Foreign Agricultural Service
GAIN Report
Global Agriculture Information Network

Voluntary Report - public distribution

Date: 2/8/2000

GAIN Report #CA0012

Canada

Biotechnology

Current Canadian Regulatory Framework

2000

Approved by:
Norval E. Francis, Jr.
U.S. Embassy
Prepared by:
L. "Bud" Locklear, Economic Section, U.S. Embassy (Ottawa)

Report Highlights:

The current Government of Canada (GOC) regulatory framework for biotechnology, particularly as it pertains to food biotechnology, is coming under scrutiny and will be the subject of an in-depth examination by an independent expert panel in the coming months. Also, new legislation to consolidate and modernize the federal food and agricultural inputs statutes is expected during the current parliamentary session.

Includes PSD changes: No
Includes Trade Matrix: No
Unscheduled Report
Ottawa[CA1], CA

Biotechnology: Current Canadian Regulatory Framework

This report outlines the current Government of Canada (GOC) regulatory framework for biotechnology in order to establish a benchmark against which any change in the framework can be measured. The current GOC regulatory framework for biotechnology, particularly as it pertains to food biotechnology, is coming under scrutiny and will be the subject of an in-depth examination by an independent expert panel in the coming months. Also, new legislation to consolidate and modernize the federal food and agricultural inputs statutes is expected during the current parliamentary session.

Biotechnology is defined in Canadian legislation 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." this broad definition covers all organisms, their parts and products, whether developed traditionally or through the newer techniques such as genetic engineering.

A key principle of the federal is the use of existing legislation and institutions to clarify responsibilities and avoid duplication. This principle means that departments that regulate products developed using traditional biotechnology techniques and processes are responsible for regulating products developed using the newer biotechnology (genetic-engineering) techniques and processes.

Who Does What?

In the federal government, legislative responsibility for health and environmental assessment of biotechnology products is divided primarily among four departments: Health Canada, the Canadian Food Inspection Agency, the Department of Fisheries and Oceans and Environment Canada. A description of which products fall under which legislation, and an outline of the regulatory measures, is set out below:

Drugs, cosmetics, medical devices and foods (Health Canada)

-- the "Food and Drugs Act" provides the authority to Health Canada for the assessment and control of the nutrition, quality and safety of food, the safety and effectiveness of human and veterinary drugs and medical devices, and the safety of cosmetics. This authority also applies to products from biotechnology. Under this authority, Health Canada can establish conditions for the manufacture, sale and advertisement of food, drugs, medical devices and cosmetics.

Fertilizers and supplements (Canadian Food Inspection Agency)

-- the "Fertilizers Act" requires that manufacturers demonstrate the safety and effectiveness of fertilizers and supplements (including novel microbial supplements) both in terms of human health and environmental safety. Specifically, the legislation outlines four key activities: standards and labeling, experimental research, registration and post-registration monitoring.

Animal feeds (Canadian Food Inspection Agency)

-- the "Feeds Act" specifies that all single ingredient feeds be evaluated prior to their use in livestock feeds. The legislation applies to imported or domestically manufactured products. The assessment of feeds focuses on toxicity to livestock, human safety in terms of transfer of harmful residues to human foodstuffs, safety of workers handling feeds and safety to the environment.

Plants, including trees (Canadian Food Inspection Agency)

-- the "Seeds Act" regulates the inspection, testing, quality and sale of seeds in Canada. Seeds that are developed through genetic engineering processes also undergo the same requirements. Testing can involve field testing under both confined and unconfined conditions. The CFIA also carries out environmental assessments on plants with novel traits, including thorough characterizations of the novel proteins and the modified plant, considerations of weediness, ability to pass genetic information, potential to become a pest, potential to cause unwanted interactions with other organisms in the environment and potential to cause negative impact on biodiversity.

Veterinary biologics (Canadian Food Inspection Agency)

-- the "Health of Animals Act" controls the importation of "all organisms that could be injurious to animals, regardless of the breeding method or process used to produce them." The legislation and regulations provide authority to regulate the production, importation, field testing and registration of veterinary biologics in Canada, produced by modern techniques of biotechnology or by traditional methods.

Pest control products (Pest Management Regulatory Agency, Health Canada)

-- under the "Pest Control Products Act", all pest control products, including microbial pesticides developed using genetic engineering, must be registered prior to being used, imported or sold in Canada. Prior to registration, microbial pest control products are subject to an assessment of the risks to human health and the environment. The value of the product, including product performance and contribution to sustainability, are also assessed.

Aquatic organisms (Department of Fisheries and Oceans)

-- regulations under the "Fisheries Act" require anyone who wishes to "deposit" a fish in any water to apply for a permit ("fish" is defined in the to include fin-fish, shellfish, crustaceans and marine animals). This requirement would apply equally to transgenic and non-transgenic organisms. Nevertheless, regulations that will enhance the current powers with respect to transgenic aquatic organisms are being drafted and will provide for the gathering of information on such organisms, containment procedures and environmental assessment.

Products for uses not covered under other federal legislation (Environment Canada)

-- the "Canadian Environmental Protection Act" (CEPA) ensures that there are no gaps in the provision for health and environmental assessments under the GOC regulatory framework. Biotechnology products (called "animate products of biotechnology" in the act) are assessed for health and environmental impacts under CEPA regulations unless they undergo such an assessment under other legislation.

Anticipated Changes to the Framework

In an effort to consolidate and modernize federal food and agricultural input statutes the GOC is expected to introduce the "Canada Food Safety and Inspection Act" during the current parliamentary session. The proposed legislation is "designed to address emerging technologies and food safety issues", and will consolidate all food safety provisions from a variety of federal legislation into one act.

The proposed act will incorporate the "Feeds Act", "Fertilizers Act", "Seeds Act" as well as the food-related provisions of the "Food and Drugs Act" - all of which are components of the GOC regulatory framework for biotechnology. (The new act will also incorporate the "Meat Inspection Act", "Fish Inspection Act", "Canada Agricultural Products Act" and the "Consumer Packaging and Labelling Act"). The Canadian Food Inspection Agency and Health Canada will maintain shared responsibility for food safety under the proposed legislation.

Comment

The GOC views the proposed "Food Safety and Inspection Act" as "enabling legislation that will provide the basis for a regulatory review". This review effort, when combined with the independent assessment of the GOC's biotechnology regulatory capacity, expected to conclude in summer 2000, may lead to the development of recommendations for further change to the biotechnology regulatory framework.

Contact

For more information, please contact Lonzell Locklear at LocklearL@state.gov

Find Us on The Web

Visit our headquarter's home page at http://www.fas.usda.gov for a complete selection of FAS' worldwide agricultural reporting.

Related FAS/Ottawa biotechnology reports:

Report Number	Title of Report	Date

CA9131	Food Industry to Develop Voluntary Standard for Labelling Biotech Foods	12/22/1999
CA0011	Future of Biotechnology in Canada - New Expert Scientific Panel	02/08/2000

FAS/Ottawa e-mail: usagr@istar.ca