BIO-TECH

REGULATIONS
RÈGLEMENT

A User's Guide

Government of Canada
Gouvernement du Canada

Government of Canada | **Gouvernement du Canada**

Agriculture Canada | **Agriculture Canada**

Environment Canada | **Environnement Canada**

Health and Welfare Canada | **Santé et Bien-être social Canada**

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Ministry of State | **Ministère d'État**

Science and Technology Canada | **Sciences et Technologie Canada**

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Foreword

This *Guide* summarizes the mandates of three federal departments — Agriculture Canada, Environment Canada and Health and Welfare Canada — to regulate the products of biotechnology. Current legislation is generally adequate to accommodate biotechnology products, but specific requirements and guidelines are under development in preparation for future need.

The *Guide* contains:

- A "Product Guide" that summarizes the biotechnology products, responsibility centres, and legislative authorities for each act. It also lists the page numbers in this publication that deal with each act.

- For each department, a section that provides:
  - —the names of those federal acts that may affect researchers, manufacturers, sellers or importers of products produced by biotechnological methods;
  - —the addresses and telephone numbers of departmental contacts that have the major responsibility for administering the requirements of each act;
  - —a listing of the types of products that are, or may be, regulated under each act;
  - —data requirements that applicants must supply when importing and registering products, or when requesting permission to perform field trials;
  - —the department's role in the approval process.

- A glossary.

Registrants may obtain copies of the federal acts listed in this *Guide* from:
Supply and Services Canada
Canadian Government Publishing Centre
Hull, Quebec
Canada
K1A 0S9

Introduction

Biotechnology

Biotechnology is the application of science and engineering to the direct or indirect use of living organisms, and their parts or products, in their natural or modified forms, to provide goods and services.

Biotechnological processes have been used to improve the quality of life for thousands of years: bread and cheese making, brewing, and plant and animal breeding are just a few examples. Such traditional biotechnological processes are already regulated.

The recent development of biotechnological techniques such as recombinant DNA and cell fusion to manipulate cells or their genetic materials has created exciting new dimensions in our potential to improve human life. With this potential has come the responsibility to ensure that the new products under development or soon to be developed will be used under conditions that will minimize the possibility of accidents and maximize safety.

The Canadian government's role in promoting safe biotechnological practices

The government's objective is to develop a coordinated approach to the regulation of biotechnology products. This *Guide* summarizes the current and interim status of biotechnology regulations by the three federal departments most directly responsible: Agriculture Canada, Environment Canada and Health and Welfare Canada.

Where needed, these departments are developing alternative or additional information requirements for genetically engineered products. The following criteria are under consideration:

- Intended use of product and comparative benefits to other approaches
- Product identification for both parent organisms and genetically engineered organisms
  - —Taxonomy, identification, source, culture, comparative genus/family relations
  - —Genetic characteristics, such as stability and potential for gene transfer
- Genetic engineering techniques used and descriptions of genotypic and phenotypic alterations and new traits
- Human health
  - —Specific information requirements for detecting potential impact on human health are under development.
  - —Currently available toxicology guidelines for naturally occurring microbial products are under review for applicability to genetically engineered products.
- Environmental considerations
  Information required to evaluate environmental impact is divided into four broad categories applicable to any release:
  - —Ability to predict fate and effects (including organism design and construction, survival, growth and reproduction, gene transfer, dispersal, effects and impact on other biota and ecosystems);
  - —Ability to monitor
  - —Ability to contain
  - —Ability to control
- Field trials will be permitted on a case-by-case basis, only after rigorous evaluation under various conditions. Field trials will also be necessary prior to granting approval for environmental application.
- Containment
  Guidelines for containment during testing or manufacture have yet to be developed.
- Waste disposal
  Criteria for the disposal of waste from biotechnology activities have yet to be determined.
- Contingency planning
  Accidental spills and release could occur at all stages of development. At present, departments are developing criteria for containment and control of biotechnology products and subsequent handling of accidents.

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Product Guide

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Agriculture Canada

1 Agriculture Canada

1. Agriculture Canada

Mandate

Agriculture Canada regulates agricultural products of biotechnology, including animal feeds, fertilizers, pesticides, seeds, products that could potentially be plant pests, and veterinary biologics. Food inspection to ensure quality, safety and purity of foods offered for sale is a second major concern. These products are regulated within the Food Production and Inspection Branch.

Agriculture Canada regulates all aspects of the life cycle development of the above types of agricultural products or activities, except where indicated.

Recommendation

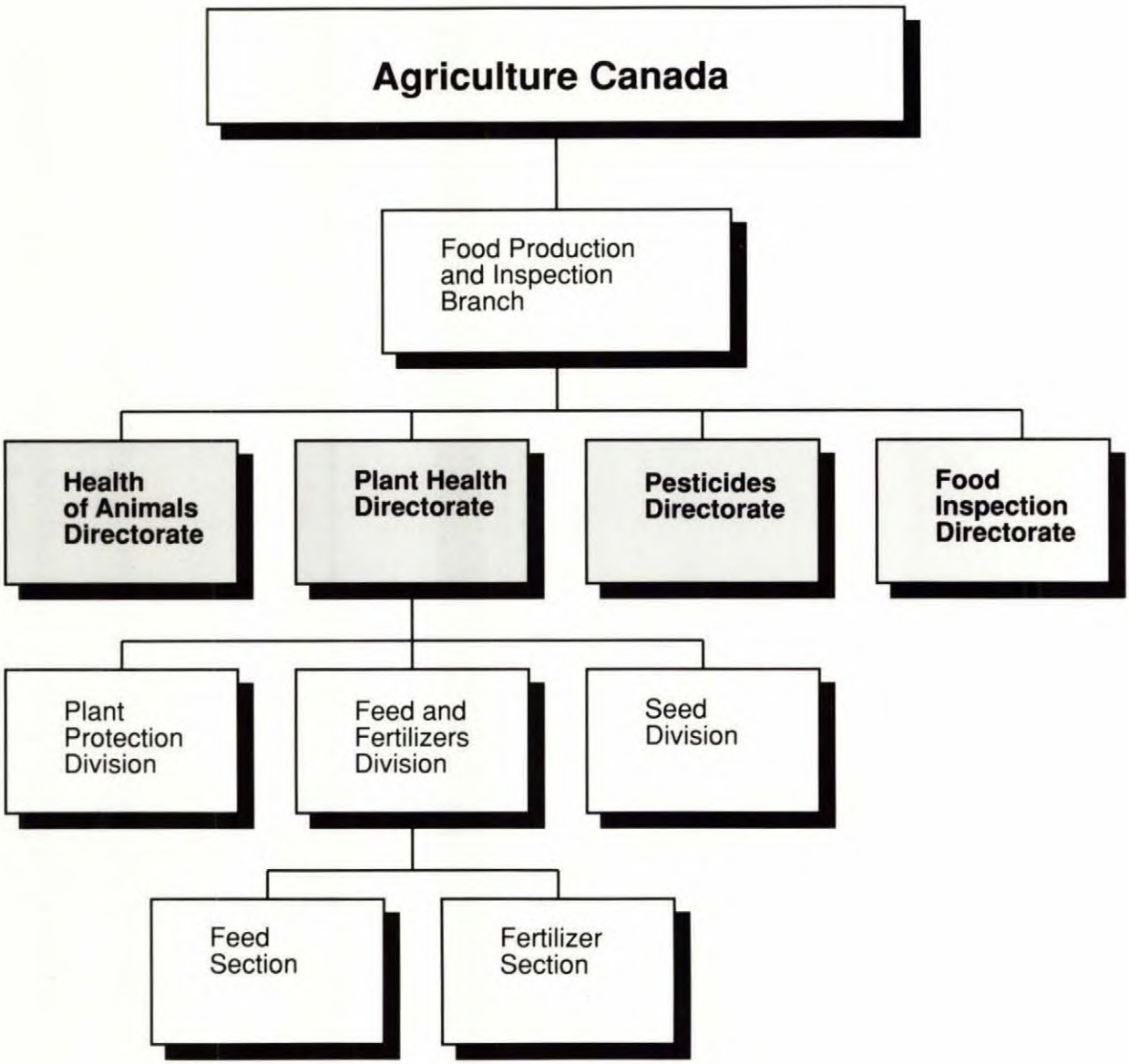
Agriculture Canada recommends that researchers and developers follow Medical Research Council (MRC) Guidelines and Good Laboratory Practices (GLP) guidelines during laboratory research. Researchers and developers are encouraged to contact Agriculture Canada at an early stage to allow for preparation and planning for further development stages.

Enquiries

Address comments and enquiries about the information contained in this portion of the *Guide* to the appropriate regulatory contact listed for each act, or to:

Chairperson, Food Production and Inspection Branch
Biotechnology Working Group
c/o Director
Issues, Planning and Priorities Division
Pesticides Directorate
Agriculture Canada
2nd Floor, SBI Building
Ottawa, Ontario
K1A 0C6
(613) 993-4544

Responsibility Centres for Biotechnology



1. 2. Feeds Act and Regulations

Departmental Authority

Agriculture Canada
Plant Health Directorate
Feed and Fertilizer Division, Feed Section

Through pre-sale registration and post-sale inspection, the Feed Section of the Plant Health Directorate regulates the manufacture, sale and importation of livestock feeds and feed ingredients, including those produced by biotechnology. (Note: The labelling of medicants added to feeds is the responsibility of the Bureau of Veterinary Drugs, Health and Welfare Canada.)

Contact

Feed Section
Feed and Fertilizer Division
Plant Health Directorate
Agriculture Canada
960 Carling Avenue
Ottawa, Ontario
K1A 0C6
(613) 995-7900

Products Regulated

☛ Products intended as livestock feeds or feed ingredients as listed in the *Feeds Act and Regulations*, including:

- yeasts
- microbes
- enzymes
- fermentation products
- single cell (biomass) protein

Requirements

The Department requires information to assess if a product is exempt for research purposes. In addition, before the product can be sold, it must be registered with Agriculture Canada.

