



ASSESSING AND MANAGING THE HEALTH RISKS OF LIVING BIOTECHNOLOGY PRODUCTS UNDER THE CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA)

The Issue

Canadians generally support the biotechnology revolution, but there are concerns that the production and release of genetically modified microorganisms might affect our health and safety.

Background

Organisms, Microorganisms, and Biotechnology

An organism is a body of living matter, such as a plant or a fish. An organism, such as bacteria or a virus, which can only be seen with a microscope, is called a microorganism. When organisms or microorganisms are used to make products, the process is called biotechnology.

Biotechnology is not new. People have used microorganisms, including bacteria, yeast, and moulds, to make products such as yoghurt, bread, beer, and cheese, for thousands of years. For several decades, we have also relied on microorganisms to perform other tasks, including the production of antibiotics and the treatment of sewage.

What is new is that scientists can now genetically modify naturally occurring organisms to produce organisms that are tailor-made for specific use or applications. For example, scientists can take genetic material from one type of bacteria that degrades oil, and transfer it to another type of bacteria that thrives in soil. The result would be a genetically modified microorganism for use in reclaiming land after an oil spill.

The Canadian Environmental Protection Act and Biotechnology Products

Environment Canada and Health Canada share responsibility for assessing and managing potential risks from toxic substances, including some biotechnology substances under the Canadian Environmental Protection Act (CEPA). Environment Canada focuses on risks to the environment, while Health Canada focuses on risks to human health.

Under CEPA, biotechnology is defined as “the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms.”

CEPA acts as a safety net by requiring environmental and health assessments for biotechnology products whose use is not regulated under other federal acts. CEPA's provisions are proactive, and prevent new biotechnology products from being imported or manufactured in Canada until the government has examined their potential risks.

The CEPA Definition of Toxic

Under the Act, a biotechnology product is considered “CEPA-toxic” if it enters or may enter the environment in amounts that may pose a risk to:

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



Health Canada's Role

Risk Assessment

If companies intend to manufacture or import new biotechnology products, they must notify the government and submit detailed scientific information about substances contained in the product. Health Canada scientists examine this information and conduct additional investigations to determine whether the product poses a risk to human health. To estimate the risks, the scientists evaluate the product's potential hazard and the potential for exposure to Canadians.

The kind of information required to evaluate potential hazards includes:

- the identity of the microorganism(s) / organism(s), including any genetic modifications
- whether the microorganism / organism is known to cause disease or other health effects in people, and whether it is related to other microorganisms that are known to cause health problems
- whether the microorganism / organism can be controlled (for example, by antibiotics), or whether it "resists" efforts to control the way it multiplies and spreads

To evaluate the potential for human exposure, Health Canada scientists consider many factors, including:

- the number of people likely to use or be exposed to the product
- the number of microorganisms / organisms in the product
- whether the microorganism(s) / organism(s) multiply rapidly, and how long they are expected to remain in the environment after they are released

Health Canada scientists also look at whether certain uses of a product could lead to unusual levels or routes of exposure, such as the inhalation of large numbers of microorganisms.

Risk Management

If Health Canada scientists conclude that a new biotechnology product poses no health risks to the general public, and Environment Canada scientists conclude no risk to the environment, import or manufacture can begin. If there is reason to suspect that a new biotechnology product may pose a health risk, Health Canada takes preventative action to manage the risks by imposing controls on the manufacture, import, use, release and / or disposal of the product.

The controls on biotechnology products can include restrictions on how and where they are produced or used, and the amount a company can produce or use in a given time period. The controls could also include an outright ban, but this is rarely used.

An Ongoing Responsibility

Health Canada and Environment Canada's responsibility to protect Canadians from the potential risks of biotechnology products does not stop after the initial risk assessment and risk management phase. Companies that manufacture or import biotechnology products are required under CEPA to report any new information, such as new findings about potential hazards, that may affect the original assessment. When this happens, Health Canada reassesses the health risks, and imposes controls, if necessary. This enables Health Canada to monitor the health effects of biotechnology products on a continuing basis.

Need More Info?

For more on Health Canada's role under CEPA, see the following It's Your Health fact sheets:

Human Health and The Canadian Environmental Protection Act – An Overview at:

http://www.hc-sc.gc.ca/english/iyh/environment/cepa_overview.html

Assessing and Managing the Health Risks of Existing Substances Under CEPA at:

<http://www.hc-sc.gc.ca/english/iyh/environment/assessing.html>

Assessing and Managing the Health Risks of New Substances Under CEPA at:

http://www.hc-sc.gc.ca/english/iyh/environment/cepa_new_substances.html

For more information on Health Canada's New Substances and Products of Biotechnology at:

<http://www.hc-sc.gc.ca/hecs-sesc/nsac/index.htm>

For more information about the Canadian Environmental Protection Act, visit Environment Canada's Web site at:

<http://www.ec.gc.ca/envhome.html>

For additional articles on this subject and other issues go to the It's Your Health Web site at:

www.healthcanada.ca/iyh

You can also call (613) 957-2991