

Safety Assessment of Genetically Modified Foods: the FSANZ Approach

Ken Buckle

*Visiting Professor, Food Science and Technology Group
The University of New South Wales
Sydney NSW 2052 Australia*

Marion Healy

*Chief Scientist, Food Standards Australia New Zealand
Canberra ACT 2610 Australia*

*Presented to the 2nd Dubai International
Food Safety Conference, Dubai, 21 February 2007*

Outline

- What is FSANZ?
- How does FSANZ change food standards?
- Standard 1.5.2 – Genetically modified foods
- The FSANZ safety assessment process
- Labelling of GM foods a review
- Future issues

What is FSANZ?

- Food Standards Australia New Zealand (FSANZ) is a bi-national statutory authority (1991 Act: NFA / ANZFA / FSANZ)
- Primary objectives:
 - protect public health and safety
 - provide adequate information to enable consumers to make informed choices
 - prevent misleading and deceptive conduct

FSANZ must *also* have regard to:

- need for standards to be based on risk analysis using best scientific evidence
- promotion of consistency between domestic and international food standards
- desirability of efficient and internationally competitive food industry
- promotion of fair trading in foods
- any written policy guidelines from ANZ Food Regulation Ministerial Council (ANZFRMC)

When does FSANZ change food standards?

- Food standards are changed when:
 - new technologies are introduced
 - existing technologies are modified
 - unusual foods are introduced to food supply
 - permissions for new food additives
 - ag/vet residues or chem/micro limits change
- Safety assessments are required for:
 - GM foods
 - novel foods
 - irradiated foods

How does FSANZ change food standards?

- Application (external) or Proposal (internal) to vary Food Standards Code
- 3 assessment reports (Initial, Draft, Final)
- DAR includes safety assessment for foods requiring pre-market clearance
- 2 calls for public comments
- FAR recommendations to ANZ Food Regulation Ministerial Council
- 12 month time limit to amend standard

ANZ Food Standards Code

The Code consists of:

- Part 1: General (horizontal) standards
- Part 2: Commodity (vertical) standards
- Part 3: Food Safety standards (Australia only)
- Part 4: Primary Product & Processing standards (Australia only)

Foods requiring pre-market assessment

- Food additives (e.g. sweeteners)
- Novel foods (e.g. plant sterols to ↓ cholesterol)
- Genetically modified (GM) foods
- Processing aids (e.g. enzymes used in cheese)
- Irradiated foods

Standard 1.5.2 – Foods Produced Using Gene Technology

- Effective 13 May 1999, revised 2000
- Regulates foods derived from GM plants
- Prohibits sale of GM foods unless listed in the standard
- GM foods or ingredients in Standard 1.5.2 must pass safety assessments before sale

AFSC Standard 1.5.2 – Foods Produced Using Gene Technology (cont)

- Does *not* apply to GM food additives or processing aids if no residues in foods (additives are addressed under Standard 1.3.1 only GM issues are addressed, e.g. genetic modification in organism from which enzyme derived)
- GM foods must be labelled

ANZ agencies involved with GM microorganisms, plants, animals

Activity	Australian Agency	NZ Agency
Safety (Code, Part 1.5.2)	FSANZ	FSANZ
Enforcement	States, Territories	NZFSA
Environmental (release of live GMOs)	DoEH, OGTR	ERMA, MoE
Broad public health issues	OGTR	MoH, NZFSA, Biosecurity NZ
Imports, exports	AQIS, DoEH, FSANZ, OGTR	NZFSA, BioNZ, ERMA
Insecticides, pesticide issues	APVMA, DoEH, FSANZ	NZFSA, ERMA, MoE, MoAF
Medicines, ethics	TGA, DoHA, DoAFF, Biotech Australia	ERMA, MoRST, MoE, MoAF, Bioethics Council

Introduction to food safety

- Consumers frequently make decisions about risk (real and perceived) associated with food
- We recognise that there may potentially be risks associated with foods
 - microbiological, chemical, physical, uncertainty around new technologies (GM etc)
- Most commonly consumed foods have a *history of safe use*
- Development, primary production, processing, storage, handling and preparation methods are well established (e.g. food safety issues relating to preparation methods)

Food-related risk factors

- Environmental contaminants
- Food additives and processing aids
- Natural toxins (marine, plant, fungal)
- Microbiological agents
- Prions
- Novel foods, ingredients
- GM foods, ingredients
- Nutrient imbalance
- Packaging materials
- Allergens
- Agricultural and veterinary chemicals
- Radionuclides

Concept of food safety

- Food is *not* inherently safe
- Food is considered to be safe (“...as safe as...”)
based on experience:
 - no history of adverse effects
 - adequate knowledge in community to address any hazards (harvest, transport, storage, preparation, cooking, preservation)