☞ **Field Trials**

Approval Process

The Department does not require research permits for livestock feeds used for experimental purposes. Experimental feeds are exempt from regulation provided they meet the requirements of Section 3(C) and 3(F) of the Feeds Regulations.

Specifically, experimental feeds must be fed only to livestock owned by or under the direct care of the establishment carrying out the research. Prior to importation, the establishment responsible must submit in writing to the Director of the Feed and Fertilizer Division all information pertinent to carrying out the test research (see "Data" section immediately following).

The Director of the Feed and Fertilizer Division must give approval to the applicant before the applicant imports the product. All research establishments must accept responsibility for the ultimate safe disposal of the products produced with the feed.

Data

General requirements for domestic and imported feeds include:

—a product sample and accompanying label
—a technical data sheet
—a description of production methods
—reports of nutrient analysis
—results of scientific investigations, including toxicity and stability data

For imported products, researchers must submit information pertinent to conducting the test research, including:

—test locations
—a description of the ingredients to be tested
—the amount of feed required to conduct the experiment
—the amount of each shipment
—the date and port of entry through which the product is imported

☞ **Commercial Use**

Approval Process: Existing guidelines are used to regulate, on a case-by-case basis, products derived from biotechnology.

Data: General requirements for livestock feeds are outlined in the Feeds Regulations, 1983. Pre-sale registration requirements are set out in Section 5.

Specifically, registrants may be asked to meet requirements in Section 8 to enable the Feed and Fertilizer Division to evaluate the health and safety of the feed.

Standards and general requirements for medicated feeds are referred to in Section 14 of the Feeds Regulations, 1983.

Labelling requirements for all feeds are outlined in Section 26 of the Feed Regulations, 1983.

☞ **Importation**

For approval process and data requirements, refer to field trials section above.

1. 3. Fertilizers Act and Regulations

Departmental Authority

Agriculture Canada
Plant Health Directorate
Feed and Fertilizer Division, Fertilizer Section

Through pre-sale registration and post-sale inspection, the Fertilizer Section regulates the sale and distribution of fertilizers and supplements. (The Act defines a fertilizer as "any substance or mixture of substances containing nitrogen, phosphorus, potassium or other plant food, manufactured ... for use as a plant nutrient." The Act defines a supplement as "any substance or mixture of substances for use in the improvement of the physical condition of soils, or to aid plant growth or crop yields.")

Contact

Fertilizer Section, Feed and Fertilizer Division
Plant Health Directorate
Agriculture Canada
960 Carling Avenue
Ottawa, Ontario
K1A 0C6
(613) 995-7900

Products Regulated

☛ Naturally occurring and genetically engineered organisms and products that:

- produce and/or provide nutrients in the soil (e.g., nitrogen-fixing bacterial seed inoculants, mycorrhizae)
- improve the availability of plant nutrients in the soil (e.g., nitrification inhibitors, phosphate solubilizing bacteria)
- promote plant growth (e.g., growth-promoting rhizobacteria, plant growth regulators)
- improve the physical condition of the soil (eukaryotic microalgal conditioners, microbial biomass)

Requirements

Products must be granted research exemptions prior to field testing and must be registered prior to sale and use in Canada.

☞ **Field Trials**

Approval Process: The Department will grant research exemptions pending the outcome of its examination of the information the applicant supplies. Each application will be reviewed on a case-by-case basis.

Data: Prior to field release of organisms to be used as supplements, the Department requires:

—identification of responsible researchers
—comprehensive descriptions of test site(s)
—experimental design
—proposed safety precautions
—taxonomic and ecological descriptions of the organism(s)
—identification and quantification of contaminants

For genetically engineered organisms, the Department requires:

—additional information that would be necessary to determine the potential impact on human, environmental and agricultural systems

☞ **Commercial Use**

Approval Process — The Department will register products pending the outcome of its evaluation of the application. It will conduct reviews on a case-by-case basis.

Data — Users must supply information that complies with the standards, guarantees and labelling requirements of the Fertilizers Regulations.

In addition to demonstration that users can guarantee agricultural, environmental and human safety, the Department requires:

—efficacy data
—an acceptable method of quantifying the "active ingredient"

1. 4. Pest Control Products Act and Regulations

Departmental Authority

Agriculture Canada
Pesticides Directorate

The Pesticides Directorate regulates the manufacture, sale and use of pest control products, which the Act defines as "any product, device, organism, substance or thing that is manufactured, represented, sold or used as a means of directly controlling, preventing, destroying, mitigating, attracting or repelling any pest." The Act defines a pest as "any injurious, noxious or troublesome insect, fungus, bacterial organism, virus, weed, rodent or other plant or animal pest, and includes any injurious, noxious or troublesome organic function of a plant or animal."

Health and Welfare Canada's Food Directorate evaluates dietary exposure to agricultural chemicals and sets residue limits under the *Food and Drugs Act and Regulations*. The Department's Environmental Health Directorate evaluates workers' and bystanders' exposures to pest control products and their environmental residues.
Environment Canada and Fisheries and Oceans Canada evaluate the environmental impact of pest control products.

Contacts

Contact for applications:
Pesticides Directorate
Agriculture Canada
2323 Riverside Drive, SBI Bldg.
Ottawa, Ontario
K1A 0C6
(613) 993-4544

Contacts for health requirements:
Chief, Pesticides Division
Environmental Health Directorate
Health and Welfare Canada
Environmental Health Centre
Tunney's Pasture
Ottawa, Ontario
K1A 0L2
(613) 957-1852

For information about pesticide residues on foods:
Chief, Chemical Evaluation Division
Bureau of Chemical Safety
Food Directorate
Health and Welfare Canada
Banting Building
Tunney's Pasture
Ottawa, Ontario
K1A 0L2
(613) 957-0973

For information about pesticides in the environment:
Chief, Pesticides Division
Commercial Chemicals Branch
Environment Canada
Hull, Quebec
K1A 0H3
(819) 953-1687

Products Regulated

- naturally occurring microorganisms (e.g., bacteria, viruses, fungi, algae, protozoans) indigenous and nonindigenous (e.g., *Bacillus thuringiensis* (B.t.); *Colletotrichum* spp.)
- genetically engineered microorganisms produced by recombinant DNA techniques, deletion, insertion, cell fusion, etc.
- their parts and products (also those of other organisms such as plants, animals, insects); e.g., allelopathic chemicals, chemicals produced by enzymes or enzyme systems
- when such products have pesticidal claims, including (but not limited to):
  - competition with pests, e.g., ice-minus bacteria
  - control post-harvest degradation or other related detrimental effects
  - combine fungicidal, bactericidal or other pesticidal activities, e.g., cell-fusion produced
  - gameticidal activity, e.g., allelopathic chemicals
  - insecticide, herbicide activities etc., but with new modes of action, new delivery systems, or other new aspects

Requirements

Companies intending to import, field test or sell pest control products in Canada must apply to the Pesticides Directorate for research permits and registration. A registration kit is available from the Directorate.

Field Trials

Approval Process: The Department requires research permits

—for importation
—prior to field testing of any microbial products

The Department grants permits on a case-by-case basis.

Agriculture Canada is preparing research permit guidelines for naturally occurring and genetically engineered microbial pesticides.

Data: General requirements include:

—safety testing data
—a description of test site(s) and conditions
—an experimental label on containers that describes contents, instructions for use and safety precautions

Commercial Use

Approval Process: All products must be registered with the Department before they may be sold in Canada.

The Department grants registration after reviewing the applicant's data.

Data: For naturally occurring microbial products:

The Department requires registrants to meet the requirements outlined in "Guidelines for the Registration of Microbial Pesticides," (R-1-229, short title: "Microbial Guidelines").

General requirements include:

—product specifications
—manufacturing methods
—quality control methods
—toxicity/infectivity/pathogenicity tests
—residue data
—environmental fate data
—non-target organism studies
—efficacy data
—proper labelling

For genetically engineered products:

—At present, companies should base their submissions on the "Microbial Guidelines" and assessment will be made on a case-by-case basis. These guidelines are currently being reviewed for the registration of genetically engineered and other biologicals.

☞ **Importation**

Approval Process

Persons wishing to import microbial pest control agents must apply to the Department for research permits.

The Department grants research permits pending its review of the application.

1. 5. Plant Quarantine Act and Regulations

Departmental Authority

Agriculture Canada
Plant Health Directorate
Plant Protection Division

The Act authorizes this Directorate to prevent the introduction or spread in Canada of pests injurious to plants.

Contact

Plant Protection Division
Plant Health Directorate
Agriculture Canada
960 Carling Ave.
Ottawa, Ontario
K1A 0C6
(613) 995-7900

Products Regulated

Products being imported or developed in Canada that are (or are likely to be) plant pests, including those plants or organisms that are genetically engineered. The Act defines a pest as any insect, plant or animal organism, virus, bacterium or disease-inciting agent that cause, or are likely to cause, injury or damage to any plant or plant part. Specific details of biotechnology products that would be subject to these Regulations are being developed.

Requirements

Approval Process

The Department requires permits for importation, and movement certificates for transport and release within Canada, of any plant, or plant part or organism likely to be or to contain a regulated pest of plants.

Data

Each permit specifies the conditions under which the product may enter or be released in Canada; these conditions may include testing prior to admission or during post-entry quarantine.

Data requirements may include:

—identification of the organism
—the amounts involved
—the locations from where and to where the organism will be transferred

1. 6. Seeds Act and Regulations

Departmental Authority

Agriculture Canada
Plant Health Directorate
Seed Division

The Seed Division regulates inspection, testing, quality and sale of seeds, which the Act defines as "any plant part of any species belonging to the plant kingdom that is represented, sold or used to grow a plant." Imported and domestic seed must be safe, pure, viable, efficacious and accurately represented to maintain identity and avoid fraud. Exported seed must meet the requirements of importing countries.

