new is the ability of scientists to work more directly with genes to shorten the process of conventional breeding. Genes are the basic unit of heredity and each gene is responsible for a particular characteristic. Using genetic engineering techniques, scientists can insert a specific gene from one organism into another organism, allowing them to develop products with new characteristics.

- With the advent of genetic engineering, it is possible that plants, animals, products and processes will be genetically engineered to be more productive, disease resistant or to meet consumer requirements more exactly. There are **many benefits** to products derived from biotechnology. However when these products are new, they will be scientifically reviewed in order to ensure that consumer and environmental safety is protected.

FOR MORE INFORMATION:

Contact: ***The Biotechnology Strategies and Coordination Office,***
Agriculture and Agri-Food Canada,
Food Production and Inspection Branch,
Nepean, Ontario K1A OY9
Tel: 613-952-8000
Fax: 613-941-9421
Internet: http://aceis.agr.ca/fpi/agbiotec/home.html/

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Regulation of Agricultural Products • Réglementation des produits agricoles

QUESTIONS AND ANSWERS ON AGRICULTURE AND AGRI-FOOD CANADA'S ACTS AND REGULATIONS

Q. What is Agriculture and Agri-Food Canada's approach when regulating products of biotechnology?

A. Agriculture and Agri-Food Canada follows several basic principles similar to those adopted by other governments and international organizations. They are:

Build on current legislation where possible. The Acts administered by Agriculture and Agri-Food Canada provide it with the legal authority to regulate agricultural products, including those derived through biotechnology. Regulatory amendments (regulations) and guidelines currently being developed for these Acts will apply to the planned release of experimental material into the environment for research purposes. Thus they will clarify the regulatory requirements for agricultural biotechnology products.

Regulate based on characteristics of the product. When reviewing researchers' requests to conduct field trials, government regulators focus primarily on the product's use and traits, rather than the methods used to produce it. In fact, Canadian regulators do not consider many products of the new biotechnology processes as being very different from those produced by conventional methods, allowing regulation to be carried out under existing legislation. A pest-control product is still a pest-control product, regardless of the process by which it was devised, what is important is that it is safe, effective and not harmful to the environment.

Whether the product is a genetically engineered tomato or bacteria that help a food crop fight insect pests, the scientific evaluation process considers its potential risks. It takes into account the product's total properties, safety, and effect on the environment. Canada's approach matches that of the Organization for Economic Co-operation and Development (OECD) and the United States.

Regulate on a case-by-case basis. In order to determine the data and studies needed to demonstrate product safety, products are evaluated individually. As new types of products become more familiar, it may become possible to reduce regulatory requirements or provide an exemption from regulation in some cases.

HEALTH OF ANIMALS ACT

Q. What type of products are regulated by the Health of Animals Act?

A. The Health of Animals Act regulates those products used for the diagnosis, treatment or prevention of infectious diseases in animals, and applies to transgenic animals that are resistant to certain diseases. The objectives of this Act are to minimize the risk of introducing foreign animal disease, to prevent the spread of disease-producing micro-organisms in Canadian livestock as a result of contaminated products, and to reduce the risk of exposing people to animal diseases that may be transmitted to humans.

Before they are registered for commercial sale, all biological products used for veterinary purposes (such as vaccines) must be shown to be safe, potent, pure and effective. To prove the safety of a product, the manufacturer must demonstrate that it will not endanger the environment, or animal and human health.

Veterinary biological products are broadly classified into two groups according to their characteristics and the safety concerns attached to them: Class I includes products prepared from inactivated organisms — such as viruses and bacteria or their derivatives or toxoids — that have been manufactured using genetic engineering techniques. Also in this group are monoclonal antibodies used to diagnose and treat diseases. Live products in this class come from organisms in which a single gene has been altered. These are very similar to modified vaccines already in commercial use. In summary, the inactive and live Class I substances pose little environmental risk or new safety concerns.

Class II includes products contaning live micro-organisms that have been modified by introducing DNA with genetic material from different organisms or different strains. Substances in this group may also use a live delivery agent such as a virus to carry genetic material, infect the host animal and, in this way, immunize it. Government, industry and university researchers are now testing vaccines genetically engineered to prevent infectious diseases that afflict cows and other domestic animals. At the same time, many laboratories are working on diagnostic kits to detect various infectious diseases. Live products of Class II require special attention and data to prove that they will not harm human and animal health, and pose minimal threat to the environment. These products are assessed under the Environmental Assessment Review Process (EARP).

Q. Are import permits required for veterinary biologics?

A. Import permits are required for all veterinary biologics, animal tissues, genetically engineered animals, infectious organisms and related materials.

