



23 November 2010

[24-10]

APPLICATION A1040 FOOD DERIVED FROM INSECT-PROTECTED AND HERBICIDE-TOLERANT COTTON LINE GHB119 APPROVAL REPORT

Executive Summary

Main points are:

- The Application seeks approval for food derived from a genetically modified (GM), insect-protected and herbicide-tolerant cotton line.
- The Safety Assessment did not identify any potential public health and safety concerns.
- At present, there is no approval to grow this GM cotton line in Australia. Food derived from it would therefore enter the food supply of Australia and New Zealand through imported products.
- In accordance with the labelling laws, food derived from this GM cotton line would have to be labelled as GM if there are detectable levels of novel DNA or protein in the final food. The most common food products of cotton are refined oil and linters neither of which, because of processing, would be expected to contain detectable levels of DNA or protein.

Purpose

Food Standards Australia New Zealand (FSANZ) received an Application from Bayer CropScience Pty Ltd (Bayer) on 16 December 2009. The Applicant requested a variation to Standard 1.5.2 – Food produced using Gene Technology, in the *Australia New Zealand Food Standards Code* (the Code), to permit the sale and use of food derived from genetically modified (GM) cotton line GHB119, conferring insect-protection and herbicide-tolerance.

This Application was assessed under the General Procedure.

Safety Assessment

A new genetically modified (GM) cotton line, GHB119, has been developed that is protected against feeding damage by Lepidopteran insect larvae, and which is also tolerant to herbicides containing glufosinate ammonium. Insect protection is conferred by expression of a modified Cry2Ae protein from *Bacillus thuringiensis* and herbicide tolerance is conferred by expression of phosphinothricin acetyltransferase (PAT) from *Streptomyces hygroscopicus*. FSANZ has previously assessed proteins from the Cry2A class (that all share 75–86% homology) and found them to be safe. The PAT protein has also been previously assessed by FSANZ and found to be safe.

FSANZ has completed a comprehensive safety assessment of food derived from cotton plants containing event GHB119 (see **Supporting Document 1**).

This assessment included consideration of (i) the genetic modification to the plant; (ii) the potential toxicity and allergenicity of the novel proteins; and (iii) the composition of cotton line GHB119 compared with that of conventional cotton cultivars.

No public health and safety concerns have been identified in this pre-market safety assessment of food derived from cotton line GHB119. On the basis of the available evidence, including detailed studies provided by the Applicant, food derived from cotton line GHB119 is considered as safe and wholesome as food derived from other commercial cotton cultivars.

Labelling

Labelling addresses the objective set out in paragraph 18(1)(b) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act); that is, the provision of adequate information relating to food to enable consumers to make informed choices. The general labelling requirements will provide consumers with information about the GM status of foods.

In accordance with general labelling provisions, food derived from cotton line GHB119, if approved, would be required to be labelled as genetically modified if novel DNA or novel protein is present in the final food.

Impact of Regulatory Options

Following satisfactory completion of the safety assessment, two regulatory options were considered: (1) rejection of the Application; or (2) approval of food derived from cotton line GHB119.

Following analysis of the potential costs and benefits of each Option on affected parties (consumers, the food industry and government), option 2, approval of this Application is the preferred option. Under Option 2, the potential benefits to all sectors outweigh the costs associated with the approval.

Assessing the Application

In assessing the Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters as prescribed in section 29 of the FSANZ Act:

- Whether costs that would arise from a food regulatory measure developed or varied as a result of the Application/Proposal outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure.
- There are no other measures that would be more cost-effective than a variation to Standard 1.5.2 that could achieve the same end.
- Any relevant New Zealand standards.
- Any other relevant matters.

Decision

To approve the variation to Standard 1.5.2 – Food produced using Gene Technology, to include food derived from insect-protected and herbicide-tolerant cotton line GHB119.

Reasons for Decision

The development of a variation to the Code to give approval to the sale and use of food derived from cotton line Ghb119 in Australia and New Zealand is proposed on the basis of the available scientific evidence, for the following reasons:

- the safety assessment did not identify any public health and safety concerns associated with the genetic modification used to produce cotton line GHB119
- food derived from cotton line GHB119 is equivalent to that derived from the conventional counterpart and other commercially available cotton cultivars in terms of its safety for human consumption and nutritional adequacy
- labelling of certain foods derived from cotton line GHB119 will be required if novel DNA or novel proteins are present in the final food
- a regulation impact assessment process has been undertaken that fulfils the requirement in Australia and New Zealand for an assessment of compliance costs. The assessment concluded that the preferred option is Option 2, a variation to the Code
- there are no relevant New Zealand standards
- there are no other measures that would be more cost-effective than a variation to Standard 1.5.2 that could achieve the same end.

Consultation

Public submissions were invited on the Assessment Report between 5 July 2010 and 16 August 2010. Comments were specifically requested on the scientific aspects of this Application, in particular, information relevant to the safety assessment of food derived from insect-protected and herbicide-tolerant cotton line GHB119. A total of 6 submissions was received. A summary of these is provided in **Attachment 3** to this Report.

As this Application was assessed as a General Procedure, there was one round of public comment following the preparation of an Assessment Report. Responses to the Assessment Report were used to develop this Approval Report for the Application. The main issues raised in public comments are discussed in the Approval Report.

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SUPPORTING DOCUMENTS

The following material, which was used in the preparation of this Assessment Report, is available on the FSANZ website at

<http://www.foodstandards.gov.au/foodstandards/applications/applicationa1040food4719.cfm>

SD1: Safety Assessment Report (Approval): Application A1040 – Food Derived from Insect-Protected and Herbicide-Tolerant Cotton Line GHB119

INTRODUCTION

On 16 December 2009, Bayer CropScience Pty Ltd (Bayer) submitted an Application seeking approval for food derived from cotton line GHB119 under Standard 1.5.2 – Food produced using Gene Technology, in the *Australia New Zealand Food Standards Code* (the Code).