Contact

Seed Division
Plant Health Directorate
Agriculture Canada
960 Carling Avenue
Ottawa, Ontario
K1A 0C6
(613) 995-7900

Products Regulated

☛ New varieties produced by biotechnology:

- cytoplasmic male sterility
- haploid induction
- protoplast fusion
- genetic transformation

☛ new forms of seed, such as encapsulated embryos

Requirements

☞ **Field Trials**

Approval Process — The Department approves each application for field testing of biotechnology plants on a case-by-case basis.

Data — The Department is currently investigating the data requirements for field-scale testing or plot trials of biotechnologically developed varieties.

☞ **Commercial Use**

Approval Process — Registration with Agriculture Canada is required before a plant variety can be sold in Canada.

All seed sold in Canada must meet the minimum requirements for purity and germination given in the Seeds Regulations. The same requirements apply to artificial seed (e.g., encapsulated embryos).

The Department registers acceptable varieties after it has examined the applicants' submissions.

Data — Varieties developed by biotechnology must meet the same merit requirements as varieties bred by conventional methods:

—agronomic performance
—pest resistance
—quality
—varietal purity

☞ **Importation**

Approval Process — The importation procedures for seed and varieties developed by biotechnology are under review.

The Department grants permits or written authorization to import after assessing submitted requirements.

Data — Under the *Seeds Act and Regulations*, there are detailed requirements for importation of new species and unregistered varieties of recognized species. Depending on the species, these include requirements for authorization prior to importation, packaging, labelling and minimum purity and germination requirements.

1. 7. Other Acts and Regulations Administered by the Food Inspection Directorate

The Food Inspection Directorate administers the *Agricultural Products Standards Act,* the *Livestock and Livestock Products Act,* and the *Meat Inspection Act.* In general, the Directorate ensures that products that are imported or exported, and that leave federally inspected (licensed or registered) establishments (including fresh fruit and vegetables moved within Canada) are safe, wholesome, graded for economically significant factors and packaged and labelled to avoid fraud.

In addition, for livestock grading, the Directorate also ensures the availability of an objective, impartial and technologically responsive national grading system for red meats and wool.

Contact

Food Inspection Directorate
Halldon House
Agriculture Canada
2255 Carling Ave.
Ottawa, Ontario
K1A 0Y9
(613) 995-5433

Products Regulated

☛ New food products produced by biotechnology under the following categories or other, related food categories:

- meat products
- processed egg products
- shell eggs
- poultry (meat)
- fresh fruit and vegetables
- livestock grading (red meat and wool)
- dairy products
- hatchery stocks
- processed fruits and vegetables
- honey and maple products

1. 8. Support Services

Laboratory Services Division

The Laboratory Services Division provides laboratory and analytical support and testing for the products that the Department's Food Production and Inspection Branch inspects and evaluates. The Laboratory's responsibilities include:

☞ For the Seed Division
- cultivar verification
- testing of genetic purity and germination of seeds
- seed-borne disease determination
- development of DNA probe tests in preparation for legislation regarding plant breeders' rights

☞ For the Pesticides Directorate
- ELISA analysis and residue testing on food, agricultural products and produce
- chemical and microbiological microcontaminant testing of pesticide formulations and active ingredients
- compliance investigations for enforcement

☞ For the Feed Section of the Feed and Fertilizer Division
- residue analysis and purity investigation for enforcement (drugs, heavy metals, chemical and biological contaminants, etc.), including method development and verification for feeds such as enzymes, microbial biomass and fermentation products

☞ For the Food Inspection Directorate
- diagnostic testing to screen, measure and assess food for compositional integrity, deleterious impurities or pathogenic organisms
- monitoring for quality control of large-scale fermentation and downstream processing (e.g. biosensors)

☞ Training
- on new techniques and equipment in the seeds, food, pesticide and feed program areas, and for laboratory accreditation of provincial, private and commercial laboratories

Contact

Director, Laboratory Services
Agriculture Canada
Ottawa, Ontario
K1A 0C6
(613) 995-4907

Health of Animals Laboratory Division

☞ **Biologics Evaluation Laboratory**
Animal Disease Research Institute, Nepean
This section develops and conducts quality assurance monitoring tests on the purity, potency, safety, and efficacy of veterinary biologics (including vaccines and diagnostic kits) produced or sold in Canada.

☞ **Health of Animals Laboratories**
These eight laboratories across Canada develop and perform laboratory tests and analyses on animals and animal products, including chemical residue analyses, pathological and microbiological investigations, drug tracebacks and drug detection.

The Central Plant Health Laboratory

☞ For the Plant Health Division
- analyzes and inspects plants and plant products for diseases and other plant pests

Research Branch

☞ For the Fertilizer Section of the Feed and Fertilizer Division
- tests *Rhizobium* inoculant products at Research Branch facilities across Canada in a cooperative program
- develops official procedures and quality standards

☞ For the Seed Division
- in cooperation with provincial governments and private industry, conducts cooperative trials to establish the merit of crop varieties and the value of new species in Canada. Testing includes agronomic merit and disease reactions as well as quality and health factors.

Agricultural Inspection Directorate

This Directorate provides support and advice on the Food Production and Inspection Branch's requirements for agricultural products. Staff in the regional and district offices inspect products, field trials and facilities and perform compliance investigations under the various acts administered by the Department.

Contact

Field Services Division
Agricultural Inspection Directorate
Agriculture Canada
Sir John Carling Bldg.
930 Carling Ave.
Ottawa, Ontario
K1A 0C5
(613) 992-2114

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Environment Canada

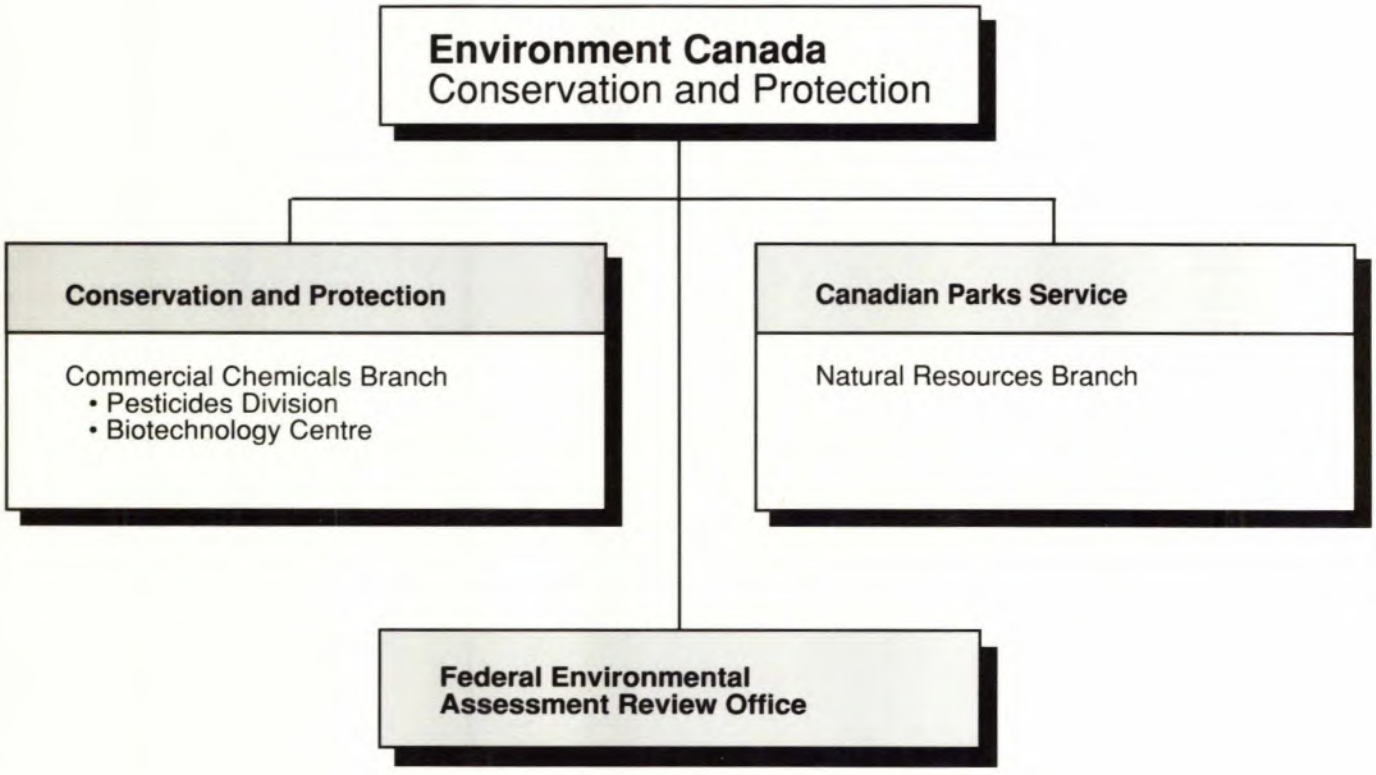
2 Environment Canada

2. Environment Canada

Mandate	Environment Canada has a mandate to conserve and protect a number of national treasures, such as parks and historic monuments, wildlife, water and the environment in general. Much of the Department's protective mandate is currently being revised and upgraded into the *Canadian Environmental Protection Act.*
Recommendation	Environment Canada recommends that researchers and developers follow Medical Research Council (MRC) Guidelines and Good Laboratory Practices (GLP) guidelines during laboratory research. Researchers and developers are encouraged to contact Environment Canada at an early stage to allow for preparation and planning for further development stages.

