



The Regulation of GM Food

HEALTH CANADA'S MANDATE

Health Canada is responsible, under the *Food and Drugs Act* and its Regulations, for provisions related to public health, food safety and nutrition. Through science-based regulation, guidelines and public health policy, as well as health risk assessments concerning chemical, physical and microbiological contaminants, toxicants and allergens in the food supply, Health Canada works to protect the health and safety of Canadians. Health Canada also conducts pre-market evaluations to assess the safety and nutritional adequacy of novel foods proposed for sale in Canada, including foods derived from biotechnology.

Biotechnology is an umbrella term that covers a broad spectrum of scientific tools and techniques, including genetic modification and genetic engineering. In Canada, foods derived from biotechnology — commonly referred to as GM or GE foods — are considered to be one class of “novel foods.” Health Canada regulates the sale of novel foods in Canada through a pre-market notification requirement which is specified under Division 28 of Part B of the *Food and Drugs Regulations* (Novel Foods).

CANADIAN REGULATION OF FOODS DERIVED FROM BIOTECHNOLOGY

- It is a seven to ten year process to research, develop, test and assess the safety of a new GM food.
- Manufacturers and importers who wish to sell or advertise a GM food in Canada, must submit data to Health Canada for a pre-market safety assessment, as required under Division 28 of Part B of the *Food and Drugs Regulations* (Novel Foods). This safety assessment provides assurance that the food is safe when prepared or consumed according to its intended use.

The steps in the regulatory process are described below:

1. Pre-submission consultation

Health Canada encourages proponents to consult with the Novel Foods Section of the Food Directorate in advance of notifying a GM food to Health Canada for safety assessment. This provides the opportunity for regulatory process requirements to be clarified and for any specific safety issues to be raised.

2. Pre-market notification

When the product's proponent believes it has sufficient information about the safety of a GM food to address Health Canada's criteria, a submission is made to the Novel Foods Section. This office coordinates a full safety assessment of the product, which involves a rigorous scientific evaluation by Health Canada scientific evaluators. These criteria are described in Health Canada's Guidelines for the Safety Assessment of Novel Foods.



3. Scientific assessment

Scientific evaluators, with individual expertise in molecular biology, toxicology, chemistry, nutritional sciences and microbiology, assess the following:

- development of the modified organism, including the molecular biological data that characterizes the genetic change;
- composition of and nutritional information about the GM food compared to a non-modified counterpart food;
- the potential for production of new toxins in the food;
- the potential for causing allergic reactions;
- microbiological and chemical safety of the food;
- the potential for any unintended or secondary effects;
- key nutrients and toxicants; and,
- major constituents (e.g., fats, proteins, carbohydrates) and minor constituents (e.g., minerals and vitamins).

4. Requests for additional information

If Health Canada evaluators find that any of the information provided about a GM food is insufficient, further documentation is requested from the proponent of the submission. Health Canada does not give any further consideration to the submission until all requested material is provided and deemed to be scientifically valid.

5. Summary report of findings

Once evaluators have completed their assessments, they summarize their findings and recommendations in a report.

6. Preparation of food rulings proposal

Once the evaluation of the product is completed, a Health Canada Food Rulings Proposal is prepared. This proposal is reviewed by senior staff (Directors and Director General) in the Food Directorate to ensure that all issues have been addressed. Once this has been done, a decision is made whether or not to approve the product.

7. Letter of no objection

If a product has successfully completed the evaluation process, and the other regulatory approvals such as environmental and feed safety are in place, a “Letter of No Objection” is sent to the product proponent. This letter indicates that the product can be sold in Canada for the intended uses, as listed in the submission, and whether there are any restrictions or requirements associated with the Health Canada decision.

8. Decision document on Health Canada’s Web site

A decision document, describing the novel food and summarizing the safety information used to determine its safety as a food, is posted on the *Novel Foods and Ingredients* page of Health Canada’s Web site.

FOOD LABELLING

Health Canada and the Canadian Food Inspection Agency (CFIA) share the responsibility for food labelling policies under the *Food and Drugs Act*. Health Canada’s responsibilities for food labelling fall within the Department’s mandate to safeguard health and safety, while CFIA leads the federal program to develop general food labelling policies and regulations. In particular, the CFIA is responsible for protecting consumers from misrepresentation and fraud with respect to food labelling, packaging and advertising, and for prescribing basic food labelling and advertising requirements.

Currently in Canada, labelling is mandatory if there is a health or safety issue with a food, which might be mitigated through labelling. For example, if the nutritional value or composition of the food has been changed, or if there is an allergen present in the food, the food must be labelled as such. In this situation, special labelling is required to alert consumers or susceptible groups in the population. This applies to all foods, including GM foods.

The Government of Canada recognizes that for many Canadians, labelling of foods derived from biotechnology is an important issue of consumer preference or choice.

Under a standards committee established by the Canadian General Standards Board, a Canadian standard for voluntary labelling of GE foods entitled Voluntary Labelling and Advertising of Foods That Are and Are Not Products of Genetic Engineering was developed to address non-health and safety labelling (rather, labelling for method of production, e.g., whether a food has or has not been produced through genetic engineering). This committee included a broad range of stakeholders, including consumer groups, food companies, producers, general interest groups, universities and government. In April 2004, the national standard was adopted by the Standards Council of Canada. The objectives of the national standard are to provide meaningful criteria for labelling, understandable messages for consumers, and a consistent policy to verify the truthfulness of labels.

GLOSSARY

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.

FOR MORE INFORMATION VISIT THE BIOTECHNOLOGY THEME AT HEALTH CANADA'S WEB SITE:

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

Or contact us at:

Health Canada
Office of Biotechnology and Science
AL 0702A, Tunney's Pasture
Ottawa, Ontario K1A 0L2
Fax: (613) 957-0362
Email: obs-bbs@hc-sc.gc.ca

Or visit the following Web addresses

Health Canada Novel Food Web page (including regulations, guidelines and decision documents applicable to GM foods):

<http://www.novelfoods.gc.ca>

Canadian General Standards Board (CGSB)

http://www.pwgsc.gc.ca/cgsb/032_025/intro-e.html

Canadian Food Inspection Agency

<http://www.inspection.gc.ca/english/sci/biotech/bioteche.shtml>

Voluntary Labelling and Advertising of Foods That Are and Are Not Products of Genetic Engineering

http://www.pwgsc.gc.ca/cgsb/032_025/standard-e.html ●