Cotton line GHB119 has been generated in order to derive, through conventional cross-breeding practices, genetically modified (GM) cotton cultivars that are protected against feeding damage by Lepidopteran insect larvae, and are also tolerant to herbicides containing glufosinate ammonium. Insect protection is conferred by expression of a modified Cry2Ae protein from *Bacillus thuringiensis* and herbicide tolerance is conferred by expression of phosphinothricin acetyltransferase (PAT) from *Streptomyces hygroscopicus*.

The purpose of the genetic modification is to optimise field performance of the cotton through reduction of Lepidopteran pest damage, and to reduce cultivation needs through the use of an alternative broad-spectrum herbicide.

FSANZ completed a full scientific evaluation of food derived from cotton line GHB119 according to FSANZ guidelines¹ to assess its safety for human consumption. The Assessment Report was released in July 2010 and public comment was sought on the safety assessment and proposed recommendations. Comments received were considered in the completion of this Approval Report.

1. The Issue / Problem

The Applicant has developed GM cotton line GHB119. Pre-market approval is necessary before food product derived from this line may enter the Australian and New Zealand food supply. A variation to the Code granting approval to food derived from cotton line GHB119 must be approved by the FSANZ Board, and subsequently notified to the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council). A variation to the Code may only be gazetted once the Ministerial Council process has been finalised.

The Applicant has sought the necessary variation to Standard 1.5.2 to include food derived from cotton line GHB119 prior to any decision to commercialise the line. The Application was assessed as a General Procedure.

2. Current Standard

2.1 Background

Approval of GM foods under Standard 1.5.2 is contingent upon completion of a comprehensive pre-market safety assessment. Foods that have been assessed under the Standard, if approved, have been listed in the Table to clause 2 of the Standard. Note, however, that the proposed legal drafting in Attachment 1 includes provision for approvals to be listed in a Schedule rather than in the Table to clause 2 (see Explanatory Statement at Attachment 2).

¹ FSANZ (2007). Safety Assessment of Genetically Modified Foods – Guidance Document. http://www.foodstandards.gov.au/srcfiles/GM%20FINAL%20Sept%2007L%20_2_.pdf

2.2 Overseas approvals

Applications concerning cotton line GHB119 have been made to the appropriate agencies for food, feed and/or environmental approvals in the United States (Food and Drug Administration, Department of Agriculture, Environmental Protection Agency), Canada (Health Canada, Canadian Food Inspection Agency), Korea (Food and Drug Administration, Rural Development Administration), Mexico (Department of Health), Colombia (Instituto Nacional de Vigilancia de Medicamentos y Alimentos - INVIMA), Japan (Ministry of Health, Labor and Welfare, Ministry of Agriculture, Forestry and Fisheries), Brazil (CTNBio) and Argentina (SENASA and CONABIA). These applications are still currently under consideration. Further applications for food import approvals in other key international markets may also be made.

The US Environmental Protection Agency (EPA) granted a temporary exemption from a food tolerance for Bt Cry2Ae protein in or on the food commodities of cotton, on 10 September 2008 (EPA, 2008). The tolerance exemption is due to expire on December 31, 2012. The exemption means that, from a safety aspect, the EPA has determined there is a reasonable certainty that no harm will result from aggregate exposure to the Bt Cry2Ae protein, including all anticipated dietary exposures and all other exposures for which there is reliable information.

The EPA, based on submitted toxicological data, established an exemption for the requirement of a tolerance of residues of PAT and the genetic material necessary for its production in all plants, on 11 April 1997 (EPA, 1997). The tolerance exemption was initially published as 40CFR 180.1151 in the Code of Federal Regulations, but is now covered by 40CFR 174.522 (EPA, 2007).

3. Objectives

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are:

- the protection of public health and safety; and
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

4. Assessment questions

In completing the assessment of this application, a number of questions have been addressed.

- Based on information provided by the Applicant on the nature of the genetic modification, the molecular characterisation, the characterisation of the novel proteins, the compositional analysis and consideration of any nutritional issues, is food derived from cotton line GHB119 comparable to food derived from conventional cultivars of cotton in terms of its safety for human consumption?
- Is other information available, including from the scientific literature, general technical information, independent scientists, other regulatory agencies and international bodies, and the general community, that should be taken into account in this assessment?
- Are there any other considerations that would influence the outcome of this assessment?

RISK ASSESSMENT

Food derived from cotton line GHB119 has been evaluated according to the safety assessment guidelines prepared by FSANZ (FSANZ, 2007) and is provided in **Supporting Document 1**. The summary and conclusions from the safety assessment are presented below.

In addition to information supplied by the Applicant, other available resource material including published scientific literature and general technical information was used in this assessment.

5. Risk Assessment Summary

5.1 Safety Assessment Process

In conducting a safety assessment of food derived from cotton line GHB119, a number of criteria have been addressed including: a characterisation of the transferred coding sequences, their origin, function and stability in the cotton genome; the changes at the level of DNA, protein and in the whole food; detailed compositional analyses; evaluation of intended and unintended changes; and the potential for any newly expressed protein(s) to be either allergenic or toxic in humans.

The safety assessment applied to food from cotton line GHB119 addresses only food safety and nutritional issues. It does not address any risks related to the release into the environment of GM plants used in food production, the safety of animal feed or animals fed with feed derived from GM plants, or the safety of food derived from the non-GM (conventional) plant.

5.2 Outcomes of the Safety Assessment

Cotton line GHB119 contains two novel gene cassettes. One contains a modified *cry2Ae* gene that encodes an insecticidal crystal protein and the other contains a *bar* gene that encodes a protein (PAT) conferring tolerance to herbicides containing glufosinate ammonium (phosphinothricin).

FSANZ has previously assessed proteins from the Cry2A class (that all share 75–86% homology) and found them to be safe. The PAT protein has also been previously assessed by FSANZ and found to be safe.

Comprehensive molecular analyses of cotton line GHB119 indicate that there is a single insertion site containing one complete copy of the two cassettes comprising the T-DNA from plasmid pTEM12. The introduced genetic elements are stably inherited from one generation to the next. There are no antibiotic resistance markers present in line GHB119.