FEEDS ACT

Q. What type of products will be regulated under the Feeds Act?

A. The Feeds Act governs livestock feeds and their ingredients, including those produced through biotechnology. There are eight broad categories of regulated feeds: complete feeds, supplements and macro premixes, micro premixes, converter feeds, specialty feeds, and single-ingredient feeds. For the most part, products of biotechnology would be regulated under the specialty feeds categories, which include products such as forage additives; enzyme, yeast, and microbial products, and all non-viable and viable products.

As of spring, 1992, no genetically engineered viable micro-organisms (yeast or bacteria) were being manu-factured in Canada. However, a number of naturally occurring live microbial products (probiotics) are currently manufactured and registered for sale in this country.

Bio-engineered feeds under development include products made by a fermentation process using genetically modified bacteria. Agriculture and Agri-Food Canada, in consultation with industry, is now establishing criteria for evaluating the safety of bio-engineered feeds. Feeds used for experimental purposes do not require permis-sion for testing from the Plant Products Division of Agriculture and Agri-Food Canada. If such feeds are to be imported, however, Agriculture and Agri-Food Canada requires details of the feeds' composition, the specific port of entry and the exact test location.

FERTILIZERS ACT

Q. What type of products are regulated by the Fertilizers Act?

A. Under the Fertilizers Act, two types of products are regulated, fertilizers and supplements. Microbial products regulated by the Fertilizers Act would be classified as supplements and include naturally occurring and genetically modified organisms that:

- produce and/or provide nutrients to the plant (namely, nitrogen-fixing bacterial seed inoculants);
- improve the availability of plant nutrients in the soil (nitrification inhibitors, phosphate solubilizing bacteria and fungi);

- promote plant growth (plant growth regulators, growth-promoting rhizobacteria); and

- improve the physical condition of the soil (eukaryotic microalgal conditioners, microbial biomass).

Q. What is required to register a supplement in Canada?

A. In order to register a supplement product, the manufacturer must demonstrate the safety and effectiveness of the product. In cases where these data do not exist, they must be collected in field tests on Canadian soil. A provision in the Fertilizers Regulations permits a product to be exempted from registration so that field tests for research purposes may be carried out.

Q. What is required to field test a supplement?

A. To obtain a research exemption, a company must aply to and acquire written permission from the Director, Plant Products Division, Agriculture and Agri-Food Canada. Guidelines describe the requirements for both naturally occurring and genetically engineered micro-organisms.

FOOD ACTS

Q. Which Acts are administered by the Food Inspection Directorate?

A. The Canada Agricultural Products Act (CAP Act) and the Meat Inspection Act.

Q. What activities are included in the inspection and regulation of agri-food products?

A. Food inspection programs protect the market competitiveness of agri-food products by monitoring the compliance of products imported, exported or processed in federally registered establishments. Products are monitored for safety, wholesomeness and accurate representation.

Monitoring programs, based on principles of crisk assessment , are carried out via the registration and inspection of establishments, licensing of dealers and operators, inspection of processes, testing for biological and chemical contaminants, and inspection of products for conformity with safety, compositional quality, packaging and labelling standards.

Q. What food products are regulated?

A. Regulated agri-food products include: meat and meat products, processed egg products, shell eggs, fresh fruit and vegetables, dairy products, processed fruits and vegetables and honey and maple products.

GENETICALLY MODIFIED MICRO-ORGANISMS

Q. Who regulates genetically modified micro-organisms?

A. It depends on the organism, its properties, and intended use. For example, microbes with pesticidal properties are registered by the Product Management Division of the Product Management Regulatory Agency of Health Canada whereas microbials used to increase crop yields or improve the physical condition of the soil are regulated by the Plant Products Division (Fertilizer Section) of the Food Inspection Directorate.

Q. What regulations or guidelines affect field trials of genetically modified micro-organisms?

A. Agriculture and Agri-Food Canada has collaborated with other government departments on the development of guidelines for microbial pest control agents. These are expected to be available in late 1996 and are expected to undergo public consultation.

Research permits are granted for the field testing of genetically modified micro-organisms and naturally occurring micro-organisms following review by Agriculture and Agri-Food Canada and its advisors in Health Canada, Environment Canada and the Canadian Forestry Service. Registration guidelines for naturally occurring micro-organisms also include requirements for genetically modified micro-organisms. These guidelines are available from the Information Division of the Plant Products Division. Guidelines for the field testing of naturally occurring biofertilizers are available from the Fertilizer Section, Plant Products Division.

PLANT PROTECTION ACT

Q. What products are regulated by the Plant Protection Act?

A. The Plant Protection Act is used to protect Canadian plant life and the agricultural and forestry sectors from potential plant pests. It regulates plant products and organisms imported or developed in Canada that are likely to be plant pests, including genetically engineered plants or organisms. The Act defines a pest as any insect, plant or animal organism, virus, bacterium or disease-inciting agent that causes, or is likely to cause, injury or damage to any plant or plant part.

