



# HEALTH CANADA'S ROLE IN THE REGULATION OF PRODUCTS FROM BIOTECHNOLOGY

In recent decades, huge leaps in technology have led to dramatic biotechnological advances, resulting in a broad range of environmental products, health products and foods. Biotechnology is a general term used to describe the use of biological, or living organisms to make products, in contrast to purely chemical processes. Biotechnology has been in practice for centuries and includes such traditional applications as the use of yeast in making beer and bread, as well as modern applications like recombinant DNA techniques to improve crops.

## MINIMIZING RISK, MAXIMIZING HEALTH AND SAFETY

The responsible use of biotechnology can bring health benefits to Canadians, however the benefits of science may be accompanied by risks. Health Canada, the Canadian Food Inspection Agency (CFIA), Fisheries and Oceans Canada and Environment Canada have joint responsibility to determine that biotechnology-derived products are safe for Canadians and their environment.

Health Canada is the federal government department responsible for helping the people of Canada maintain and improve their health. We regulate health products, food products and environmental/industrial products, and much of our work involves assessing and managing the risks associated with their use.

It takes seven to ten years of development and testing to bring a new biotechnology-derived product to the Canadian market. By keeping up with scientific change, funding cutting-edge research and hiring top-notch professionals, Health Canada enhances the capacity of its science-based regulatory system. As well, only where there is sufficient evidence supporting the safe and effective use of a product will it be authorized for sale in Canada.

## GLOBAL STANDARDS

Health Canada works with international partners to harmonize global approaches to biotechnology regulation. We also work with international experts on how to effectively monitor products that are on the market. This international collaboration allows regulators to maintain common standards that can be compared and that are objective and verifiable.

Products from biotechnology can be broadly classified into three groups – health products, food and environmental/industrial products. The regulatory process for each of these types of products is detailed in the next sections.



Health  
Canada

Santé  
Canada

Canada 

## Health Products

Biotechnology gives Canadians a wide variety of new and important health products to prevent disease, diagnose and treat illness and improve health. Some of the diseases currently treated or diagnosed with biotechnology-based products are diabetes, haemophilia, rheumatoid arthritis, multiple sclerosis and cancer.

Biotechnology-based health products include:

- biologics, such as vaccines, and products made from animal and human fluids, tissues and organs, recombinant proteins (including blood products), hormones, growth factors and enzymes manufactured in bacterial, yeast or mammalian cell lines, gene therapy and cell therapy products
- radiopharmaceuticals that contain a biotechnology-derived component
- pharmaceuticals regulated as chemical drugs, such as certain antibiotics and enzymes
- medical devices and certain diagnostic tests and kits such as radio labelled biotherapeutics used for diagnosis and imaging

No health product is 100% effective or 100% safe. Indeed, the more powerful and effective a drug product, the higher the probability of it having significant side effects. Our work to minimize the risk of health products falls into three main areas:

- review and evaluation
- compliance and enforcement activities
- monitoring and tracking

### REVIEW AND EVALUATION

Health products are assessed for risks and verified for quality and efficacy before being allowed to be used by Canadians. Regulations defining the conditions for activities and materials associated with the testing, manufacture, preparation, preservation, packaging, administration, storage and sale of any health product are set out in the *Food and Drugs Act*, the *Food and Drug Regulations* and the *Medical Devices Regulations*.

The detailed information submitted for review to Health Canada by manufacturers includes:

- pre-clinical studies done *in vitro* (test tube) and *in vivo* (using animals) to assess drug performance, including the extent of any toxic effects;
- results of clinical trials (for all drugs) or medical device investigational testing involving humans;
- the way the product is manufactured or produced - including quality controls and evidence of consistent manufacture and stability;
- packaging and labelling;
- therapeutic or diagnostic claims for the product;
- conditions for use; and
- potential side effects.

In the case of biologics, manufacturers must also provide samples of at least three lots of the product for testing as part of our product evaluation activities. When we receive a new biotechnology-based health product submission, we screen the content to make sure it is complete and of suitable quality to be reviewed, and review the information that the manufacturer proposes to give to health care providers and consumers (for example, on the label or in the product monograph).