Cry2Ae protein is detectable in all plant parts tested but does not appear in nectar; it is lowest in pollen and highest in leaves during the early stages of growth (av. of 9.33 µg/g fresh weight). PAT is probably expressed in all plant parts tested but is often at levels below the Limit of Detection. It is likely to be highest in young leaves (av. of 27.4 µg/g fresh weight). Both Cry2Ae and PAT are detectable in fuzzy cottonseed² and a range of processed products derived from fuzzy cottonseed but not in the oil.

Studies have demonstrated that the Cry2Ae and PAT proteins conform in size and amino acid sequence to that expected, do not exhibit any post-translational modification including glycosylation and exhibit the expected activity.

Bioinformatic studies have confirmed that both proteins lack any significant amino acid sequence similarity to known protein toxins or allergens, and digestibility studies have demonstrated that both proteins would be rapidly degraded in the stomach following ingestion. Acute oral toxicity studies in mice have also confirmed their absence of toxicity in animals. Both proteins exhibit a degree of heat stability, however given their digestive lability, this does not raise any safety concerns. Taken together, the evidence indicates that the Cry2Ae and PAT proteins are unlikely to be toxic or allergenic to humans.

Detailed compositional analyses were done of fuzzy seed derived from GHB119 plants. Analyses were done of proximates (crude protein, crude fat, ash and total carbohydrates), acid detergent fibre, neutral detergent fibre, fatty acids, amino acids, micronutrients (minerals and α-tocopherol) and anti-nutrients (gossypol, phytic acid and cyclopropenoid fatty acids). The levels were compared to levels in the non-GM parent as well as to the ranges found in commercial cotton cultivars reported in the literature. Additional comparisons were also done using the GM cultivar known as 'TwinLink'TM, which is a conventional cross between line GHB119 and line T304-40 (another insect-protected, herbicide-tolerant cotton line)³. Taken overall, the compositional data are consistent with the conclusion that there are no biologically significant differences in the levels of key components in seed from cotton containing event GHB119 when compared with conventional cotton cultivars currently on the market.

Although not essential for establishing the safety of the food, one broiler feeding study using meal from TwinLinkTM cottonseed was evaluated as additional supporting data. Such studies are not toxicity studies and are intended to address only whether food derived from the GM plant is able to sustain normal growth and well being. It was concluded from the study that cottonseed meal containing event GHB119 was nutritionally adequate, and equivalent to that derived from a non-GM control cotton and a commercial non-GM cultivar, in its ability to support typical growth and well being.

² Fuzzy (or whole) cottonseed is the raw agricultural commodity. It is the linted cottonseed remaining after the ginning process which removes fibres

³ Refer to Application A1028

5.2.1 Conclusion

No potential public health and safety concerns have been identified in the assessment of cotton line GHB119. On the basis of the data provided in the present Application, and other available information, food derived from cotton line GHB119 is considered as safe for human consumption as food derived from conventional cotton cultivars.

RISK MANAGEMENT

6. Issues raised

In accordance with general labelling provisions, food derived from cotton line GHB119, if approved, would be required to be labelled as genetically modified if novel DNA and/or novel protein is present in the final food.

As part of the Application, the Applicant is required to confirm that there is detection methodology for the GM food. For cotton line GHB119, this methodology involves the use of the polymerase chain reaction for DNA detection and immunoassay and/or lateral flow strip technology for protein detection. Because of the technology involved, these detection methods are likely to be restricted to specialist laboratories.

7. Options

There are no non-regulatory options for this Application. The two regulatory options available for this Application are:

7.1 Option 1 – Reject Application

Reject the Application, thus maintaining the *status quo*.

7.2 Option 2 – Develop a food regulatory measure

Proceed to development of a food regulatory measure to vary Standard 1.5.2 to permit the sale and use of food derived from insect-protected and herbicide-tolerant cotton line GHB119, with or without specified conditions.

8. Impact Analysis

In the course of developing food regulatory measures suitable for adoption in Australia and New Zealand, FSANZ is required to consider the impact of all options on all sectors of the community, including consumers, the food industry and governments in both countries. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits of the regulation, and its health, economic and social impacts.

8.1 Affected Parties

The affected parties may include the following:

- Consumers of cotton-containing food products, particularly those concerned about the use of biotechnology to generate new crop varieties.

- Industry sectors:
 - food importers and distributors of wholesale ingredients
 - processors and manufacturers of cotton-containing food products
 - food retailers
- Government:
 - enforcement agencies
 - national Governments, in terms of trade and World Trade Organization (WTO) obligations.

It is the Applicant's hope that cotton lines containing event GHB119 be commercially cultivated in major cotton-producing countries, including Australia. Such cultivation in Australia or New Zealand could have an impact on the environment, which would need to be independently assessed by the Office of the Gene Technology Regulator (OGTR) in Australia, and the Environmental Risk Management Authority (ERMA) in New Zealand before commercial release in either country could be permitted.

8.2 Benefit Cost Analysis

8.2.1 Option 1 – Reject Application

Consumers: Possible restriction in the availability of imported cottonseed products to those products that do not contain cotton line GHB119.

No impact on consumers wishing to avoid GM foods, as food from cotton line GHB119 is not currently permitted in the food supply.

Potential increase in price of imported cottonseed foods due to requirement for segregation of cotton line GHB119.

Government: Potential impact if considered inconsistent with WTO obligations but impact would be in terms of trade policy rather than in government revenue.

Industry: Possible restriction on imports of cottonseed food products once cotton line GHB119 is commercialised overseas.

Potential longer-term impact - any successful WTO challenge has the potential to impact adversely on food industry.

8.2.2 Option 2 – Develop a draft regulatory measure

Consumers: Broader availability of imported cottonseed products as there would be no restriction on imported foods containing cotton line GHB119.

Potentially, no increase in the prices of imported foods manufactured using comingled cottonseed products.

Appropriate labelling would allow consumers wishing to avoid GM cottonseed products to do so.

