Novel Food Regulations in Canada

CIHPI St John’s NL
Dec 7, 2010

Overview

• Regulation of Novel Foods

• Food Safety Assessment

• Labelling
Why Regulate?

- Globalization of food supply and the rapid advances in technology have brought novel food products to Canada, *one’s not seen before*

- *Health Canada’s Role*: Standards and policies for the safety and nutritional quality of all foods, including novel foods

Regulation of Novel Foods

- *Food & Drugs Act and Regulations*

  - **Division 28: Novel Foods**
    - Canada Gazette Part II, October 27, 1999
    - Notification prior to sale or advertising
    - Safety assessment is conducted before it is permitted for sale
What is a Novel Food?

- Foods that meet any of these 3 definitions would require a pre-market notification:

  1. **no history of safe use** as a food
  2. **process that has not been previously applied** to food and causes the food to undergo a **major change**
  3. **food** derived from a **genetically modified** plant, animal or microorganism

1. History of Safe Use

- A food is considered to have a history of safe use if:
  - part of the diet for a number of generations in a large, genetically diverse human population
  - used in ways and at levels that are similar to those in the Canadian market.

- A history of use in a jurisdiction with a similar food safety system would increase the level of confidence.
2. Novel process resulting a major change

"major change" = change in the food outside the natural variation

including:
- composition, structure or nutritional quality of the food or its physiological effects;
- manner in which the food is metabolized in the body; or
- microbiological safety, the chemical safety or the safe use of the food.

3. Genetic Modification (GM)

- GM = change the heritable traits of a plant, animal or microorganism by means of intentional manipulation regardless of the process used:
  - Ex. Traditional Breeding, Mutagenesis, Genetic Engineering
- Canada’s regulations unique, they are “product based”, versus most other jurisdictions regulations being “process based”.
Examples of Novel Foods?

• No History of Safe Use
  - Camelina oil
  - Purified EPA and DHA oils from fish
  - Phytosterols
  - Eggs with increase levels of lutein

• Process resulting in major change
  - High Hydrostatic Pressure
  - Ultraviolet light treated Apple Cider

Examples of Novel Foods?

• Foods from genetically modified plants:
  1. By traditional breeding (Canola) **
  2. By Mutagenesis (Clearfield™ Sunflower) **
  3. Modern Biotechnology (Bt Corn)

** The regulation of products derived from traditional breeding is unique to Canada
Approved to date

- 127 novel foods
  - 26 products with “no history of safe use”
    - Phytosterols
  - 5 novel processes
    - High Pressure for RTE meats, UV treated Apple Cider
  - 96 products of genetic modification
    - Round-up Ready Corn, Clearfield Rice

- No foods from biotechnology-derived animals

Who does what?

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<tr>
<th>Health Canada</th>
<th>Canadian Food Inspection Agency</th>
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<td>Evaluation for human consumption</td>
<td>1. Environmental Evaluation</td>
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<tr>
<td>→ Bureau of Chemical Safety</td>
<td>→ Plant Biosafety Office</td>
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<tr>
<td>→ Bureau of Nutritional Science</td>
<td>→ Plant and Biotechnology Environmental</td>
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<tr>
<td>→ Bureau of Microbial Hazards</td>
<td>→ Release Assessment Unit</td>
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2. Animal Feed Evaluation
   → Animal Feed Division

No split approval policy, all parties must have completed the assessment before approval is granted
Approach to GM Foods

- Canadian approach is based on internationally developed guidance
Evaluation of GM Foods

- Team of scientific experts conducts review

Molecular Biology  Chemistry
Toxicology  Nutrition
Microbiology *

* This is pertinent to evaluation of novel foods that are not GM

8 General Considerations

1. History of safe use
2. Dietary exposure
3. History of organism
4. Parental lineage
5. Genetic modification
6. Nutrition
7. Toxicology and Allergenicity
8. Chemistry
History of Safe Use

• Ongoing part of diet:
  • Multiple generations
  • Large, genetically diverse population
  • at levels that are similar to those expected in Canada

• Similarity to foods already available

Dietary Exposure

• Frequency and amount consumed as part of the diet

• Impact of food on total dietary intake of nutrients

• Potential exposure to anti-nutrients, toxins, or contaminants, if occurring
History of Organism(s)

- Information regarding the organisms used in the development of the modified plant can, in part, lead to a better understanding of what needs to be assessed.

