

Biotechnology and Human Health

Safeguarding and
Enhancing the Health
of Canadians



<http://www.healthcanada.ca/biotech>



Health
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Canada 

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The world has witnessed extraordinary advances in science over the last few decades. Biotechnology — one such area of growth — is an umbrella term covering a broad spectrum of scientific applications used in many sectors, such as health and agriculture. It involves the use of living organisms, or parts of living organisms, to provide new methods of production and make new products.

From new vaccines to prevent disease to genetically modified plants with resistance to pests; from replacement heart valves that are better accepted by the body to treatments for human infertility; and from bacteria capable of cleaning up oil spills to environmentally friendly biofuels — biotechnology (sometimes also referred to as life sciences, genetic modification, or genomics), like any new technology, offers us potential benefits and potential risks.

Health Canada's Role

Health Canada's mission is to help Canadians maintain and improve their health. It is our responsibility to:

- develop national health policy in partnership with the provinces and territories;
- enforce health regulations;
- evaluate the safety and effectiveness of health products, and the safety of food;
- assess the human health risks of environmental products;
- monitor potential long-term health trends associated with health products and food; and
- promote disease prevention and healthy living.

For products of biotechnology, our responsibilities are the same. With a rigorous system in place to regulate and assess products, Health Canada's paramount concern is the health and safety of Canadians and our environment.

If, in its scientific assessment, Health Canada has any concerns about the safety of a product, it is not approved for sale in Canada. The 21st century, with its rapid scientific and technological development, may require new approaches to how we regulate. Smart regulation should support both social and economic achievement — providing consumers with the protection they need to feel safe, supporting sustainability, encouraging a more dynamic economy and creating opportunities for Canadians and a model of regulatory excellence in the world.

In support of its role regulating biotechnology, Health Canada funds research in a variety of areas, such as health policy, regulation, population and public health, healthy environments and consumer safety, and health products and food.

Examples of Products of Biotechnology Regulated by Health Canada

Genetically-modified (GM) foods

- corn
- soybeans
- cotton seed
- potatoes
- flax
- tomatoes
- sugar beets
- squash
- canola
- papaya
- rice

Biotechnology-derived health products

Therapeutic agents:

- recombinant blood products
- cytokines
- monoclonal antibodies
- interferons
- insulins
- tissue engineered products such as bone grafts, heart valves, xenografts, and collagen
- agents used in gene therapies
- molecular farming products



Diagnostic and preventative agents:

- drugs and medical devices derived from biotechnology such as:
 - diagnostic test kits
 - viral, bacterial and rickettsial vaccines
 - radiolabelled biotherapeutics used for diagnosis and imaging

Environmental products*

- bioremediation, the use of bacteria to clean up environmental contaminants, such as oil spills
- biomass conversion, such as converting plant waste to ethanol for use as biofuels
- biological enzymes, such as those used by the pulp and paper industry
- biological drain cleaners and grease trap cleaners

Bio-based pest control products

- biological herbicides
- insecticides
- fungicides

* Health Canada's role in regulation of these products is assessment of risks to human health through environmental exposure to them. These products are also regulated by Environment Canada, under the Canadian Environmental Protection Act.



A Seven to Ten Year Process for New Biotechnology Products to Reach the Canadian Market

Assessing the Safety of GM Foods

Health Canada scientists, with individual expertise in molecular biology, toxicology, chemistry, nutritional sciences and microbiology, look at the process used to develop a GM food. They assess the chemical and nutritional composition of the food and whether or not there is the presence of, or potential for production of a toxin or allergenic substance in the food. As well, GM foods are assessed for any potential risk to human health through environmental exposure to them. Only if all of Health Canada's stringent criteria are met, is a GM food approved for sale in Canada.

Safe and Effective Health Products

Health products subject to the *Food and Drugs Act*, such as drugs, including those derived from biotechnology, are strictly regulated by Health Canada. Health Canada works to maximize the safety, quality and effectiveness of biologics such as vaccines, gene therapies and reproductive technologies.

Evaluation of Pest Control Products

Before any herbicide, insecticide and fungicide — including those derived from biotechnology — is considered for registration in Canada, it must undergo extensive testing to determine the pesticide's value for managing pests and any potential risks it may pose to human health and the environment.

Assessing Environmental Products

Biotechnology-derived environmental products, such as microorganisms used to clean up an oil spill, are subject to the *Canadian Environmental Protection Act*. Health Canada shares responsibility with Environment Canada for the risk assessment of these products, including assessment of risks to human health through environmental exposure to them and environmental impact of the product. Assessment takes place prior to 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.

Challenges and Commitments

Like many other scientific advances, biotechnology challenges our values and beliefs, and forces us to confront complex legal and ethical questions. What Canadians think about the ability to modify life forms; their views on privacy of genetic information; and how they feel about the different ways in which biotechnology is used; all must be taken into consideration as Health Canada carries out its roles and responsibilities concerning biotechnology.

Health Canada is committed to both discussing biotechnology issues with Canadians and communicating with them about products of biotechnology. To assist in this, the Canadian Biotechnology Advisory Committee (CBAC) — an expert arms-length advisory body — consults with individuals and groups on issues including the ethical, social, regulatory, economic, environmental and health aspects of biotechnology. Based on their findings, CBAC advises Health Canada and other federal government departments.

Health Canada also works with national and international partners to develop harmonized approaches to regulation of biotechnology and to ensure the best science and highest standards are used to evaluate biotechnology products. Likewise, we are working with international experts on how to effectively monitor products after they are approved and on the market.

Additionally, we ensure we have the expertise to meet the demands, as more and more complex biotechnology products are developed.

Health Canada recognizes that responsible and ethical use of modern biotechnology can help maintain and improve the health of Canadians. However, the same science and technology that offers potential benefits, can bring with it potential risks. Our goal is to assess and mitigate any risks, while maximizing the benefits for the health of Canadians.

**For more information visit the
biotechnology theme at Health
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<http://www.healthcanada.ca/biotech>

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