Agriculture and Agri-Food Canada requires that importers of plant products genetically engineered or otherwise (that could carry pests) apply for a permit specifying conditions under which these products may enter or be released in Canada. The government may ask importers to conduct certain tests before the products are allowed into the country. Or, the products may be allowed entry but be kept in quarantine for testing and examination. To help evaluate possible risks connected with the products of biotechnology, Agriculture and Agri-Food Canada is using a database listing the most significant plant pests to watch for.

Q. Do I need a permit to import plants or other live organisms?

A. Yes. The Import Permit Office within the Plant Protection Division of Agriculture and Agri-Food Canada issues permits for the importation into Canada of plants and plant parts including seeds from all countries. To obtain an importation permit, request application form AGR-1274, and the Notice to Importer N.L34B from the Plant Protection Division. The Notice to Importer lists all materials subject to prohibition or specific restrictions and is available from the permit office at Plant Protection Division.

SEEDS ACT

Q. What types of products are regulated under the Seeds Act?

A. The Seeds Act regulates the inspection, testing, quality and sale of seeds in Canada. Seeds developed through biotechnology must meet the same requirements as those developed by conventional methods. The regulated products include new crop varieties produced by biotechnology with genes novel to the crop species. Work is now focused on lines that have novel pest resistance, pesticide resistance, altered nutritional value or stress tolerance. New forms of seed, such as encapsulated embryos, are also regulated. Since 1988, confined field trials have been carried out using the seed of several genetically modified plants in Canada, including canola, flax, alfalfa, potatoes, tobacco and tomatoes.

Q. Are guidelines outlining data requirements for confined and unconfined testing available?

A. Applications for field testing genetically engineered plants are evaluated on a case-by-case basis by the Variety Section of the Plant Products Division, Food Inspection Directorate. A detailed description of the data requirements can be obtained by contacting the Variety Section of the Plant Products Division.

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GLOSSARY OF TERMS

Act, Regulation, Guideline An Act is a law governing specific activities. A regulation guides the enforcement of that law. A guideline interprets the regulation and assists in its application.

Amino Acid Any of a class of 20 molecules that can be combined to form *proteins* in living things. The sequence of amino acids in a protein and hence the function are determined by the *genetic code*.

Antibodies Proteins produced by the body in response to the introduction of molecules called antigens. Most often, antibodies react specifically with these (sometimes harmful) molecules to prevent infection or disease.

Bacteria A type of single-cell organism. One member, *E. coli*, is commonly used in genetic engineering for the production of proteins and other biochemicals.

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.

Cell The basic structural unit of all living organisms.

Chromosome A structure in a cell that contains the genetic material (genes).

DNA Deoxyribonucleic acid, the substance from which genes are made, that determines heredity. All cells contain DNA.

Enzymes A group of multi-purpose, yet individually specialized, biological proteins. One type of enzyme is proficient at cutting DNA at pinpoint locations, making it possible to add or to remove genes.

Gene A small portion of a chromosome that contains the hereditary information for a particular trait, determined by specific sequences of DNA.

Genetic Code The DNA sequence of a gene which can be used to predict the amino acid sequence, and thus the functions of a living organism.

Genetic engineering A technique involving the transfer of specific genetic information from one organism to another. Also referred to as *Recombinant DNA technology*.

Genetically modified organism An organism whose genetic information has been altered by any technique including natural processes, mutagenesis, genetic engineering or others.

Monoclonal antibodies Antibodies produced against a specific portion of a molecule, such as a protein, and derived from a single cell. Because of the specificity of monoclonal antibodies for a portion of a molecule, scientists can use them for diagnosis or protection against a disease-causing organism.

Mutagenesis A process by which the genetic information of an organism is changed in a stable, heritable manner, either in nature or induced experimentally via the use of chemicals or radiation. In agriculture, these genetic changes are used to improve agronomically useful traits.

Plasmid A plasmid is a small, circular piece of DNA found naturally in certain species of bacteria and functioning independently of the bacterial chromosome. Plasmids are the principal means of inserting new genetic information into micro-organisms or plants.

Protein A large molecule composed of one or more chains of amino acids in a specific order. Proteins are required for the structure, function, and regulation of the body's cells, tissues, and organs. Each protein has unique functions. Examples are hormones, enzymes and antibodies.

Recombinant DNA Technology A procedure used to join together DNA segments in an environment outside a cell or organism. This is also referred to as *Genetic Engineering*.

Trait A distinguishing characteristic or quality of an organism.

Transgenic A plant, animal or micro-organism containing one or more new genes introduced by genetic engineering.

Veterinary biologics Vaccines and diagnostic kits used for the prevention, treatment and diagnosis of disease in animals.

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