Government: Benefit that if cotton line GHB119 was detected in cottonseed imports, approval would ensure compliance of those products with the Code. This would ensure no potential for trade disruption on regulatory grounds.

Approval of cotton line GHB119 would ensure no conflict with WTO responsibilities.

Monitoring of the food supply is required to ensure compliance with the labelling requirements and to ensure unapproved foods are not illegally entering the food supply. The costs of monitoring are thus expected to be comparable, whether a GM food is approved or not.

Industry: Importers of processed foods containing cottonseed derivatives would benefit as foods derived from cotton line GHB119 would be compliant with the Code, allowing broader market access and increased choice in raw materials. Retailers may be able to offer a broader range of cottonseed products or imported foods manufactured using cottonseed derivatives.

Possible cost to food industry as some food ingredients derived from cotton line GHB119 would be required to be labelled.

8.3 Comparison of Options

As food from cotton line GHB119 has been found to be as safe as food from conventional cultivars of cotton, Option 1 is likely to be inconsistent with Australia's and New Zealand's WTO obligations. Option 1 would also offer little benefit to consumers, as approval of cotton line GHB119 by other countries could limit the availability of imported cottonseed products in the Australian and New Zealand markets. In addition, Option 1 would result in the requirement for segregation of any products containing cotton line GHB119 from those containing approved cotton lines which would be likely to increase the costs of imported cottonseed foods.

Based on the conclusions of the safety assessments, the potential benefits of Option 2 outweigh the potential costs. A variation to Standard 1.5.2 giving approval to insect-protected, herbicide tolerant cotton line GHb119 is therefore the preferred option.

8.4 Proposed changes to legal drafting in Standard 1.5.2

In the Assessment Report, additional legal drafting, separate to that specifically applying to Application A1040, was proposed (refer to Attachment 1B) in order to reorganise the list of approved GM foods from a Table into a Schedule, and to correct minor inconsistencies in wording that have occurred over time since the Standard came into force in April 1999. The Schedule was in a format that is more easily read than the Table since the approvals were listed by commodity and, within this grouping, by chronological order.

Following comments received from the New Zealand Food Safety Authority (NZFSA) on the Assessment Report, as well as recommendations from a legal audit of the Code, the addition of two approvals to Standard 1.5.2 in the intervening time, changes to the FSANZ Act and minor errors picked up in the drafting for the Assessment Report, a number of changes to the drafting were made for the Approval stage (see Attachment 1A). The most significant of these is a change to the heading for Column 3 and corresponding re-wording for the items listed in Column 3 to denote either 'food derived from...' or 'food developed from...'. The revised drafting is given in Attachment 1A. The Explanatory Statement pertaining to Attachment 1A is at Attachment 2.

COMMUNICATION AND CONSULTATION STRATEGY

9. Communication

FSANZ applied a basic communication strategy to this Application. Public comment on the assessment was sought prior to preparation of this Approval Report. As normally applies to all GM food assessments, the Assessment and Approval Reports will be available to the public on the FSANZ website.

The Applicant and individuals and organisations that made submissions on this Application were notified at each stage of the assessment.

This Approval Report and the decision of the FSANZ Board to approve the variation to Standard 1.5.2, if made, will be notified to the Ministerial Council. If the approval of food derived from insect-protected and herbicide-tolerant cotton line GHB119 is not subject to review, the Applicant and stakeholders, including the public, will be notified of the gazettal of the variation to the Code in the national press and on the website.

10. Consultation

10.1 Public Consultation

The Assessment Report was advertised for public comment between 5 July 2010 and 16 August 2010. Comments were specifically requested on the scientific aspects of this Application, in particular, information relevant to the safety assessment of food derived from cotton line GHB119. As this Application was assessed under a General Procedure, there was one round of public comment.

A total of 6 submissions was received. A summary of these submissions is provided in **Attachment 3** to this Report. FSANZ has taken the submitters' comments relevant to food safety into account in preparing the Approval Report for this Application. The OGTR in Australia and ERMA in New Zealand are the agencies responsible for any issues of public concern regarding the growing of GM crops and the environment.

Responses to general issues raised, such as the safety of GM food, GM food labelling, the relevance of long term feeding studies and data used to inform the Safety Assessment, are available from the FSANZ website (see Table 1). In relation to the Safety Assessment, it should be noted that the data submitted by an Applicant and the conduct of the studies are subject to strict requirements outlined in the FSANZ *Application Handbook*. In turn, these requirements are guided by concepts and principles developed through the work of the Organisation for Economic Cooperation and Development, Food and Agriculture Organization of the United Nations, World Health Organisation and Codex Alimentarius Commission.

Table 1: Sources of Information, available on the FSANZ website, regarding GM Food

Issue	Specific web link
Safety of GM food	Safety Assessment of Genetically Modified Foods http://www.foodstandards.gov.au/srcfiles/GM%20Foods_text_pp_final.pdf
	Frequently Asked Questions on GM foods http://www.foodstandards.gov.au/foodmatters/gmfoods/frequentlyaskedquest3862.cfm
Labelling of GM food	Appendix 3: Safety Assessment of Genetically Modified Foods http://www.foodstandards.gov.au/srcfiles/GM%20Foods_text_pp_final.pdf
	Frequently Asked Questions on GM foods

Issue	Specific web link
	Part III. Labelling of GM Foods http://www.foodstandards.gov.au/foodmatters/gmfoods/frequentlyaskedquest3862.cfm
	GM Labelling Review Report http://www.foodstandards.gov.au/newsroom/publications/gmlabellingreviewrep2460.cfm
Long term feeding studies	Section 7.6: Safety Assessment of Genetically Modified Foods http://www.foodstandards.gov.au/srcfiles/GM%20Foods_text_pp_final.pdf
	Role of animal feeding studies in the safety assessment of genetically modified foods http://www.foodstandards.gov.au/consumerinformation/gmfoods/roleofanimalfeedings3717.cfm
Data used to inform the Safety Assess.	Food Matters GM Foods http://www.foodstandards.gov.au/foodmatters/gmfoods/

The main issues raised in submissions are discussed below.