Enquiries	General enquiries about environmental protection and biotechnology products should be addressed to: Chief Biotechnology Centre Commercial Chemicals Branch Environment Canada Hull, Quebec K1A 0H3 (819) 953-1197

Responsibility Centres for Biotechnology



2. 1. Canadian Environmental Protection Act and Regulations

Departmental Authority

Environment Canada
Commercial Chemicals Branch

This legislation supersedes the *Environmental Contaminants Act* and provides the main statutory authority by which Environment Canada regulates biotechnology products. Although extensive, the powers of the Act that apply to biotechnology are specifically those for notification of new substances.

Health and Welfare Canada will have authority for prescribing and evaluating human health information. Toxicology tests will apply to naturally occurring and genetically engineered organisms.

The proposed regulatory scheme was issued in December 1987 for consultation.

Contacts

Contact for notification:
Chief
Biotechnology Centre
Commercial Chemicals Branch
Environment Canada
K1A 0H3
(819) 953-1197

Contact for health requirements:
Director
Bureau of Chemical Hazards
Environmental Health Directorate
Health and Welfare Canada
Ottawa, Ontario
K1A 0L2
(613) 957-3133

Products Regulated

☛ Products created through biotechnological processes not regulated by any other federal acts and regulations; these products include naturally occurring and engineered organisms used in such activities as:

- pollution degradation
- waste disposal
- mineral leaching
- chemical production
- lignin degradation

☛ Any life cycle stage of a product from research, manufacture, use, transport and disposal that is not regulated by any other federal Act.

Requirements

☞ **Field Trials**
Products being developed for environmental application will be subject to field trials prior to commercial manufacture. Field trials will be designed to provide information on the organism's behaviour in environments representative of sites of commercial use. Field trials must be approved by the Departments before being conducted.

Approval Process: The Departments will base approval for field trials on evaluation of data supplied by the applicant.

Data — Applicants should consult Schedule VI of the draft Regulations for a detailed description of the data requirements. Data requirements include but are not restricted to the following:

—an explanation of the proposed use
—identity and physiological characteristics of the organism
—genetic manipulation
—identification of contaminants
—human and animal toxicology/pathogenicity and human exposure estimation
—organism behaviour in microcosms
—proposal for field trial, including site description, experimental design, date and duration of trial, contingency plans in case of accident, and procedures for monitoring, containment, decontamination and disposal

☞ **Commercial Manufacture**

Approval Process — The Departments will evaluate the information supplied by the applicant. Commercial manufacturers may have to meet conditions additional to those outlined for field trials.

Data — The Departments require not only the data described under field trials, but also the results of the field trials and the data outlined in Schedule VII of the draft Regulations, including but not restricted to:

—design and safety of manufacturing process
—effluent and emission controls
—waste disposal during production
—methods of application, monitoring, containment and waste disposal during use
—contingency plans for accidents that may occur during manufacture, transportation, storage and use

☞ **Importation**

Approval Process — The Departments will evaluate the information supplied by the applicant.

Data — The Departments require not only the data described under field trials, but the results of any field trials in the country of origin and the data outlined in Schedule VII of the draft Regulations, including but not restricted to:

—methods of application, monitoring, containment and waste disposal during use
—contingency plans for accidents that may occur during transportation, storage and use

☞ **Waivers**

For inanimate products, applicants may obtain a waiver based on absence of biological contamination, enabling them to replace the data requirements listed above with a minimum chemical data package.

☞ **Exemptions**

Products similarly regulated under different acts are exempt. Environment Canada will consider exempting other products in the future.

2. 2. Environmental Contaminants Act and Regulations

Departmental Authority

Environment Canada
Commercial Chemicals Branch

The powers of this Act, which has been superseded by the *Canadian Environmental Protection Act* (see previous pages), are limited to inanimate matter.

The *Environmental Contaminants Act* is administered by Environment Canada. Health and Welfare Canada has the authority to evaluate the human health effects of environmental contamination.

Contacts

Contact for notification:
Director
Commercial Chemicals Branch
Environment Canada
Hull, Quebec
K1A 0H3
(819) 997-1449

Contact for health requirements:
Director
Bureau of Chemical Hazards
Environmental Health Directorate
Health and Welfare Canada
Ottawa, Ontario
K1A 0L2
(613) 957-3133

Products Regulated

☛ All chemicals (except pesticides) manufactured or imported into Canada for the first time, in quantities greater than 500 kilograms per calendar year

Requirements

☞ **Field Trials**

Approval Process	No procedures
Data	No requirements

☞ **Commercial Manufacture**

Approval Process	Manufacturers must notify Environment Canada within three months after manufacturing, for the first time, a chemical in excess of 500 kilograms per calendar year.
Data	Manufacturers must submit any information in their possession respecting any danger to human health and the environment.

☞ **Importation**

Approval Process	Importers must notify Environment Canada within three months of importing a chemical in excess of 500 kilograms per calendar year.
Data	Importers must submit any information in their possession respecting any danger to human health and the environment.

2. 3. National Parks Act and Related Acts and Regulations

Mingan Archipelago National Park Act

Historic Sites and Monuments Act

Act Respecting National Battlefields Quebec

Heritage Canals Regulations

Departmental Authority

Environment Canada, Parks

These acts give Environment Canada, Parks regulatory authority for activities in national parks, national park reserves, national historic parks and sites, and heritage canals.

Contact

Director, Natural Resources Branch
Room 208, Les Terrasses de la Chaudiere
10 Wellington Street
Hull, Quebec

Mailing address:
Ottawa, Ontario
K1A 0H3
(819) 994-2639

Products Regulated

☛ Environment Canada will evaluate biotechnology products, processes and organisms proposed for use on property under Parks jurisdiction in light of the protection mandate, policy and Regulations.

Requirements

☞ **Environmental Applications**

Approval Process	All approvals are subject to Environmental Assessment Review Process (EARP), with additional responses to be determined by Parks.
Data	To be determined by Parks. Requirements vary according to individual proposals.

☞ **Exemptions**
No exemptions.

2. 4. Environmental Assessment and Review Process Guidelines

Departmental Authority

All federal departments and agencies whose activities may have an impact on the environment.

Under authority of a Cabinet Directive, every federal department and agency must examine the environmental implications of all proposals within its decision-making authority which require:

- federal authority
- federal financial commitment
- location of federal lands, including those offshore

Contact

Director General
Policy and Administrative Directorate
Federal Environmental Assessment Review Office
Environment Canada
Ottawa, Ontario
K1A 0H3
(819) 997-2711

Requirements

Approval Process

Initiating departments may undertake self-assessment, unless Environment Canada determines there are significant implications, in which case the Department refers the proposal to the Minister of the Environment for public review by the Environmental Assessment Review Board.

Data

The initiating department shall consider:

—any environmental or social effects
—public concerns

2. 5. Pest Control Products Act and Regulations: Environmental Impact Evaluation

Departmental Authority

Agriculture Canada (See Section **1.4.**1 of this *Guide*)

Agriculture Canada has the lead responsibility for this Act, but delegates authority for environmental impact evaluation to Environment Canada.

Contacts

Contact for registration:
Pesticides Directorate
Agriculture Canada
2323 Riverside Drive, SBI Building
Ottawa, Ontario
K1A 0C6
(613) 993-4544

Environment Contact:
Chief
Pesticides Division
Commercial Chemicals Branch
Environment Canada
Hull, Quebec
K1A 0H3
(819) 953-1687

Product guide

Biotechnology Products/Organisms	Act	Contact	Address	Guide Section
Animal pathogens/veterinary biologics/animal products and byproducts				
—veterinary biologics, including vaccines, antisera, diagnostic reagents —imported/indigenous animal pathogens or materials of animal origin	*Animal Disease and Protection Act and Regulations*	Veterinary Biologics Animal Health Division Health of Animals Directorate Agriculture Canada	801 Fallowfield Road Nepean, Ontario K2H 8P9 (613) 998-9320	1.1
Drugs and cosmetics				
—hormones and cell growth factors —drugs produced through recombinant DNA procedures —blood products such as human serum albumin, antihemophilic factor, thrombolytic and fibrinolytic enzymes —vaccines —monoclonal antibodies —allergenic extracts	*Food and Drugs Act and Regulations*	Drug Regulatory Affairs Division Drugs Directorate Health and Welfare Canada	Health Protection Building Tunney's Pasture Ottawa, Ontario K1A 0L2 (613) 957-0372	3.3
—radiopharmaceuticals		Legislative and Regulatory Processes Environmental Health Directorate Health and Welfare Canada	Environmental Health Centre Tunney's Pasture Ottawa,Ontario K1A 0L2 (613) 957-3142	3.3
Feeds and feed additives				
—livestock feeds (e.g., yeasts, microbes, enzymes, fermentation products, single cell (biomass) protein)	*Feeds Act and Regulations*	Feed Section Feed and Fertilizer Division Plant Health Directorate Agriculture Canada	K.W. Neatby Building 960 Carling Avenue Ottawa, Ontario K1A 0C6 (613) 995-7900	1.2
Fertilizers/supplements				
—capable of producing and/or providing nutrients to plants —improving availability of plant nutrients —improving the physical condition of the soil —promoting plant growth	*Fertilizers Act and Regulations*	Fertilizer Section Feed and Fertilizer Division Plant Health Directorate Agriculture Canada	K.W. Neatby Building 960 Carling Avenue Ottawa, Ontario K1A 0C6 (613) 995-7900	1.3