If we conclude that the benefits outweigh the risks and that risks can be mitigated and/or managed, we provide the manufacturer with a Drug Identification Number (DIN) which gives them authorization to sell the product in Canada. This is referred to as a Notice of Compliance (NOC) or medical device license.

## **COMPLIANCE AND ENFORCEMENT ACTIVITIES**

- **Education, Consultation and Information:** We encourage industry, consumers and other stakeholders to take part in developing health and safety standards and policies for health products.
- **Compliance Monitoring:** We monitor industry activities to make sure they follow established policies and procedures.
- **Compliance Verifications and Investigations:** When we have reason to suspect a product or activity may not be following regulations, we investigate to verify the information. If there is a problem, we work with the party responsible to correct it.
- **Enforcement:** If a party is unable or unwilling to comply with regulations, we take appropriate enforcement action.

## MONITORING AND TRACKING

Health Canada continues to monitor the safety, effectiveness and quality of health products after they reach the marketplace. This provides new and up-to-date information that only becomes available after people start using health products under “real life” conditions.

When we identify a signal that there may be a problem with a product on the market, Health Canada evaluators do further research and look for patterns. This helps determine whether there is a safety issue that requires action. Some of the actions we may take to address safety issues for biotechnology-based health products on the market include:

- continuing to monitor the product;
- reassessing the risk/benefit profile of the product;
- asking the manufacturer to make changes to the labelling (for example, changes to directions for use, warnings about side-effects or interactions with other products);
- issuing advisories or warnings for health care professionals, hospitals and consumers; and/or
- removing the product from the marketplace.

Although biotechnology-based health products are often copies or are very similar to naturally occurring proteins, they still require close post-market surveillance.

## Food Products

Modern biotechnology techniques allow for the development of new food products. These new foods are referred to as “novel foods.” Novel foods result from a process not previously used for food, products that have never been used as a food, or foods that have been modified by genetic manipulation, also known as genetically modified (GM) foods or genetically engineered (GE) food.

All novel crop plants and their products are subjected to a rigorous environmental, livestock feed and food safety assessment. Scientists from Health Canada and the CFIA are responsible for a pre-market review of the data collected from laboratory and field experiments carried out by the product’s developer.

### Genetically Modified

An organism, such as a plant, animal or bacterium, is considered genetically modified if its genetic material has been altered through any method, including conventional breeding. A “GMO” is a genetically modified organism.

### Genetically Engineered

An organism is considered genetically engineered if it was genetically modified using techniques that permit the direct transfer or removal of genes in that organism. Such techniques are also called recombinant DNA or rDNA techniques.

### Foods Derived from Biotechnology

To date, over 100 novel foods have been approved for sale by Health Canada. They include foods such as wheat, corn, canola, soybeans, sugar beets, lentils and tomatoes.

Health Canada establishes science-based regulations, guidelines and public health policies for these novel foods. The main concern in regulating food products is the health and safety of Canadians, animals and our environment. If there are any questions about the safety of a product, it is not approved.

CFIA’s role is to protect Canada’s food supply and the health of plants and animals. It carries out safety assessments for the release into the environment of plants with novel traits. It also assesses livestock feed, seeds, plant and soil supplements and veterinary biologics – including those made through biotechnology.

## PRE-MARKET ASSESSMENT

Pre-market assessment of novel foods and novel food ingredients is required under the *Food and Drug Regulations*. This science-based safety and nutritional assessment includes:

- a review of the molecular biological data which characterize the genetic change (not all novel foods go through this change);
- the composition of the novel food compared with the same non-modified food;
- the nutritional information compared with information on non-modified counterparts;
- the potential for introducing new toxins;
- the potential for causing allergic reactions.

## LETTER OF NO OBJECTION

If a product successfully passes the assessment process and the other regulatory approvals from CFIA for environmental and feed safety (when applicable), a “letter of no objection” is sent to the product developer. This letter indicates that the product can be sold in Canada for the uses listed in the submission. The letter also outlines any restrictions or requirements relevant to the Health Canada decision.

