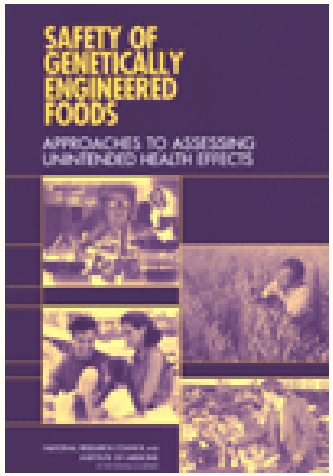
Canadian Assessment of Foods and Feeds derived from rDNA animals: team work approach

Luc Bourbonnière (Health Canada) & Annie Savoie (CFIA)

August 2014

Novelty Based System



- Novelty is the trigger
- Product-based system, not process-based
  - Examples of unintended effects introduced into crops via conventional methods
    - high glycoalkaloid Lenape potatoes (1970s),
    - high psoralene celery (1980s)
- Robust
- Flexible: based on risk
- Case-by-case
- NAS report: Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects (2004)

Novel Food Definition

- A substance, including a microorganism, that does not have a history of safe use as a food;

- A food that has been manufactured, prepared, preserved or packaged by a process that:
  - has not been previously applied to that food, and
  - causes the food to undergo a major change

Novel Food Definition (cont'd)

- A food that is derived from a plant, animal or microorganism that has been genetically modified such that:
  - the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism
  - the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or
  - one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism

  - Trigger for GM organisms which are rDNA organisms:
    event based: <u>insertion event</u>

Feeds Requiring An Assessment

- Any feed ingredient that is new (i.e., not listed in the Schedules), or has been modified such that it differs from conventional parameters, is required to undergo a pre-market assessment
- Feeds with novel traits can be developed by such methods as traditional breeding, mutagenesis, cell fusion, recombinant DNA techniques, etc.
- Products derived from Biotechnology (microbial, plant or animal sources) are not treated differently than other non-biotech feeds

Why Regulate Feed?

- **Feed versus Food, consider:**

- Daily feed consumption
- Limited variety
- Different components are consumed
- No processing or different processing
- Animal health and production
- Food chain (milk, meat, eggs)
- Efficacy

Food/ Feed Assessments Process

- Pre-consultation (optional and encouraged) to discuss (JOINT):
  - the characteristics of the food/feed
  - the intended use of the food/feed
  - data requirements to demonstrate safety (and efficacy-feeds)
- Entry into system (administrative requirements)-SEPARATE
  - Necessary to manage the large volume of clients/files
  - Designed to protect confidential business information
- Pre-screening (SEPARATE)
  - Ensure a file is 'complete'

The Process 2

- Review (partly joint)
  - Files are often multidisciplinary
  - Communication with colleagues, both within and outside of the Division, as appropriate
  - Communications between HC and CFIA
  - Communication with proponent as appropriate
- Decision-making coordination between HC and CFIA
- Decision making (SEPARATE)
- Average turn around time for the novel plant file reviews ~ 1 – 2 years

Assessment Principles

Assessment Principles

- **Tiering of data requirements:**
  - The degree of scientific support required is adjusted based on the complexity/familiarity of the product
- **Case-by-case**
  - Products can vary greatly in terms of their characteristics
  - No one set of prescribed data requirements is feasible
  - Data requirements are, instead, determined on the basis of the characteristics of the product in question
- **Familiarity:**
  - With particular products/characteristics
  - With assessing particular products/characteristics
- **Valid Scientific Rationale**
  - Can be used in place of data or to bridge data

Assessment Principles

Other Principles:

- **Weight of Evidence**
  - It is the sum of the overall data submitted that provides the context for determining efficacy and safety
- **Efficacy/Safety**
  - The assessment considers the likelihood that unintended effects may be present in the modified plant in question.
- **Comparators**
  - Must be appropriate for the product in question

General Considerations of an Assessment of GM foods/feeds

8 General Considerations

1. **History of safe use**
2. **Dietary exposure**
3. **History of organism(s)**
4. **Characterization of the derived line in relation to parental varieties**
5. **Genetic modification considerations**
6. **Nutritional Considerations**
7. **Toxicological and allergenicity considerations**
8. **Chemical considerations**

Evaluation of GM Foods/Feeds

- The review is conducted by a team of scientific experts in a number of fields.

- Molecular Biology
- Chemistry
- Toxicology
- Nutrition
- Veterinary Science*
- Microbiology*

*** Where pertinenant to evalution**

Evaluation Team for rDNA animals

- Health Canada
  - > Food Directorate
    - – Bureau of Microbial Hazards Molecular Biology
    - – Bureau of Chemical Safety- toxicology and allergenicity
    - – Bureau of Nutritional Science- Composition
  - > Veterinary Drugs Directorate
    - – Animal Health
- Canadian Food Inspection Agency
  - > Animal Feeds Division
    - – Biotechnology and Microbiology Section: Molecular Characterization
    - – Risk Analysis and Toxicology Section: Toxicology
    - – Feed Evaluation and Nutrition Section : Compositional

Co-ordinating Assessments

- Evaluators in both CFIA and HC regular meet to discuss the status of all files under review

- Regular communication between evaluators on a file specific basis
  - Ex. Molecular evaluators will meet to discuss findings and develop joint requests for additional information

Co-ordinated Authorizations

- Authorizations are co-ordinated under HC and CFIA's "no split" approval policy (2000)
  - Crops determined to be novel by the respective groups
  - Extended to animals (CFIA and HC)
  - If multiple groups determine a crop to be novel then:
    - Assessors work together to evaluate the product
    - Authorization of the product is co-ordinated
  - Used to minimize the potential for unapproved products to enter the Canadian environment, food or feed supplies.

GM Foods/Feeds approved to date

- 140 GM foods
- 130 GM feeds
- No products of biotechnology-derived animals

Key Points (Food/Feed)

- Product base regulations
- Authority within regulations for departments to approve products derived from biotechnology after completion of safety reviews
- Products of biotechnology are not treated differently than other foods/feeds

For more information concerning Novel Foods in Canada

Health Canada Web address:

http://www.hc-sc.gc.ca

HC-Novel Foods Web address :

http://www.novelfoods.gc.ca

For more information concerning Regulations of Livestock Feeds in Canada

CFIA Web address:

http://www.inspection.gc.ca

CFIA - Feed Web Address:

http://www.inspection.gc.ca/english/anima/feebet/feebete.shtml

Annie Savoie

Animal Feed Division

59 Camelot Drive,

Ottawa, ON K1A 0Y9

Telephone: 613-773-7510

Fax: 613-773-7565

E-mail : annie.savoie@inspection.gc.ca

Canada