“Food is considered safe if there is a reasonable certainty that no harm will result from its consumption under anticipated conditions of use”

OECD 1993

FSANZ food safety assessment principles for GM foods

- Based on best current scientific knowledge and FSANZ risk assessment
- Carried out on a case-by-case basis
- Fully consider the safety of each component in GM food
- Consider intended and unintended effects of genetic modification
- Invite public comment through consultation

Best current scientific knowledge gained from

- the applicant who seeks approval
- published scientific literature
- general technical information
- independent scientists
- other regulatory agencies
- international bodies
- independently audited laboratories

International collaboration on GM food safety

- OECD
- WHO / FAO Expert Consultations on GM foods (several since 1990)
- Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology (convened 2000, restarted 2006)
- NZ Royal Commission on Genetic Modification (2001)

Case-by-case assessments

- History of use of donor and recipient organisms
- Each genetic modification assessed separately
- Food from GM plants and enzymes from GM microorganisms assessed to date
- In principle, safe GM organisms, especially microorganisms, can be used as ingredients

Information required for safety assessment of a GM food

- Identity of host and donor organisms
- Known pathogenicity in host or donor organisms
- Previous use of host or donor organisms in food production
- New genetic material introduced:
 - origin, nature, purpose, function
 - method of introduction into host organism

continued

Information required for safety assessment of a GM food (cont)

- New genetic material in GM organism
 - DNA sequence and border regions
 - number of complete / incomplete copies present
 - stable through generations
- New protein(s) in GM organism
 - purpose, physical and biological characteristics
 - expression profile (in which tissues found?)
- Potential adverse effects
 - similarity of new protein to known allergens
 - physical features characteristic of allergens
 - acute toxicity (animal studies)

continued

Information required for safety assessment of a GM food (cont)

- Composition compared to non-GM counterpart (nutrients, anti-nutrients, allergens, toxins)
- Impact on human health from transfer of genetic material in human digestive tract
- End uses of food (process before eating?)
- Ability of food to promote growth, well being (animal feeding studies)
- Any other relevant information

Unintended effects

- Levels of toxins (e.g. glycoalkaloids)
- Presence / levels of allergenic components
- Levels of nutrients (vitamins/minerals) and anti-nutrients (e.g. trypsin inhibitors)
- Genetic material moving to bacterial cells in human gut?
- **Difference DOES NOT = less safe** (each difference must be evaluated for its impact on the safety of the food)

GM food safety

“The goal of the assessment is not to establish absolute safety but to consider whether the genetically modified food is as safe as its traditional counterpart, where such counterpart exists”

Report of a Joint FAO/WHO Expert Consultation
on Foods derived from Biotechnology (June 2000)

FSANZ safety report

GM food is safe if FSANZ is satisfied that:

- All new genetic material has been examined
- New genetic material stays the same from generation to generation
- All new protein(s) have been examined
- New protein(s) are unlikely to be toxic or allergenic
- New proteins are not detectably toxic in animal studies
- Transfer of genetic material to bacterial cells unlikely to be harmful to human health

GM plant development (5-10 y)

- Product concept
- Plant transformation / laboratory studies
- Glasshouse and field evaluation
- Line selection
- Variety development using conventional breeding
- Field production
- Commercialisation

The vast majority of unintended effects are eliminated during glasshouse / field evaluation and line selection stages

Approved GM food crops in ANZ

30 plant crops assessed to date, 3 under assessment

Crop	Trait	Examples
Soybean (3)	Herbicide tolerance High oleic acid content	Tofu, soy oil, flour, beverages
Canola (3) (oilseed rape)	Herbicide tolerance	Canola oil
Corn (maize) (14)	Insect protection, Herbicide tolerance, IP + HT	Kernels, oil, flour, sugar, syrup & snack products
Potato (3)	IP + virus protection	Whole potatoes, snack products
Sugar beet (2)	Herbicide tolerance	Beet sugar
Cotton (8)	IP, HT, IP + HT	Cottonseed oil, linters

Use of animal feeding studies

- **Used widely for food additives, drugs and chemicals used for agricultural or veterinary purposes**
 - useful for chemicals normally consumed in small amounts
 - dose-response can be achieved by giving large dose levels
 - generally no nutritional consequences

Use of animal feeding studies (cont)

■ Limited usefulness for whole foods

- foods are a complex mixture of compounds
- large dose levels are impractical
- dose-response difficult to achieve
- effects are likely to be the result of adverse nutritional consequences
- interpretation can be complex

Use of animal feeding studies (cont)