Biotechnology Products/Organisms	Act	Contact	Address	Guide Section
Foods and food additives				
—food microorganisms —food enzymes —single cell proteins —fatty acids —oils	*Food and Drugs Act and Regulations*	Food Regulatory Affairs Division Food Directorate Health and Welfare Canada	Room 200 Health Protection Bldg. Tunney's Pasture Ottawa, Ontario K1A 0L2 (613) 957-1748	3.3
Medical devices				
—*in vitro* diagnostic kits	*Food and Drugs Act and Regulations*	Legislative and Regulatory Processes Environmental Health Directorate Health and Welfare Canada	Environmental Health Centre Tunney's Pasture Ottawa, Ontario K1A 0L2 (613) 957-3142	3.3
Pest control agents				
—naturally occurring and genetically engineered organisms; their parts and products that have pesticidal claims	*Pest Control Products Act and Regulations*	**Notification:** Pesticides Directorate Agriculture Canada	2nd Floor, SBI Building 2323 Riverside Drive Ottawa, Ontario K1A 0C6 (613) 993-4544	1.4
		Health: Legislative and Regulatory Processes Environmental Health Directorate Health and Welfare Canada	Room 128 Environmental Health Centre Tunney's Pasture Ottawa, Ontario K1A 0L2 (613)957-3142	3.5
	Food and Drugs Act and Regulations	Food Regulatory Affairs Division Food Directorate Health and Welfare Canada	Room 200 Health Protection Building Tunney's Pasture Ottawa, Ontario K1A 0L2 (613) 957-1748	3.3
Plant pests				
—products that are, or are likely to be plant pests	*Plant Quarantine Act and Regulations*	Plant Protection Division Plant Health Directorate Agriculture Canada	K.W. Neatby Building 960 Carling Avenue Ottawa, Ontario K1A 0C6 (613) 995-7900	1.5
Plants/seeds				
—new varieties of plants/seeds produced by biotechnology	*Seeds Act and Regulations*	Seed Division Plant Health Directorate Agriculture Canada	K.W. Neatby Building 960 Carling Avenue Ottawa, Ontario K1A 0C6 (613) 995-7900	1.6

Biotechnology Products/Organisms	Act	Contact	Address	Guide Section
Products not covered above				
Consumer products				
products that are: —poisonous —toxic —inflammable —explosive —corrosive	*Hazardous Products Act and Regulations*	**Notification:** Product Safety Branch Bureau of Consumer Affairs Consumer & Corporate Affairs Canada	Place du Portage, Phase I 50 Victoria St. Hull, Quebec K1A 0C9 (819) 997-1194	3.4
		Health: Legislative and Regulatory Processes Environmental Health Directorate Health and Welfare Canada	Environmental Health Centre Tunney's Pasture Ottawa,Ontario K1A 0L2 (613) 957-3142	
Chemical products				
—enzymes, complex lipids, aromatic compounds, polysaccharide biopolymers, and other chemicals produced by biotechnology processes	*Canadian Environmental Protection Act and Regulations*	**Notification:** Commercial Chemicals Branch Environment Canada	Place Vincent Massey 351 St. Joseph Blvd. Hull, Quebec Mail: Ottawa, Ontario K1A 0H3 (819) 994-3236	2.1
		Health: Legislative and Regulatory Processes Environmental Health Directorate Health and Welfare Canada	Environmental Health Centre Tunney's Pasture Ottawa, Ontario K1A 0L2 (613)957-3142	3.1
Other products used for:				
—pollution control —mineral leaching —chemical residue destruction —waste disposal —novel uses not covered by other acts	*Canadian Environmental Protection Act and Regulations*	**Notification:** Biotechnology Centre Commercial Chemicals Branch Environment Canada	Place Vincent Massey 351 St. Joseph Blvd. Hull, Quebec Mail: Ottawa, Ontario K1A 0H3 (819) 994-3236	2.1
		Health: Legislative and Regulatory Processes Environmental Health Directorate Health and Welfare Canada	Environmental Health Centre Tunney's Pasture Ottawa, Ontario K1A 0L2 (613) 957-3142	3.1

1. 1. Animal Disease and Protection Act and Regulations

Departmental Authority

Agriculture Canada
Health of Animals Directorate, Animal Health Division

The Animal Health Division regulates the production, evaluation, distribution, importation and disposal of veterinary biologics, animal products and byproducts, and animal pathogens.

Contact

Chief, Veterinary Biologics
Animal Health Division
Health of Animals Directorate
Agriculture Canada
801 Fallowfield Road
Nepean, Ontario
K2H 8P9
(613) 998-9320 Extension 4872

Products Regulated

☛ Veterinary biologics used for the diagnosis, treatment or prevention of animal diseases, including:

- live or killed microorganisms, helminths or their products; antisera; and diagnostic reagents produced by traditional or new biotechnological processes such as:
  - —recombinant DNA technology
  - —use of monoclonal antibodies
  - —molecular immunology
  - —enzyme assays
  - —biofermentation

☛ Indigenous or imported animal pathogens and materials of animal origin (animal products and byproducts)

Requirements

☞ **Field Trials**
Guidelines and requirements are available for traditional products and are under development for recombinant DNA products.

☞ **Commercial Use**

Approval Process	Products must be registered prior to sale. Before registration, Agriculture Canada will ensure that veterinary biologics are pure, safe, potent and efficacious. The Department will issue licences for commercial use following its inspection of premises to ensure that facilities meet the standards outlined immediately below.
Data	Manufacturers must prove that facilities for manufacturing meet Agriculture Canada's standards for manufacturing, preserving, packing, labelling, storing, testing, selling, transporting and disposing of veterinary biologics, animal pathogens, and material of animal origin.

☞ **Importation**

Approval Process	The Department grants permits to qualified importers. (Guidelines and requirements are available from the Health of Animals Directorate.)
Data	Importers must demonstrate they are qualified to import veterinary biologics, animal pathogens and material of animal origin.

BIO-TECH

REGULATIONS
RÈGLEMENT

3

Health and Welfare Canada

3 Health and Welfare Canada

3. Health and Welfare Canada

Mandate

Health and Welfare Canada regulates drugs (for both human and veterinary use), cosmetics, medical devices, radiation-emitting devices, foods and food additives, chemicals and other products that may affect human health. The Department also establishes regulations to prevent specific human diseases from entering Canada. In addition, the Department shares responsibilities with and advises other federal agencies.

Recommendation

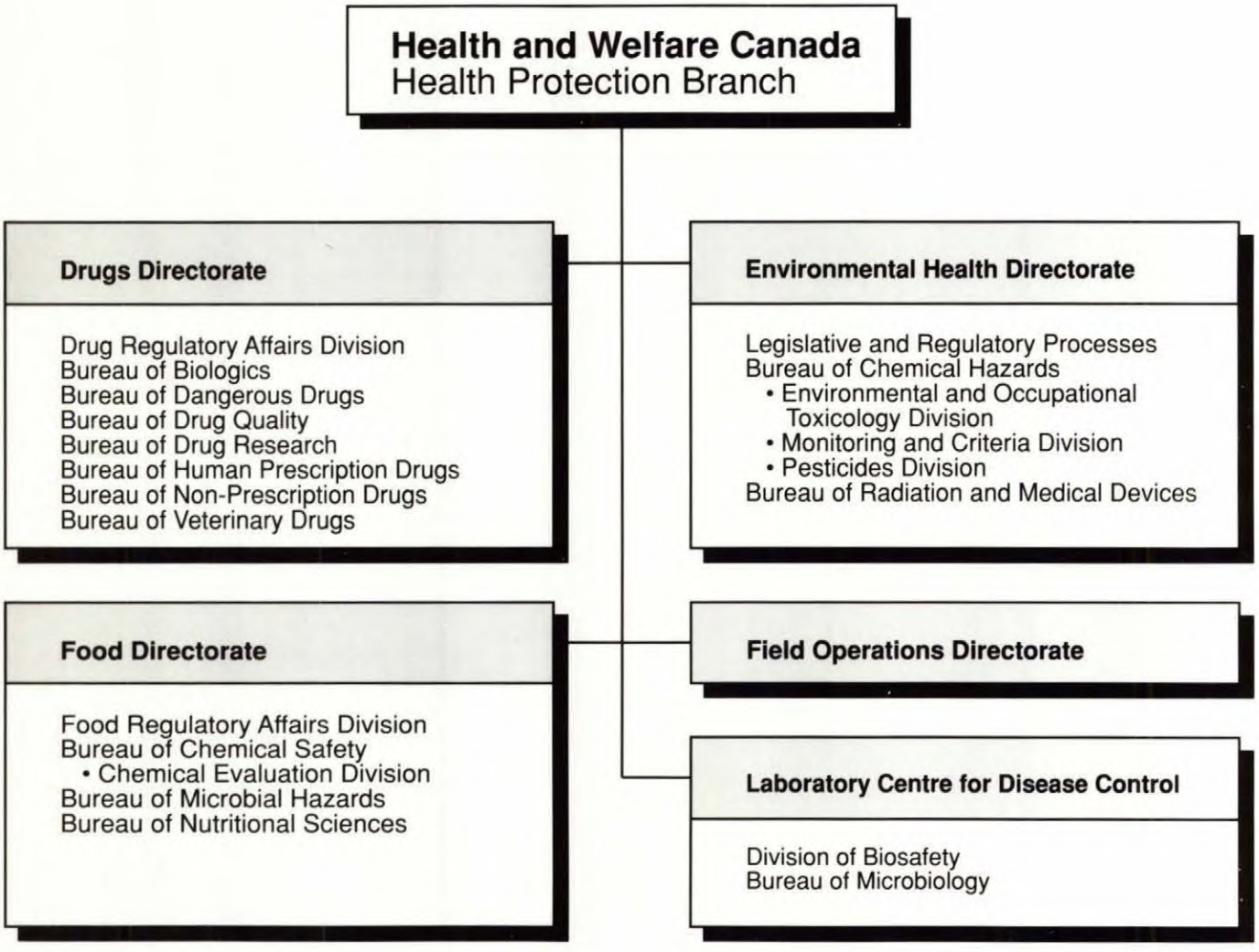
Health and Welfare Canada recommends that researchers and manufacturers follow the MRC guidelines (Guidelines for the Handling of Recombinant DNA Molecules and Animal Viruses and Cells), and the Supplement to the MRC Guidelines (The Biohazard Laboratory) during laboratory research. In addition, individuals should follow the principles behind Good Laboratory Practices (GLP) when undertaking biotechnological research. Manufacturers are encouraged to contact the Department at an early stage in product development, to allow for preparation of information required to assess their product.