10.1.1 *The impartiality of the FSANZ Board*

One private submitter is concerned that the composition of the FSANZ Board suggests conflict of interest in making decisions on applications.

10.1.1.1 Response

FSANZ Board members are subject to the requirements of the *Commonwealth Authorities and Companies Act 1997* and the FSANZ Act. This means that when a new Board member is appointed they are required to complete various declaration forms concerning pecuniary, academic and other interests that could give rise to a conflict involving FSANZ's business and operations. These declaration forms are tabled at Board meetings and amended from time to time as members' interests change. Additionally, at each Board meeting, members must identify agenda items for which they may have a conflict of interest. Where the Board considers that such a conflict exists, the Board member is either required to be absent during consideration of the item in question or to not vote.

The Board receives advice on conflict of issues from its employed legal counsel, and seeks external legal advice from the Australian Government Solicitor on a regular basis to ensure that its conflict of issues processes are robust.

10.1.2 *The safety of food derived from cotton line GHB119*

A private submitter is concerned that there is no evidence to show food derived from cotton line GHB 119 is safe.

10.1.2.1 Response

The approach used by FSANZ for the safety assessment of food derived from cotton line GHB119 is the same as that used for all GM applications (see information included in http://www.foodstandards.gov.au/srcfiles/GM%20Foods_text_pp_final.pdf) and involves a weight-of-evidence analysis of a number of different scientific studies which considers the characteristics of the new food. No GM food is permitted for sale in Australia or New Zealand if there is any evidence that such a food could pose any public health and safety concerns

Additionally, FSANZ also maintains a close watch on any information pertinent to any of the GM applications that have been approved, or are in the process of being considered, and would immediately withdraw an approval or not make an approval if new, valid scientific evidence suggested there may be a safety concern.

10.1.3 Appropriateness of broiler feeding studies

A private submitter suggests that the broiler feeding study accompanying the Application (Section 6.1 of Safety Assessment) is not of long enough duration to provide assurance of the safety of food derived from GHB119.

10.1.3.1 Response

The broiler study was undertaken using appropriate internationally recognised Good Laboratory Practice regulations pertinent to the design and execution of feeding studies.

Notwithstanding the above, as stated in the Safety Assessment ...'where a GM food has been shown to be compositionally equivalent to conventional varieties, the evidence to date indicates that feeding studies using target livestock species will add little to the safety assessment and generally are not warranted'.

The FSANZ decision regarding the nutritional adequacy of food derived from cotton line GHB119 was based on evidence from a consideration of protein characterisation and compositional analyses. The broiler study was included in the Safety Assessment as additional supporting information but was not an essential component of the safety consideration.

10.1.4 Allergen concerns

A private submitter has asked what evidence there is that allergens might not be produced once the line is widely grown.

10.1.4.1 Response

Food allergies are primarily the result of immune responses to food proteins

As discussed in the Safety Assessment, the novel Cry2Ae and PAT proteins present in cotton line GHB119 do not raise allergenicity concerns, and extensive testing of the genetic material associated with GHB119 indicates that no unintended proteins have been produced.

To date there has not been any clinically proven identification of allergies associated with consumption of cotton products. The major food products derived from cotton are oil and linters, neither of which would be expected to contain significant levels of any kind of protein. In the course of processing to food grade quality oil, proteins are destroyed by high temperatures and pressure, or are separated out by extraction with a non-polar solvent and destroyed by the temperature of solvent recovery. Linters are made up of 99% cellulose and are therefore a source of fibre. These points apply whether the cotton is GM or non-GM.

10.1.5 Clarification of statistical analysis used for compositional data

NZFSA requests clarification of the wording used in the discussion of statistical data in the compositional data.

10.1.5.1 Response

This request has been addressed in an amended Safety Assessment (SD1).

10.1.6 *Cost benefit analysis*

Queensland Health requested information on advice provided by FSANZ regarding Application A1040 to the Office of Best Practice Regulation, and hence seeks an explanation of the conclusions reached in the Benefit Cost Analysis.

10.6.1 Response

Where applications or proposals assessed by FSANZ are deemed to be of a routine or mechanical nature, the Office of Best Practice Regulation classifies them as 'minor' and does not require the preparation of a Regulatory Impact Statement.

10.1.7 *Future findings that may influence an approval decision*

Queensland Health was concerned about further GM approvals being made until the findings of the *Review of Food Labelling Law and Policy* are released.

10.1.7.1 Response

The Labelling Review Committee met for the first time in November 2009 and a final report is due to be provided to the Ministerial Council at the end of 2010 and to the Council of Australian Governments in 2011.

FSANZ has a statutory obligation to consider all applications seeking to amend the Code. Further, there is a statutory timeframe associated with this consideration and FSANZ therefore cannot hold up a consideration process on the grounds that information may become available at a future point.

10.1.8 *Costs to jurisdictions of GM testing of foods*

Queensland Health was concerned about the costs of GM testing associated with each approval.

10.1.8.1 Response

As discussed in the Benefit Cost Analysis (Section 8.2.2), the costs to jurisdictions of monitoring are expected to be comparable, whether a GM food is approved or not.

10.1.9 *Status of applications on GHB119 made by the Applicant to other regulatory agencies*

Queensland Health requested advice on the progress of applications made to other regulatory agencies regarding GHB119.

10.1.9.1 Response

As at late August 2010, there had been no change to the progress status of applications from that first given in Section 2.2 of the Assessment Report. There had been additional applications to Brazil, Argentina and the Ministry of Health, Labour and Welfare in Japan and these updates have been added to the Approval Report.

10.1.10 Comments on legal drafting

NZFSA provided detailed comments on the legal drafting.

10.1.10.1 Response

FSANZ thanks NZFSA for the valuable comments on the legal drafting. These comments are reflected in an amended approved version of the drafting (refer to Attachment 1A).

