Regulation and Safety Assessment of Novel Foods in Canada

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Health Canada
Regulation of Products of Biotechnology in Canada

- Health Canada - Foods, drugs, cosmetics, medical devices, pest control products

- Canadian Food Inspection Agency (CFIA) - Plants, animal feeds, fertilizers, veterinary biologics

- Environment Canada - Microorganisms used in bioremediation, waste disposal, mineral leaching or enhanced oil recovery, etc.
Regulatory Responsibility in Food Biotechnology:

- Health Canada’s responsibility in the area of food biotechnology is to regulate the human health safety of these products.

- An Office of Food Biotechnology (OFB) has been established to coordinate the safety evaluation of novel foods, including foods through genetic modification and intended for human consumption in Canada.
Canadian Regulation and Assessment of Novel Foods

- Canadian Food & Drugs Act
- Novel Foods Regulation
  - Canada Gazette Part II, October 27, 1999
  - Notification prior to sale or advertising
What is a Novel Food?

- No history of safe use as a food
  - novel fibres
  - single-cell protein

- Is manufactured using a process not previously applied to that food
  - pulse light technology applied to milk

- Existing foods that have been genetically modified
  - herbicide tolerant soybean
  - insect resistant corn
Safety Assessment


- Based upon scientific principles developed through expert international consultations with WHO, FAO and OECD

- Data and scientific protocols are reviewed by a team of scientific evaluators with expertise in molecular biology, toxicology, chemistry, nutritional sciences and microbiology
Safety Assessment

- Based upon concept of substantial equivalence
- Comparative approach to existing foods with a history of safe use in the diet
- Differences identified in the comparison are subjected to further studies as appropriate
- Assessment considers impact of new trait or component in the modified organism, and the final food
- Additional research testing may be required
The Safety Assessment of Foods Derived from Biotechnology Involves:

- How the food crop was developed, including the molecular biological data which characterizes the genetic change;
- Composition of the novel food compared to non-modified counterpart foods;
- Nutritional information for the novel food compared to non-modified counterparts;
- Potential for new toxins; and
- Potential for causing allergic reaction.
Health Canada has indicated no objection to the use of 49 products derived from biotechnology.

Most of these products are crop plants (corn, canola, soybean and potato) with improved agronomic traits such as:

- crop yield
- hardiness
- uniformity
- insect and virus resistance
- herbicide tolerance
Labelling of Genetically Modified Foods in Canada

Health Canada and CFIA guidelines:

- Require mandatory labelling of a health or safety concern such as allergenicity, compositional or nutritional changes are identified;

- Ensure that labelling in understandable, truthful and not misleading;

- Permit voluntary positive (does contain) and voluntary negative (does not contain) labelling
National Labelling Standard

Led by Canadian Council of Grocery Distributors with Canadian General Standards Board

**Objective**

- Develop meaningful criteria for labelling
- Understandable messages for consumer
- Consistent policy to verify truthfulness of label
International Labelling Initiatives

Codex Committee on Food Labelling

- Guidelines for the labelling of food and food ingredients obtained through certain techniques of genetic modification/ genetic engineering

- Next meeting April 30 – May 4th, 2001, Ottawa
Health Canada, under its mandate for health and safety, reviews products by a science-based assessment process

Social, ethical and environmental issues will be considered by the new CBAC advisory committee

CBAC is an expert, arms length committee formed to advise Ministers on issues related to biotechnology

CBAC will work to raise the public’s awareness of the regulatory process and provide an ongoing forum for the public to voice their views

Website: http://cbac.gc.ca
Expert Scientific Panel on the Future of Food Biotechnology

- Royal Society of Canada Expert Scientific Panel to advise HC, the CFIA and EC on future scientific/regulatory capacity needs

- Report published on February 5, 2001

- Recommendations will help strengthen the regulatory system to better meet future needs

- Website: http://www.rsc.ca
Health Canada’s Website:
http://www.hc-sc.gc.ca/food-aliment

- Health Canada Decisions on New Products
- Novel Food Regulations
- Guidelines for the Safety Assessment of Novel Foods
- Novel Food Decisions Summaries