Enquiries

Enquiries about Health and Welfare Canada's policies on biotechnology regulation and research may be addressed to:

Chairman
Branch Biotechnology Committee
Health Protection Branch
Health and Welfare Canada
3rd Floor, Banting Building
Ottawa, Ontario
K1A 0L2
(613) 957-1059

Responsibility Centres for Biotechnology



3. 1. Canadian Environmental Protection Act and Regulations

Departmental Authority

Environment Canada (See Section **2.1.1** of this *Guide*)
Health and Welfare Canada

The *Canadian Environmental Protection Act* is administered primarily by Environment Canada. Health and Welfare Canada has authority for prescribing and evaluating human health information. The new Act supersedes the *Environmental Contaminants Act* and contains amendments, including testing and information requirements related to human health. Its regulations will incorporate requirements for naturally occurring and genetically engineered organisms.

Contacts

Contact for notification:
Chief, Biotechnology Centre
Commercial Chemicals Branch
Environment Canada
Ottawa, Ontario
K1A 0H3
(819) 997-1499

Contact for health requirements:
Director, Bureau of Chemical Hazards
Environmental Health Directorate
Health and Welfare Canada
Ottawa, Ontario
K1A 0L2
(613) 957-3133

Associated Divisions

—Environmental and Occupational Toxicology Division (613) 957-1848
—Monitoring and Criteria Division (613) 957-3128

3. 2. Environmental Contaminants Act and Regulations

Departmental Authority

Environment Canada
Health and Welfare Canada

The powers of this Act, which has been superseded by the *Canadian Environmental Protection Act* (see previous pages), are limited to inanimate matter.

The *Environmental Contaminants Act* is administered by Environment Canada. Health and Welfare Canada has the authority to evaluate the human health effects of environmental contamination.

Contacts

Contact for notification:
Director, Commercial Chemicals Branch
Environment Canada
Ottawa, Ontario
K1A 0H3
(819) 997-1499

Contact for health requirements:
Director, Bureau of Chemical Hazards
Environmental Health Directorate
Health and Welfare Canada
Ottawa, Ontario
K1A 0L2
(613) 957-3133

Associated Divisions

—Environmental and Occupational Toxicology Division (613) 957-1848
—Monitoring and Criteria Division (613) 957-3128

3. 3. Food and Drugs Act and Regulations

Departmental Authority

Health and Welfare Canada
Health Protection Branch

The Health Protection Branch ensures that foods, drugs, veterinary drugs, cosmetics and medical devices sold in Canada are safe, and that drugs and medical devices are effective.

- **Drugs Directorate**
  This directorate and its bureaus regulate the manufacture, packaging, labelling, storage, sale, importation and advertising of human and veterinary drugs. It also regulates the manufacture, packaging, importation, sale and storage of cosmetics.

- **Food Directorate**
  This directorate conducts programs related to the safety, quality and nutritional value of foods. These programs involve regulation, evaluation and research to ensure that foods sold in Canada are nutritious and are protected from chemical and microbiological hazards.

- **Environmental Health Directorate**
  This directorate develops policies and programs concerning the manufacture, sale, importation and advertising of medical devices and diagnostic radiopharmaceuticals.

Drugs Directorate

Contacts

Chief
Drug Regulatory Affairs Division
Drugs Directorate
Room 139, Health Protection Building
Health and Welfare Canada
Ottawa, Ontario
K1A 0L2
(613) 957-0372

Associated Bureaus

—Bureau of Biologics (613) 957-8065
—Bureau of Human Prescription Drugs (613) 991-0107
—Bureau of Non-Prescription Drugs (613) 954-6493
—Bureau of Veterinary Drugs (613) 957-3824
—Bureau of Drug Research (613) 957-1059
—Bureau of Drug Quality (613) 957-1831
—Bureau of Dangerous Drugs (613) 954-6522

Products Regulated

Drugs, veterinary drugs and cosmetics that are produced through various biotechnological processes, such as genetic engineering and attenuation, including:

- hormones and cell growth factors
- drugs obtained by recombinant DNA procedures
- disinfectants used in medical care and food processing
- blood products such as human serum albumin, immunoglobulins, antihemophilic factor and thrombolytic and fibrinolytic enzymes
- vaccines
- monoclonal antibodies
- allergenic extracts

Requirements

Commercial Manufacture and Use—Cosmetics

Data — Section 29 of the Cosmetics Regulations may require manufacturers to submit sufficient data to establish the safety of any cosmetic.

Section 30 of the Cosmetic Regulations requires registrants to submit, within 10 days of the initial sale of a cosmetic, a list of ingredients and the concentration range of each ingredient.

NOTE: Cosmetics are also subject to the *Consumer Packaging and Labelling Act and Regulations*, administered by Consumer and Corporate Affairs Canada.

To assist manufacturers, the Health Protection Branch's Bureau of Non-Prescription Drugs has published "A Guide for the Labelling of Cosmetics."

Commercial Manufacture and Use—Drugs

Drugs listed in Schedules C and D of the *Food and Drugs Act* cannot be sold without a Ministerial indication that the manufacturing premises, processes and conditions are adequate to ensure that the drug will be safe for use (Section 12).

Schedule D lists drugs obtained by recombinant DNA procedures and some drugs that are prepared or originate from human or animal tissue or from microorganisms.

Approval Process — Manufacturers of drugs listed in either Schedule C or D of the Act must be licensed. Manufacturers of a new drug must obtain a "Notice of Compliance" before they may sell the drug, and must obtain a Drug Identification Number (DIN) for all drugs except radiopharmaceuticals, and sensitivity disks and tablets.

Data — The reference list of this *Guide* lists various guidelines, available from the appropriate bureau, to assist manufacturers in submitting data. Two are currently under development for biotechnology products:

—"Guidelines for the Manufacture of Monoclonal Antibody Products for Human Use"
—"Guidelines for the Production and Testing of New Drugs and Biologicals Produced by Recombinant DNA Technology"

Division 4 (Part C) of the Food and Drug Regulations requires specific information on the safety and efficacy of Schedule D drugs (biologicals).

Division 8 (Part C) of the Food and Drug Regulations outlines the requirements for establishing the safety and efficacy of a new drug.

☞ **Commercial Manufacture and Use—Veterinary Drugs**

The Department is currently drafting a "Guide for Use in the Preparation of Veterinary New Drug Submissions."

Division 15 (Part B) of the Food and Drug Regulations specifies the levels of drug residue that may be allowed in certain foods.

☞ Veterinary biologics such as vaccines, antisera, toxoids and bacterins are excluded from regulation under the Act. (See *Animal Disease and Protection Act*, Section **1.1.1** of this *Guide*.)

☞ **Importation**

Approval Process — The Drugs Directorate may inspect, analyze or examine imported cosmetics or drugs and may require manufacturers to re-label or modify the product prior to its sale in Canada.

Data — The requirements for drugs and cosmetics imported into Canada are identical to those required for products manufactured in Canada, as outlined under the preceding headings.

Drugs containing material of animal origin, and originating from outside North America, should also be cleared by Agriculture Canada (Animal Health Directorate).

Food Directorate

Contacts

Chief
Food Regulatory Affairs Division
Food Directorate
Health Protection Building
Health and Welfare Canada
Ottawa, Ontario
K1A 0L2
(613) 957-1748

Associated Bureaus

—Bureau of Chemical Safety (613) 957-0973
—Bureau of Microbial Hazards (613) 957-0880
—Bureau of Nutritional Sciences (613) 957-0911

Products Regulated

- Food and food packages as defined in the Act
- Agricultural chemicals, food additives and food ingredients as defined in the Regulations
- Food microorganisms, food contaminants and residues that are produced through (or as a result of) various biotechnological processes, (e.g., food enzymes, single cell proteins, fatty acids, and oils)

Requirements

Commercial Manufacture and Use

Approval Process

Section 4 of the Act prohibits the sale of food that is unsafe or adulterated. Section 5 deals with fraud. Section 6 deals with infringement on prescribed standards. Section 7 prohibits the manufacture, preparation, preservation, packaging and storage of any food under unsanitary conditions.

Data

The onus is upon manufacturers to submit information to support introduction of a new food additive into the marketplace. The requirements for this type of information are detailed in the Food and Drugs Regulations, Division 16, Section B. 16.002. Manufacturers may wish to consult the "Guide for Preparation of Submissions on Food Additives" (available from the Bureau of Chemical Safety).

Where manufacturers request that a food additive be placed on the list of permissible additives, or where a change is proposed in the use or amount of a food additive, manufacturers must comply with requirements under Division 16 of the Regulations.

Similarly, the onus is upon industry to support introduction of a new agricultural chemical into the marketplace. For prescreening, manufacturers may wish to consult the "Pesticide Submissions Checklist" (available from the Bureau of Chemical Safety). Manufacturers should also consult information requirements under the *Pest Control Products Act* (see Section **1.4.1** of this *Guide*).

The same requirements that apply to food additives are applicable to agricultural chemicals, whether or not those chemicals are used in Canada or are applied to food imported into Canada.

Importation

The Act prohibits the sale of imported foods and food additives that violate the Act or any Regulation.

Data

Imported foods, food additives and agricultural chemicals are subject to the same data requirements as those manufactured and sold in Canada.