10.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

The draft variation to the Code would have a trade enabling effect as it would permit food derived from insect-protected, herbicide-tolerant cotton line GHB119 to be imported into Australia and New Zealand and sold, where currently it is prohibited. For this reason it was determined there was no need to notify this Application as a Sanitary and Phytosanitary (SPS) measure in accordance with the WTO Agreement on the Application of SPS Measures.

CONCLUSION

11. Conclusion and Decision

Decision

To approve the variation to Standard 1.5.2 – Food produced using Gene Technology, to include food derived from insect-protected and herbicide-tolerant cotton line GHB119.

11.1 Reasons for Decision

The development of a variation to the Code to give approval to the sale and use of food derived from insect-protected herbicide-tolerant cotton line GHB119 in Australia and New Zealand is proposed on the basis of the available scientific evidence, for the following reasons:

- the safety assessment did not identify any public health and safety concerns associated with the genetic modification used to produce insect-protected herbicide tolerant cotton line GHB119
- seed from insect-protected herbicide-tolerant cotton line GHB119 is equivalent to other commercially available cotton cultivars in terms of its safety for human consumption and nutritional adequacy
- labelling of certain foods derived from insect-protected herbicide-tolerant cotton line GHB119 will be required in the ingredients list if novel DNA or novel protein are present in the final food

- a regulation impact assessment process has been undertaken that fulfils the requirement in Australia and New Zealand for an assessment of compliance costs. The assessment concluded that the preferred option is Option 2, a variation to the Code, and
- there are no other measures that would be more cost-effective than a variation to Standard 1.5.2 that could achieve the same end.

12. Implementation and Review

The FSANZ Board's decision will be notified to the Ministerial Council. Following notification, the proposed variation to the Code is expected to come into effect on gazettal, subject to any request from the Ministerial Council for a review of FSANZ's decision.

REFERENCES

EPA (1997) Phosphinothricin Acetyltransferase and the Genetic Material Necessary for Its Production in All Plants; Exemption From the Requirement of a Tolerance On All Raw Agricultural Commodities. *Federal Register* 62(70):17717-17720. <http://www.epa.gov/EPA-PEST/1997/April/Day-11/p9373.htm>. Accessed 6 May 2010

EPA. (2007) Administrative revisions to plant-incorporated protectant tolerance exemptions. *Federal Register* 72(79):20431-20436.

EPA (2008) *Bacillus thuringiensis* Cry2Ae in Cotton; Temporary Exemption from the Requirement for a Tolerance. *Federal Register* 73:52591-52594, U.S. Environmental Protection Agency. <http://www.epa.gov/EPA-PEST/2008/September/Day-10/p20728.htm>. Accessed 6 May 2010

FSANZ (2007) *Safety Assessment of Genetically Modified Foods – Guidance Document*. Document prepared by Food Standards Australia New Zealand. http://www.foodstandards.gov.au/srcfiles/GM%20FINAL%20Sept%2007L%20_2_.pdf. Accessed 6 May 2010

ATTACHMENTS

- 1A. Draft variations to the *Australia New Zealand Food Standards Code* (at Approval)
- 1B. Draft variations to the *Australia New Zealand Food Standards Code* (at Assessment)
2. Explanatory statement of draft variations to the *Australia New Zealand Food Standards Code* (at Approval)
3. Summary of issues raised in public submissions

Draft variations to the *Australia New Zealand Food Standards Code* (at Approval)

Section 94 of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunseting

To commence: on gazettal

[1] **Standard 1.5.2** of the *Australia New Zealand Food Standards Code* is varied by –

[1.1] *omitting the Purpose clause, substituting –*

Simplified outline of this Standard

Division 1 of this Standard sets out the permission and conditions for the sale and use of foods produced using gene technology.

Division 2 of this Standard specifies the labelling and other information requirements for foods produced using gene technology.

[1.2] *omitting subparagraph (b)(ii) from the definition of line in clause 1, substituting –*

- (ii) any other plant that contains a transformation event or events, whether expressed as a line or event, that is listed in Column 3 of the Schedule;

[1.3] *inserting the subclause number (1) before the words For the purposes of this Standard in clause 1, and inserting after that subclause –*

(2) To avoid doubt, columns 1 and 2 of the Schedule contain additional information that is not part of this Code. Information in these columns may be added to or edited in any published version of this Code.

[1.4] *omitting clause 2, substituting –*

2 General prohibition on the sale and use of food produced using gene technology

A food produced using gene technology, other than a substance regulated as a food additive or processing aid, must not be sold or used as an ingredient or component of any food unless it is listed in Column 3 of the Schedule and complies with any corresponding conditions in Column 4.

[1.5] *omitting from clause 7 –*

Notwithstanding the provisions of this Division, Column 2 of the Table to clause 2 may specify labelling or other information requirements in relation to food produced using gene technology listed in Column 1 of the Table where –

substituting –

Notwithstanding the provisions of this Division, Column 4 of the Schedule may specify labelling or other information requirements in relation to food produced using gene technology listed in Column 3 of the Schedule where –

[1.6] *inserting after clause 7 –*

SCHEDULE

Column 1	Column 2	Column 3	Column 4
Commodity	Item	Food produced using gene technology	Special conditions
Canola	1.1	Food derived from herbicide-tolerant canola line GT73	
	1.2	Food derived from herbicide-tolerant canola Topas 19/2 and T45 and herbicide-tolerant and pollination-controlled lines Ms1, Ms8, Rf1, Rf2, Rf3	
	1.3	Food derived from herbicide-tolerant canola line Westar-Oxy-235	
Corn	2.1	Food derived from herbicide-tolerant corn line GA21	
	2.2	Food derived from insect-protected corn line MON810	
	2.3	Food derived from herbicide-tolerant and insect-protected corn line Bt11	
	2.4	Food derived from insect-protected corn line Bt176	
	2.5	Food derived from herbicide-tolerant corn line T25	
	2.6	Food derived from herbicide-tolerant corn line NK603	
	2.7	Food derived from herbicide tolerant and insect-protected corn line DBT418	
	2.8	Food derived from herbicide-tolerant and insect-protected corn line 1507	
	2.9	Food derived from insect-protected corn line MON863	
	2.10	Food derived from herbicide-tolerant and insect-protected corn line DAS-59122-7	
	2.11	Food derived from herbicide-tolerant and insect-protected corn line MON88017	
	2.12	Food derived from insect-protected corn line MIR604	