## LABELLING OF FOODS DERIVED FROM BIOTECHNOLOGY

Under the *Food and Drugs Act*, labelling is mandatory if there is a health or safety issue with a food. For example, if the nutritional value or composition of the food has been changed, or if there is an allergen present in the food, special labelling is required to alert consumers or susceptible groups in the population. This applies to all foods, including those made through genetic engineering. Health Canada and CFIA share the responsibility for food-labelling policies.

For many Canadians, labelling of foods derived from biotechnology is an important issue. A Canadian standard for voluntary labelling of GE foods has been adopted by the Canadian General Standards Board. The objectives of this national standard are to provide meaningful criteria for labelling, understandable messages for consumers, and a consistent policy to verify the truthfulness of labels.

## Environmental/Industrial Products

Environmental and industrial biotechnology uses molecular biology and cell manipulation to develop new products or alternative methods for producing traditional products.

Many industrial sectors use bio-based processes to make and improve their products:

- Agriculture – pest control products such as biological herbicides, insecticides and fungicides
- Energy and fuel industry – bioenergy such as biogas, biodiesel, bioethanol and biofuels
- Environmental management – biomining/leaching of metals and minerals, bioremediation (the use of bacteria to clean up oil spills)
- Pulp and paper industry – tree biotechnology, biopulping and biobleaching for paper and wood products, and reduction in forest industry waste
- Day-to-day consumer goods – cosmetics, chemicals and plastics, leather goods and textiles, as well as biological drain cleaners and grease trap cleaners

Health Canada and Environment Canada have joint responsibility under the *Canadian Environmental Protection Act, 1999* (CEPA 1999), for the risk assessment of environmental and industrial products produced using biotechnology. The two departments manage substances that pose a risk to human health or the environment, whether they occur naturally or are genetically modified. All products designed to manage, destroy, attract or repel pests that are used, sold or imported into Canada are regulated by Health Canada's Pest Management Regulatory Agency (PMRA) under the *Pest Control Products Act*. Information on these products, submitted by the product's developer, is assessed and a decision is made on their safety before being made available for sale in Canada.

### POLICIES AND REGULATIONS

To meet its obligation of protecting the health and safety of Canadians and our environment, Health Canada has in place a rigorous system to regulate and assess products of biotechnology. Evaluators assess the information submitted by product developers to determine whether a substance is toxic or capable of becoming toxic. A substance is considered toxic if it enters or may enter the environment in amounts that pose a risk to:

- human health
- the environment, such as fish and wildlife and/or
- the environment upon which life depends, such as water, soil and air

If Health Canada believes that a new substance that is a product of biotechnology may pose a health risk, it takes preventive action to manage the risk by imposing controls on the manufacture, import, use, release and/or disposal of the product.

The health risk assessment for products of biotechnology considers the following issues:

- identification and strain history of the organism;
- documented involvement of the organism in adverse human health effects;
- relationship to known pathogens;
- tests for antibiotic susceptibility;
- tests for pathogenicity;
- potential to cause adverse immunological reactions; and
- the estimated number of persons that may be exposed and degree of exposure.

Assessment takes place before manufacture or import, and for some substances, at the research and development stage. If a risk is identified, measures are taken to reduce it by controlling or even banning the substance or product.

## **MONITORING AND TRACKING**

To protect the health and safety of Canadians, Health Canada has the capacity to monitor and track specific environmental biotechnology products and byproducts (both pre-and post-market) by collecting, integrating, analyzing and interpreting data and disseminating the information to those who need to know. Monitoring and tracking of environmental health impacts is done to maintain and improve understanding of health and safety issues, standards and security, and to use the information for research and advise others in policy and regulatory domains.

Health Canada systematically conducts monitoring as a countermeasure and foresight activity in accordance with the North Atlantic Treaty Organization (NATO) principles of intelligence gathering through surveillance and active field work.

## Keeping Canadians Informed

The Canadian public expects to be informed about the regulation and safety of products they use. One of Health Canada's roles is to make the regulatory review process for novel foods and health products available, clear and understandable.