- Consider, for instance traits in the host and donor organisms that may impact on human/livestock health:
  - Toxins
  - Allergens
  - Anti-nutrients
  - History of use as food/feed

Parental Lineage

- 2 basic ways used to characterize a plant:
  - Comparisons with an appropriate counterpart
  - Phenotypic comparisons with an appropriate counterpart

- Differences will be discussed in terms of potential beneficial and adverse effects.
Gene Modification

• Information about the genetic characteristic can help to understand what needs to be assessed

• **Consider:**
  • the genetic makeup leading to the new characteristic,
  • the effect(s) of this genetic change on the plant

• **For products of rDNA, consider:**
  • All genetic material potentially transferred to plant host
  • Characterize DNA shown to be transferred

Nutrition

• Compare composition to parent plant to determine nutritional quality and consider impact of any changes

• For most plant species, consider:
  • proximates (crude protein, crude fat, ash, and fibre)
  • fatty acids
  • amino acids
  • vitamins
  • minerals
  • known antinutrients
Toxicology & Allergenicity

1) Toxins & Allergens
   - Consider elevated levels of toxins and allergens from host/donor/parental organisms
   - Compare modified plant with an appropriate counterpart

2) Newly Expressed Material – Toxicity
   - Amino acid comparisons with known toxins
   - Digestive stability
   - Heat stability
   - Additional toxicity studies (ex. acute oral)

3) Newly Expressed Material – Allergenicity
   - Amino acid comparisons with known allergens
   - Digestive stability
   - Heat stability
   - Allergy testing with blood serum
Chemistry

- Consider the potential for elevated levels of chemical contaminants
  
  - Mycotoxin levels
  - Uptake of heavy metals

GM Animals and Fish

- No foods derived from GM animals have been authorized for sale
- Health Canada is currently drafting guidelines specific to GM animals, based on the *Codex Alimentarius* guidelines
- In general, the factors considered in the assessment would be the same as those for plants
  - With animals, Codex recommends that an animal health assessment be completed
### Who does what?

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<th>Environment Canada</th>
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| Evaluation for human consumption  
  - Food Directorate  
  - Evaluation of Animal Health  
  - Veterinary Drugs Directorate | Animal Feed Evaluation  
  - Animal Feed Division | Environmental Assessment  
  - Biotechnology Section |
| In collaboration with Department of Fisheries and Oceans |

### Labelling of GM Foods

- Health Canada and the Canadian Food Inspection Agency (CFIA) share food labelling policies under the *Food and Drugs Act*.

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<td>• develops policy and setting standards related to the health and safety</td>
<td>• protects consumers from fraud through accurate food labelling,</td>
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Labelling of GM foods

- Labelling is required for all foods (including GM foods) when there are safety issues that could be reduced through labelling.
  - Ex. a label that identifies changes in nutritional composition or the presence of allergens

- The GoC recognizes that consumers want to know as much information as possible about the foods on the market

- Labelling to indicate whether a product contains ingredients derived from biotechnology is permitted, provided that the statement is factual and not misleading

Labelling of GM Food

- 1993-1994 Extensive consultations on the labelling of GM food
  - Recommendation: in the absence of potential health and/or safety risks or changes in nutritional composition, it is not necessary to indicate on the label that has been derived from genetic engineering

  - provides guidance to food companies to address the consumers demand for the labelling of genetically modified foods in Canada
  - [http://www.tpsgc-pwgsc.gc.ca/cgsb/on_the_net/032_0315/standard-.html](http://www.tpsgc-pwgsc.gc.ca/cgsb/on_the_net/032_0315/standard-.html)