Column 1	Column 2	Column 3	Column 4
Commodity	Item	Food produced using gene technology	Special conditions
	2.13	Food derived from high lysine corn line LY038	Unless the protein content has been removed as part of a refining process, the label on or attached to a package of a food derived from high lysine corn line LY038 must include a statement to the effect that the food has been genetically modified to contain increased levels of lysine.
	2.14	Food derived from amylase modified corn line 3272	
	2.15	Food derived from insect-protected corn line MON89034	
	2.16	Food derived from insect-protected corn line MIR162	
	2.17	Food derived from herbicide-tolerant corn line DP-098140-6	
	2.18	Food derived from drought-tolerant corn line MON87460	
Cotton	3.1	Food derived from insect-protected cotton lines 531, 757 and 1076	
	3.2	Food derived from herbicide-tolerant cotton line 1445	
	3.3	Food derived from herbicide-tolerant cotton lines 10211 and 10222	
	3.4	Food derived from insect-protected cotton line 15985	
	3.5	Food derived from insect-protected cotton line COT102	
	3.6	Food derived from herbicide-tolerant and insect-protected cotton line MXB-13	
	3.7	Food derived from herbicide-tolerant cotton line LL25	
	3.8	Food derived from herbicide-tolerant cotton line MON88913	
	3.9	Food derived from herbicide-tolerant cotton line GHB614	
	3.10	Food derived from insect-protected cotton line COT67B	
	3.11	Food derived from herbicide-tolerant and insect-protected cotton line T304-40	
	3.12	Food derived from herbicide-tolerant and insect-protected cotton line GHB119	
Lucerne	4.1	Food derived from herbicide-tolerant lucerne lines J101 & J163	

Column 1	Column 2	Column 3	Column 4
Commodity	Item	Food produced using gene technology	Special conditions
Potato	5.1	Food derived from insect-protected potato lines BT-06, ATBT04-06, ATBT04-31, ATBT04-36, and SPBT02-05	
	5.2	Food derived from insect- and virus-protected potato lines RBMT21-129, RBMT21-350 and RBMT22-82	
	5.3	Food derived from insect- and virus-protected potato lines RBMT15-101, SEM15-02 and SEM15-15	
Rice	6.1	Food derived from herbicide-tolerant rice line LLRICE62	
Soybean	7.1	Food derived from herbicide-tolerant soybean line 40-3-2	
	7.2	Food derived from herbicide-tolerant soybean lines A2704-12 and A5547-127	
	7.3	Food derived from herbicide-tolerant soybean line MON89788	
	7.4	Food derived from herbicide-tolerant soybean line DP-356043-5	
	7.5	Food derived from high oleic acid soybean line DP-305423-1	
	7.6	Food derived from insect-protected soybean line MON87701	
Sugarbeet	8.1	Food derived from herbicide-tolerant sugarbeet line 77	
	8.2	Food derived from herbicide-tolerant sugarbeet line H7-1	

[1.7] *updating the Table of Provisions to reflect the above variations*

**Draft variations to the *Australia New Zealand Food Standards Code*
(at Assessment)**

Section 87(8) of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunseting

To commence: on gazettal

[1] **Standard 1.5.2** of the *Australia New Zealand Food Standards Code* is varied by –

[1.1] *omitting subparagraph (b)(ii) from the definition of line in clause 1, substituting –*

- (ii) any other plant that contains a transformation event or events, whether expressed as a line or event, that is listed in Column 3 of the Schedule;

[1.2] *omitting clause 2, substituting –*

2 General prohibition on the sale and use of food produced using gene technology

(1) A food produced using gene technology, other than a substance regulated as a food additive or processing aid, must not be sold or used an ingredient or component of any food unless it is listed in Column 3 of the Schedule and complies with any corresponding conditions in Column 4.

(2) To avoid doubt, column 1 of the Schedule contains additional information that is not part of this Code. Information in this column may be added to or edited in any published version of this Code.

[1.3] *omitting the Table to clause 2*

[1.4] *omitting from clause 7 –*

Notwithstanding the provisions of this Division, Column 2 of the Table to clause 2 may specify labelling or other information requirements in relation to food produced using gene technology listed in Column 1 of the Table where –

substituting –

Notwithstanding the provisions of this Division, Column 4 of the Schedule may specify labelling or other information requirements in relation to food produced using gene technology listed Column 3 of the Schedule where –

[1.5] *inserting after clause 7 –*

SCHEDULE

Column 1	Column 2	Column 3	Column 4
Commodity	Item	Food derived from ...	Special conditions
Canola	1.1 1.2 1.3	herbicide-tolerant canola line GT73 herbicide-tolerant canola Topas 19/2 and T45 and herbicide-tolerant and pollination-controlled lines Ms1, Ms8, Rf1, Rf2, Rf3 herbicide-tolerant canola line Westar-Oxy-235	
Corn	2.1 2.2 2.3 2.4 2.5 2.6 2.7 2.8 2.9 2.10 2.11 2.12 2.13 2.14 2.15 2.16 2.17	herbicide-tolerant corn line GA21 insect-protected corn line MON810 herbicide-tolerant and insect-protected corn line Bt11 insect-protected corn line Bt176 herbicide-tolerant corn line T25 herbicide-tolerant corn line NK603 herbicide tolerant and insect-protected corn line DBT418 herbicide-tolerant and insect-protected corn line 1507 insect-protected corn line MON863 herbicide-tolerant and insect-protected corn line DAS-59122-7 herbicide-tolerant and insect-protected corn line MON88017 insect-protected corn line MIR604 high lysine corn line LY038 amylase modified corn line 3272 insect-protected corn line MON89034 insect-protected corn line MIR162 Food derived from herbicide-tolerant corn line DP-098140-6	Unless the protein content has been removed as part of a refining process, the label on or attached to a package of a food derived from high lysine corn line LY038 must include a statement to the effect that the food has been genetically modified to contain increased levels of lysine.