Information is available on the benefits and the risks of biotechnology to help Canadians make healthy choices and informed decisions. As well, Canadians can participate directly in shaping biotechnology policies governing health products and food through provincial governments, patient and consumer organizations, industry and direct citizen involvement.

When a novel food has been submitted for assessment, a description of the product and the data received are posted on the CFIA's Web site as part of the joint Health Canada/CFIA Notices of Submission Project. Decision documents, describing the novel food and summarizing the assessment and any labelling requirements, are posted on both Health Canada's and the CFIA's Web sites. In addition, you can send comments on these submissions through these sites.

For health products, Health Canada has developed Canadian Summary Basis of Decisions (SBD) documents. This system, related to drug submissions and medical device applications outlines the scientific and benefit/risk-based reasons for Health Canada's decision to give market authorization for a health product. Canadian health care professionals and consumers can access this information to make informed treatment choices.

Health Canada is currently posting SBDs on its Web site for market authorizations related to New Drug Submissions (NDSs) for New Active Substances (NASs) and a subset of Class IV medical device applications. Future phases of the SBD project may be the publication of these documents for other types of drug submissions and medical device application types, including Supplemental New Drug Submissions (SNDS) and an expanded set of Class IV device applications, respectively.

Similar to the regulations of foods and health products, Health Canada also publishes risk assessment summary reports for environmental/industrial products on its Web site. Also you can visit the Canadian Node of Biosafety Clearing House Web site where you will find information on biotechnology risk assessment decisions that Health Canada and Environment Canada have made. This list will continue to expand to include assessment decisions for new and past decisions.

## LINKS

*Food and Drugs Act:* <http://laws.justice.gc.ca/en/F-27/>

*Food and Drug Regulations:* <http://laws.justice.gc.ca/en/F-27/C.R.C.-c.870/index.html>

*Medical Devices Regulations:* <http://laws.justice.gc.ca/en/f-27/SOR-98-282/>

Voluntary Labelling And Advertising of Foods That Are and Are Not Products of Genetic Engineering - Canadian General Standards Board:

[http://www.pwgsc.gc.ca/cgsb/on\\_the\\_net/032\\_0315/standard-e.html](http://www.pwgsc.gc.ca/cgsb/on_the_net/032_0315/standard-e.html)

*Canadian Environmental Protection Act, 1999 (CEPA 1999):*

[http://www.ec.gc.ca/CEPARRegistry/the\\_act/](http://www.ec.gc.ca/CEPARRegistry/the_act/)

Health Canada/CFIA Notices of Submission Project:

<http://www.inspection.gc.ca/english/plaveg/bio/subs/subliste.shtml>

Decision documents for novel foods:

Health Canada: [http://www.hc-sc.gc.ca/fn-an/gmf-agm/appro/index\\_e.html](http://www.hc-sc.gc.ca/fn-an/gmf-agm/appro/index_e.html)

CFIA: <http://www.inspection.gc.ca/english/plaveg/bio/dde.shtml>

Canadian Summary Basis of Decisions (SBD) documents:

[http://www.hc-sc.gc.ca/dhp-mps/prodpharma/sbd-smd/phase1-decision/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/sbd-smd/phase1-decision/index_e.html)

*Pest Control Products Act:* <http://laws.justice.gc.ca/en/P-9/>

New Substances Web site: [http://www.ec.gc.ca/substances/nsb/eng/bio\\_decisions\\_e.shtml](http://www.ec.gc.ca/substances/nsb/eng/bio_decisions_e.shtml)

Canadian Node for the Biosafety Clearinghouse: <http://www.bch.gc.ca/>

For more information, visit the biotechnology theme at Health Canada's website:

[http://hc-sc.gc.ca/sr-sr/biotech/index\\_e.html](http://hc-sc.gc.ca/sr-sr/biotech/index_e.html)

Or contact us at:

Health Canada

Departmental Biotechnology Office

200 Tunney's Pasture Driveway PL 0702A

Ottawa, Ontario K1A 0L2

Fax: (613) 957-0362

E-mail: [obs-bbs@hc-sc.gc.ca](mailto:obs-bbs@hc-sc.gc.ca)