Environmental Health Directorate

Contacts

Chief
Legislative and Regulatory Processes
Environmental Health Directorate
Environmental Health Centre
Health and Welfare Canada
Ottawa, Ontario
K1A 0L2
(613) 957-3142

Associated Bureau

—Bureau of Radiation and Medical Devices (613) 954-6647

Products Regulated

☛ Medical devices such as *in vitro* diagnostic kits (e.g., AIDS Associated Retrovirus Test kit), and radiopharmaceuticals originating from biotechnological processes.

Requirements

☞ **Commercial Manufacture and Use—Medical Devices**
Section 19 of the Act prohibits the sale of any device that, when used according to directions or under customary conditions, may cause injury to the health of the purchaser or user.

Approval Process — Sections 34 and 35 of the Medical Devices Regulations require manufacturers to obtain a "Notice of Compliance" from the Environmental Health Directorate prior to the sale of a new medical device. As a precondition to receiving the Notice of Compliance, manufacturers must submit information detailed in Part V of the Medical Devices Regulations.

Data — The "Guide to the Preparation of a Submission Pursuant to Part V of the Medical Devices Regulations" describes the data that manufacturers must submit. Manufacturers may also wish to consult "Medical Devices, Canadian Regulatory Requirements: Questions and Answers" (available from Legislative and Regulatory Processes).

Medical devices containing material of animal origin and imported from outside North America should also be cleared with Agriculture Canada, Animal Health Division.

Prior to sale, applicants must conduct tests to justify the benefits and performance of the device and, if the Directorate requests, provide information on test methods (Sections 14 and 15).

Within ten days of first selling a device, manufacturers must submit information detailed under Part II of the Medical Devices Regulations.

☞ **Commercial Manufacture and Use—Radiopharmaceuticals**
Data — Division 3 (Part C) of the Act requires manufacturers to submit specific information on the safety and efficacy of Schedule C drugs (radiopharmaceuticals).

Section C.03201 of the Regulations outlines the requirements, which relate primarily to labelling and information to be inserted in the package. Registrants should consult the Regulations for additional requirements regarding sale of these products.

☞ **Importation**
Data — Importers of medical devices must either test the device in Canada, or have available for examination evidence that the device has been satisfactorily tested outside Canada.

3. 4. Hazardous Products Act and Regulations

Departmental Authority

Consumer and Corporate Affairs Canada
Health and Welfare Canada

Consumer and Corporate Affairs Canada administers this Act, and Health and Welfare Canada has authority to recommend that the advertising, sale or importation of a product be prohibited. The Department forwards information on health concerns related to the regulation of hazardous products to Consumer and Corporate Affairs for appropriate action.

Contacts

Contact for notification:
Director, Product Safety Branch
Bureau of Consumer Affairs
Consumer and Corporate Affairs Canada
Place du Portage, Phase 1
50 Victoria Street
Hull, Quebec
K1A 0C9
(819) 997-1194

Contact for health requirements:
Chief, Legislative and Regulatory Processes
Environmental Health Directorate
Environmental Health Centre
Health and Welfare Canada
Ottawa, Ontario
K1A 0L2
(613) 957-3142

Associated Bureaus

—Bureau of Chemical Hazards (613) 957-3133
—Bureau of Radiation and Medical Devices (613) 954-0297

Products Regulated

☛ Consumer products that are considered hazardous and that are developed through biotechnological processes, including naturally occurring and genetically engineered organisms not already covered by the *Food and Drugs Act*, the *Pest Control Products Act*, the *Explosives Act* and the *Atomic Energy Control Act*.

Requirements

☞ **Commercial Use**

Approval Process — Parts I and II of the Act describe which products are prohibited from advertisement or sale (Section 3).

The Act authorizes an inspector to enter any place where a hazardous product is manufactured, packaged, stored or sold and to examine any products, equipment, packages, books and records associated with products subject to the Act.

Data — Section 10 authorizes the Minister of Health and Welfare to compel manufacturers to submit information on products in order to assess their safety to human health. Manufacturers should consult the Regulations for specific data requirements.

☞ **Importation**

The Act prohibits importation of a hazardous product listed in Part I of the Schedule. Applicants may import products under the conditions stipulated in Part II of the Schedule of Regulations.

3. 5. Pest Control Products Act and Regulations: Health Evaluation

Departmental Authority

Agriculture Canada (See Section **1.4.** of this *Guide*)

Agriculture Canada regulates pest control products for use in Canada under the *Pest Control Products Act*. Health and Welfare Canada advises on potential health effects. Health and Welfare's Food Directorate evaluates exposure to food residues and establishes maximum residue levels for agricultural chemicals in food under the *Food and Drugs Act and Regulations*. The Environmental Health Directorate (Pesticides Division) evaluates workers' and bystanders' exposure to pest control products and their environmental residues.

Contacts

Contact for registration:
Pesticides Directorate
Agriculture Canada
2323 Riverside Drive
2nd Floor, SBI Building
Ottawa, Ontario
K1A 0C6
(613) 993-4544

Contact for health requirements:
Chief, Pesticides Division
Environmental Health Directorate
Health and Welfare Canada
Environmental Health Centre
Tunney's Pasture
Ottawa, Ontario
K1A 0L2
(613) 957-1852

For information about pesticide residues on foods:
Chief, Chemical Evaluation Division
Bureau of Chemical Safety
Food Directorate
Health and Welfare Canada
Banting Building
Tunney's Pasture
Ottawa, Ontario
K1A 0L2
(613) 957-0973

3. 6. Support Services

Field Operations Directorate	This Directorate provides support and advice on the Department's policies on biotechnology. Staff in regional and district offices inspect the products and facilities regulated through the various acts administered by the Department.
Contact	Chief Program Development and Evaluation Field Operations Directorate (613) 957-3833
Laboratory Centre for Disease Control	LCDC provides microbiological services and biosafety consultative services. Specifically, the Bureau of Microbiology conducts research in cell-fusion technology, molecular probes, etc., as part of an active program on diagnostic reagents and standards, and on the evaluation of therapeutic agents. Purified microbial antigens and human globulins produced *in vitro* are evaluated for therapeutic use as immunizing agents.
Contacts	Chief, Division of Biosafety (613) 957-1771 Director, Bureau of Microbiology (613) 957-1329
Bureau of Biologics, Drugs Directorate	The Bureau evaluates submissions from manufacturers concerning the use in humans of all biologics, including drugs manufactured by biotechnological processes. Manufacturers' premises are subject to inspection by Health and Welfare, and the Bureau's laboratories conduct evaluations of products and processes. The Bureau also licenses manufacturers and their products.
Contact	Director, Bureau of Biologics (613) 957-8065
Bureau of Drug Research, Drugs Directorate	The Bureau carries out laboratory investigations in support of the Directorate's regulatory programs. Basic pharmaceutical and toxicological research is undertaken.
Contact	Director, Bureau of Drug Research (613) 957-1059

3. 7. Reference List

Health and Welfare Canada

- MRC Guidelines:
  "Guidelines for the Handling of Recombinant DNA Molecules and Animal Viruses and Cells" and "The Biohazard Laboratory: Supplement to the MRC Guidelines"
  —Both documents are currently being updated and offer valuable information on safety procedures in conducting biotechnology-related research. The Medical Research Council guidelines are voluntary and are mandated only at institutions that receive MRC and NSERC funding. Available from MRC.
- "Good Manufacturing Practices for Drug Manufacturers and Importers"
  —available from the Bureau of Drug Quality, Drugs Directorate
- "A Guide for the Labelling of Cosmetics"
  —available from the Bureau of Non-Prescription Drugs, Drugs Directorate
- "Guidelines for the Production and Testing of New Drugs and Biologicals Produced by Recombinant DNA Technology"
  —available from the Bureau of Biologics, Drugs Directorate
- "Guidelines for the Manufacture of Monoclonal Antibody Products for Human Use"
  —available from the Bureau of Biologics, Drugs Directorate
- "Guide for the Preparation of Submissions on Food Additives"
  —available from the Bureau of Chemical Safety, Food Directorate
- "Guide to the Preparation of a Submission Pursuant to Part V of the Medical Devices Regulations"
  —available from the Bureau of Radiation and Medical Devices, Environmental Health Directorate
- "Medical Devices, Canadian Regulatory Requirements: Questions and Answers"
  —available from Legislative and Regulatory Processes, Environmental Health Directorate
- "Final Report of the Environmental Contaminants Act Amendments Consultative Committee"
  —available from the Bureau of Chemical Hazards, Environmental Health Directorate
- "Guide for Use in the Preparation of Veterinary New Drug Submissions"
  —available from the Bureau of Veterinary Drugs, Drugs Directorate

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Glossary

Glossary

Active ingredient	Ingredient to which effects of a product are attributed.
Allelopathic chemical	Secondary metabolite or byproduct (produced generally by plants) that has an adverse and/or inhibitory effect on seedlings of its own species, or other plants and organisms.
Allergen	A substance capable of inducing hypersensitivity.
Anther culture	Production of plant embryos with new genetic characteristics from anthers containing immature pollen by genetic manipulations using tissue culture techniques.
Antibody	Modified soluble protein (an immunoglobulin molecule) having a specific amino acid sequence, produced by plasma cells in response to an antigen. The specific sequence enables each antibody to adhere to and interact only with antigens related to the antigen that induced its synthesis.
Antigen	Any substance capable, under appropriate conditions, of inducing the formation of an antibody and of reacting specifically in some detectable manner with the antibody so induced. Antigens may be soluble substances, such as toxins and foreign proteins, or particulates, such as bacteria and tissue cells.
Antihemophilic factor	Coagulation factor necessary for the normal clotting of blood, absent in hemophiliacs.
Attenuation	The change in the virulence of a pathogenic microorganism induced by passage through another host species, decreasing its virulence for the native host and increasing it for the new host (the basis for the development of live vaccines).
Bacteriocidin	A bacteriocidal antibody.
Biocatalyst	An enzyme that plays a fundamental role in living organisms or industrially by activating or accelerating a process.
Biofermentation	See fermentation.
Biologics	Vaccines, therapeutic serums, toxoids, antitoxins, and analogous biological products used to induce immunity to infectious disease.
Biosensor	A device consisting of a biologically selective material in which some biological process is converted into a detectable event. In some cases, the material is immobilized in the vicinity of a transducer whose function is to relay the changing parameter (heat, light, sound, current, capacitance, potential, etc.) as an electrical signal.
Biotransformation	The process by which a cell's characteristics are changed by modifying its genetic material.
Cell fusion	The fusion of two different cells (protoplasts for plants or bacteria) to form a single hybrid cell containing genetic material and cytoplasm from both parents.
Contagious	Capable of being transmitted from one organism to another only by direct physical contact.