Column 1	Column 2	Column 3	Column 4
Commodity	Item	Food derived from ...	Special conditions
Cotton	3.1	insect-protected cotton lines 531, 757 and 1076	
	3.2	herbicide-tolerant cotton line 1445	
	3.3	herbicide-tolerant cotton events 10211 and 10222	
	3.4	insect-protected cotton lines containing event 15985	
	3.5	insect-protected cotton line COT102	
	3.6	herbicide-tolerant and insect-protected cotton line MXB-13	
	3.7	herbicide-tolerant cotton line LL25	
	3.8	herbicide-tolerant cotton line MON88913	
	3.9	herbicide-tolerant cotton line GHB614	
	3.10	insect-protected cotton line COT67B	
	3.11	herbicide-tolerant and insect-protected cotton line T304-40	
	3.12	herbicide-tolerant and insect-protected cotton line GHB119	
Lucerne	4.1	herbicide-tolerant lucerne lines J101 & J163	
Potato	5.1	insect-protected potato lines BT-06, ATBT04-06, ATBT04-31, ATBT04-36, and SPBT02-05	
	5.2	insect- and virus-protected potato lines RBMT21-129, RBMT21-350 and RBMT22-82	
	5.3	insect- and virus-protected potato lines RBMT15-101, SEM15-02 and SEM15-15	
Rice	6.1	herbicide-tolerant rice line LLRICE62	
Soybean	7.1	herbicide-tolerant soybean line 40-3-2	
	7.2	herbicide-tolerant soybean lines A2704-12 and A5547-127	
	7.3	herbicide-tolerant soybean line MON89788	
	7.4	herbicide-tolerant soybean line DP-356043-5	
	7.5	high oleic acid soybean line DP-305423-1	
Sugarbeet	8.1	herbicide-tolerant sugarbeet line 77	
	8.2	herbicide-tolerant sugarbeet event H7-1	

[1.6] *updating the Table of Provisions to reflect the above variations*

Explanatory statement of draft variations to the *Australia New Zealand Food Standards Code* (at Approval)

Apart from adding food derived from herbicide-tolerant and insect-protected cotton line GHB119 to Standard 1.5.2 the draft variations, in broad terms, allow the replacement of the Table to clause 2 with a Schedule. The items listed below reflect wording changes that are required to accommodate this replacement.

Item 1.1

This item omits the *Purpose* clause and replaces it with a *Simplified outline of this Standard*. This simplification has been done following the recommendation of a recent legislative audit of the Code by the Office of Legislative Drafting and Publishing.

Item 1.2

This item omits the reference to the Table to clause 2 and inserts reference to the Schedule. It also indicates that the major listing is now in Column 3 of the Schedule.

Item 1.3

This item gives subclause status to the part in *Interpretation* beginning 'For the purpose of this Standard' and then adds a second subclause which clarifies the status of Column 1 and Column 2 of the Schedule.

Items 1.4 and 1.5

These items omit the reference to the Table to clause 2 and insert reference to the Schedule.

Item 1.6

This item allows insertion of the Schedule into Standard 1.5.2

In terms of structure, the Schedule has the following characteristics:

- Approvals are listed according to commodity type, and presented in the Schedule in alphabetical order.
- Within commodity categories, the approvals are listed chronologically by item number according to the date of gazettal for each approval.

In terms of wording, there have also been minor changes in order to correct inconsistencies that have arisen over the years. Included in these is the change of wording for the canola approvals to read 'food derived from...' rather than 'oil derived from...'

One item (Food derived from high oleic acid soybean lines G94-1, G94-19 and G168) that occurred in the Table to clause 2 has been removed from the Schedule since the lines are no longer produced and do not occur in the food chain.

Item 1.7

This item allows updating of the *Table of Provisions* to reflect the variations.

Summary of issues raised in public submissions

Submitter	Option ¹	Comments
Christine Bennett (Private)	1	<ul style="list-style-type: none"> Consumers are buying 'in the dark' without definitive labelling of GM foods. FSANZ rubber stamps applications
Paul Elwell-Sutton (Private)	1	<ul style="list-style-type: none"> Studies supporting the Application have all been performed by the Applicant and are not independent. The composition of the FSANZ Board suggests conflict of interest in making decisions on applications. The current labelling laws regarding GM foods are inadequate and do not allow consumers to avoid foods produced using gene technology. There are no benefits to consuming GM foods but there are recorded risks.
Food Technology Association of Australia	2	<ul style="list-style-type: none"> Supports the Application
Pedro & Martina Tschirky (Private)	1	<ul style="list-style-type: none"> There is no evidence that food derived from line GHB119 is safe. Broiler feeding studies are not of long enough duration to provide evidence of food safety. Given the statement made in the Safety Assessment that the composition of cotton can vary significantly with the agricultural conditions and seasons, what evidence is there that allergens might not be produced once the line is widely grown? Requests clear labelling of GM food to allow consumers to avoid it if they wish.
New Zealand Food Safety	-	<ul style="list-style-type: none"> Does not object to the application. Seeks clarification on the statistical analysis of the compositional data particularly regarding the term 'significant treatment x site' interactions. Makes a number of comments about the proposed legal drafting and suggests wording changes.
Queensland Health	-	<ul style="list-style-type: none"> Does not object to the application. Requests advice on the progress of applications concerning line GHB119 made to other agencies. Expresses concern about the lack of independence of study data. Requests advice provided by FSANZ to the Office of Best Practice Regulation on Application A1040. Expresses concern about the cost to jurisdictions of GM testing of foods. Suggests that a decision on the application should be deferred until the outcomes of the Council of Australian Governments Review of Food Labelling and Policy are known.

¹ Option 1 – Reject the application

Option 2 – Proceed to development of a food regulatory measure to vary Standard 1.5.2 to permit the sale and use of food derived from insect-protected and herbicide-tolerant cotton line GHB119, with or without specified conditions.