- Used as an adjunct to compositional analyses
 - typically done to confirm the nutritional adequacy or 'wholesomeness' of the food
- NOT toxicity studies
- Numerous animal feeding studies have been conducted on GM foods / feeds
- Demonstrate nutritional equivalence

Future challenges for safety assessment

■ New techniques

- profiling techniques to detect unintended changes
- animal models to predict allergenicity of proteins

■ 'Next generation' of GM plants

- complex / multiple modifications to metabolic pathways
- plants with improved / enhanced nutritional characteristics
- functional foods

■ GM animals

Meat and milk from cloned animals

- On 28 December 2006 USFDA released draft RA suggesting meat, milk from cloned adult cattle, pigs and goats is safe to eat
- FSANZ is assessing food safety evidence and will provide report to Australian Government in due course
- FSANZ has been monitoring international developments for some years
- Increasing discussion among scientists, government policy makers, public
- **Voluntary moratorium on cloned animals and offspring entering food chain in Australia**

Labelling of GM foods

- Foods, ingredients, food additives and processing aids **must be labelled as 'genetically modified'** if they contain novel DNA or protein from approved GM food
- Labelling required if 'characteristics altered':
 - composition or nutritional parameters outside normal range for existing counterpart
 - levels of toxicants / anti-nutritional factors significantly different
 - known allergens present
 - intended use is different to existing counterpart

GM labelling exemptions

Exempt if:

- no novel DNA or protein in highly refined foods (e.g. oils, sugars)
- no novel DNA or protein from additives or processing aids remains in final food
- GM food, ingredient or processing aid unintentionally present at <1% in final food (e.g. where manufacturers have sought not to use a GM food or ingredient)

GM labelling exemptions (cont)

Exempt if:

- GM flavours at $<0.1\%$ in final food
- GM food is for immediate consumption prepared and sold from premises, e.g. restaurants, take-away (consumers can ask for information)

Voluntary negative claims

- Not addressed in Standard 1.5.2
- Laws pertaining to false, misleading and deceptive claims may apply (e.g. *Trade Practices Act 1974, New Zealand Fair Trading Act 1986*)
 - claims (e.g. “GM free”) must not be false or misleading
 - may need to substantiate claims (analyses, tracing of sources)

GM labelling review

- 2001 - Mandatory labelling for GM foods introduced
- 2003 – ANZ Food Regulation Ministerial Council requested FSANZ “...review GM labelling requirements against international practice...”
- 472 submissions (92% from individuals) to stakeholder consultations

Terms of reference

1. Review GM labelling legislation internationally with focus on EU, USA, Canada, APEC
2. Compare ANZ requirements with countries listed
3. Examine consumer attitudes to GM
4. Summarise developments in Codex
5. Prepare report on implementation and compliance to date in Australia and NZ

Review findings

- ANZ GM labelling requirements among most comprehensive in any country
- Majority of consumers welcome mandatory GM food labelling
- High level of industry compliance in 2 surveys (Australia and NZ)
- GM labelling compliance can be effectively enforced (check documentation + random product testing)
- International regulations vary widely

Major elements of labelling regimes in various countries	Examples of Countries	
Mandatory labelling regime fully regulated	<p>Method of production labelling - mandatory labelling of all foods derived from or containing ingredients derived from organisms produced using gene technology.</p>	European Union
	<p>Composition of food labelling - Mandatory labelling of all GM foods and ingredients where novel DNA and/or protein are present in the final food.</p>	Australia/New Zealand, Russia
	<p>Composition of food labelling (narrow capture) - Mandatory labelling of designated food items that contain GM foods or ingredients as major components of food only where novel DNA and/or protein are present in the final food.</p>	Japan, Chinese Taipei, Korea, Thailand, and Malaysia (proposed)
Labelling regime mix of regulatory and voluntary approach	<p>Equivalence labelling - Mandatory labelling of GM food only where it is significantly different from its conventional counterpart.</p>	Canada, USA, Hong Kong (proposed)
	<p>Voluntary labelling - Voluntary regime (where GM is similar to conventional counterpart) reliant on general provisions in food or fair trading law relating to false, misleading and deceptive labelling or advertising and an Industry Code of Practice developed to assist with compliance.</p>	Canada, USA
No regulation	<p>Other - No regulation in place. May allow for voluntary labelling but no evidence of guidelines or Code of Practice.</p>	Philippines, Singapore

The future

- Views on GM foods differ between countries
- Few GM foods or ingredients currently available in Australia / NZ market
- Some anti-GM market segments emphasise organic or 'clean green' image
- Safety of cloned meats being assessed following FDA approval
- Considerable consumer education required to increase acceptability of GM foods / ingredients

Thank you!

k.buckle@unsw.edu.au

marion.healy@foodstandards.gov.au