Containment

- Biological — the use of genetically altered bacteria, phages, and plasmids that are unable to complete essential functions (e.g., — growth, DNA replication, DNA transfer, infection and/or propagation) except under specific conditions for the purpose of diminishing or eliminating the possibility of their survival and/or transmission.
- Physical — the use of laboratory design and practice (e.g., limited access, safety cabinets, aerosol control, protective clothing, pipetting aids) for the purpose of reducing the likelihood of personnel infection and/or the spread of organisms or genetic material (see MRC Guidelines).

Cytoplasmic male sterility

A condition where the male plant does not produce pollen, controlled by factors in the cytoplasm.

Diagnostic reagents

Substances used to produce chemical/biological reactions for the purpose of diagnosis.

DNA

Deoxyribonucleic acid; polymer composed of deoxyribonucleotide units; genetic material of most organisms.

DNA probe

A sequence of DNA that is used to detect the presence of a complementary nucleotide sequence.

Donor

An organism or a substance/compound that contributes part of itself to another organism or substance/compound.

Downstream processing

The separation, purification or modification of a product after initial production.

Drug

Any substance or mixture of substances manufactured, sold or represented for use in

- the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or the symptoms thereof, in man or animal,
- restoring, correcting or modifying organic functions in man or animal, or
- disinfection in premises in which food is manufactured, prepared or kept, or for the control of vermin in such premises.

Drug Identification Number (DIN)

Unique identification number assigned to all drug products prior to their sale in Canada, based upon their medicinal ingredient, manufacturer's name, strength, dosage form and route of administration.

ELISA analysis

ELISA is an acronym for ENZYME-LINKED IMMUNOSORBENT ASSAY, a type of enzyme immunoassay (E.I.A.) technique in which an antibody or antigen is adsorbed onto a solid support (solid phase). Quantities of sample, conjugate, and enzyme substrate are incubated with the antibody or antigen attached to the solid phase. Only that amount which reacts with the previously added reactant remains. The final enzyme-substrate reaction is used to detect the presence and/or amount of the antibody or antigen in the sample.

Embryo culture

A tissue culture technique for growing plants from embryos *in vitro.*

Eukaryotic microalgal conditioner

A product consisting of eukaryotic microalgae represented to improve the physical condition of a growing medium.

Fermentation

An anaerobic bioprocess. Fermentation is used in various industrial processes for manufacture of organic chemicals such as alcohols, acids, and cheese by microorganisms (e.g., yeasts, molds, bacteria). The process can also be used to produce large amounts of specific microorganisms.

Fibrin

An insoluble protein which forms the basis of a blood clot.

Fibrinolytic enzyme

An enzyme that breaks down fibrin.

Food

Any article manufactured, sold or represented for use as food or drink for humans, chewing gum, and any ingredient that may be mixed with food for any purpose whatever.

Food additive

Any substance including any source of radiation, the use of which results, or may reasonably be expected to result in it or its by-products becoming a part of or affecting the characteristics of a food, but does not include:

- any nutritive material that is used, recognized or commonly sold as an article or ingredient of food,
- vitamins, mineral nutrients and amino acids,
- spices, seasoning, flavouring preparations, essential oils, oleoresins and natural extractives,
- agricultural chemicals,
- food packaging materials and components thereof, and
- drugs recommended for administration to animals that may be consumed as food.

Field trial

Any planned application outside of contained facilities during product development and including pre-commercial testing.

Gene

The basic unit of heredity; a segment of DNA, comprising an ordered sequence of nucleotide bases. A gene contains the sequence of DNA that encodes one polypeptide chain, via RNA.

Gene transfer

The artificial introduction of foreign genes into recipient cells or the natural movement of genetic information between organisms in the environment.

Genetic engineering

Production of new genetic combinations not known to occur naturally and generated by techniques which are artificial mechanisms not known to occur in nature.

Genotypic

Pertaining to the genetic constitution of an individual or group; the genetic information which determines a particular characteristic (compare phenotypic).

Haploid induction

Production of plants with half the normal number of chromosomes for that species using microspore culture, anther culture and chromosome elimination.

Helminth

A parasitic worm.

Host

An animal or plant that harbors and provides sustenance for another organism.

Human globulins

Proteins found in human plasma, insoluble in water but soluble in saline solution.

Human growth hormone

A substance that stimulates growth in humans by influencing protein, carbohydrate and lipid metabolism; normally a secretion of the anterior lobe of the pituitary gland.

Human Serum Albumin (HSA)

Abundant protein in human blood; used in medicine to treat burn, trauma and shock patients.

Immunizing agents

Substances that induce immunity.

Immunity

An organism's ability to resist infection.

Immunoassay

Chemical measurement (assay) using an immune reaction as part of the method. Various methods are used in measuring this immune reaction, including the linking (conjugating) of enzymes, radioisotopes, fluorescent compounds, etc., to the antibody or antigen in the immune reaction. Hence, enzyme immunoassay (E.I.A.), radio immunoassay (R.I.A.), immunofluorescence assay, etc.

Immunoglobulins

A group of structurally related proteins (globulins) that may act as antibodies.

Indigenous

Naturally occurring in an ecosystem.

Interferon	A class of small soluble proteins, released by cells, which induces in noninfected cells the formation of an antiviral protein that inhibits viral multiplication. Interferon may be released in response to viral infection and certain other nonviral and infectious agents (e.g., bacteria and synthetic polymers).
In vitro	Pertaining to biological reactions or processes taking place outside the living body; sometimes used to include the growth of cells from multicellular organisms under cell culture conditions.
In vivo	Pertaining to biological reactions or processes taking place in a living cell or organism.
Lignin	A polysaccharide which along with cellulose forms the cell wall of plants and wood.
Lymphokines	Proteins that mediate interactions among lymphocytes and which are vital to proper immune function.
Maximum residue level	Limit of the amount of a substance, either man-made or naturally occurring, that is allowable in a food commodity.
Medical device	Any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in • the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or the symptoms thereof, in man or animal, • restoring, correcting or modifying a body function or the body structure of man or animal, • the diagnosis of pregnancy in humans or animals, or • the care of humans or animals during pregnancy and at and after birth of the offspring, including care of the offspring, and includes a contraceptive device but does not include a drug.
Medical Research Council (MRC)Guidelines	Guidelines produced by the MRC of Canada for conducting hazardous or potentially hazardous research.
Merit requirements	Characteristics of a seed variety which determine whether it is of high enough quality to be registered.
Microbe	Microorganism — any organism too small to be visible to the naked eye. Includes bacteria, some fungi, protozoa, mycoplasmas, microalgae, rickettsiae and viruses.
Microbial antigens	Antigens originating directly, or indirectly via their metabolites from microbes.
Microcosm	Enclosed microenvironment (such as a greenhouse) that simulates the characteristics of a real macroenvironment.
Monoclonal antibodies	Homogeneous antibodies derived from a single clone of hybridoma cells that recognize only one molecular structure with high specificity.
Mycorrhiza	A symbiotic association of fungus and plant roots.
Neuroactive peptide	Peptides that exhibit pharmacologic action on the nervous system.
Nitrification	The bacterial oxidation of ammonia and organic nitrogen to nitrites and nitrates in the soil.
Nitrogen fixing bacteria	Bacteria capable of reducing atmospheric nitrogen gas to ammonia.
Non-indigenous	Organisms not naturally occuring in an ecosystem.

Notice of Compliance	A document issued by the regulatory agency to a manufacturer before the sale of a product is permitted. It affirms that the manufacturer has adhered to the regulatory guidelines governing the research, production, safety and effectiveness of such product(s).
Parent organism	A donor or a recipient of genetic material during genetic engineering.
Pathogenic	Producing disease in living organisms.
Peptide	A linear polymer of amino acids.
Phenotypic	Pertaining to the observable characteristics of an organism which result from interaction between its genetic constitution (genotype) and environment.
Phosphate solubilizing bacteria	Bacteria capable of increasing the solubility of phosphates.
Radiopharmaceutical	Medical drug containing a radioactive isotope.
Recipient organism	Organism which receives the new genetic material.
Recombinant DNA	Hybrid DNA sequences, from the same or different organisms, assembled *in vitro* in a novel configuration. Such 'recombinant' molecules can be replicated in a living cell.
Sensitivity disks (tablets)	Absorbent material or tablets impregnated with antibiotics, sulphonamides or other preparations which possess inhibitory action on the growth of microorganisms.
Single cell protein	Protein derived from microorganisms such as bacteria.
Therapeutic agents	Substances used for the treatment of disease.
Thrombolytic enzymes	Enzymes such as streptokinase and urokinase that initiate the dissolution of blood clots.
Vaccine	Antigenic material (attenuated or killed bacteria or virus, or portions thereof) used to stimulate the development of antibodies and thus confer active immunity against a specific disease.
Vector agent	Vehicle by which foreign DNA is transferred from one cell to another; e.g., viruses, *Agrobacterium* sp.
Waiver	An application for an exemption from either notification or the provision of information.