FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

APPLICATION A1028
FOOD DERIVED FROM INSECT-PROTECTED & HERBICIDE-TOLERANT COTTON LINE T304-40
EXPLANATORY STATEMENT

Executive Summary

Purpose

Food Standards Australia New Zealand (FSANZ) received an Application from Bayer CropScience Pty Ltd (Bayer) on 5 June 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 T304-40, conferring insect-protection and herbicide-tolerance.

This Application was assessed under the General Procedure.

Safety Assessment

A new genetically modified (GM) cotton line, T304-40, 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 Cry1Ab protein from *Bacillus thuringiensis* and herbicide tolerance is conferred by expression of phosphinothricin acetyltransferase (PAT) from *Streptomyces hygroscopicus*.

FSANZ has completed a comprehensive safety assessment of food derived from cotton plants containing event T304-40 (see **Supporting Document 1**[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 T304-40 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 T304-40. On the basis of the available evidence, including detailed studies provided by the Applicant, food derived from cotton line T304-40 is considered as safe and wholesome as food derived from other commercial cotton cultivars.

[1] SD1 Updated Safety Assessment for Application A1028 (http://www.foodstandards.gov.au/foodstandards/applications/applicationa1028oild4457.cfm)

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 T304-40, if approved, would be required to be labelled as genetically modified if novel DNA and/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 T304-40.

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 *Food Standards Australia New Zealand Act 1991* (FSANZ Act):

- whether costs that would arise from a food regulatory measure developed or varied as a result of the Application 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 T304-40 in the Table to clause 2.

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 T304-40 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 T304-40

- food derived from cotton line T304-40 is equivalent to that from other commercially available cotton cultivars in terms of its safety for human consumption and nutritional adequacy

- labelling of certain foods derived from cotton line T304-40 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 16 December 2009 and 10 February 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 T304-40. A total of 12 submissions were received. A summary of these is provided in **Attachment 2** 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 DOCUMENT

The following material, which was used in the preparation of this Approval Report, is available on the FSANZ website at
http://www.foodstandards.gov.au/foodstandards/applications/applicationa1028oild4457.cfm

SD1: Updated Safety Assessment Report: Application A1028 – Food derived from Insect-Protected & Herbicide-Tolerant Cotton Line T304-40

INTRODUCTION

On 5 June 2009, Bayer CropScience Pty Ltd (Bayer) submitted an Application seeking approval for food derived from cotton line T304-40 under Standard 1.5.2 – Food produced using Gene Technology, in the *Australia New Zealand Food Standards Code* (the Code).

Cotton line T304-40 has been generated in order to derive, through normal 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 Cry1Ab 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 T304-40 according to FSANZ guidelines[2] to assess its safety for human consumption. The Assessment Report was released in December 2009 and public comment was sought on the safety assessment and proposed recommendations. Comments received were considered in completion of this Approval Report.

1. The Issue / Problem

The Applicant has developed GM cotton line T304-40. Pre-market approval is necessary before food products 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 T304-40 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 T304-40 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, are listed in the Table to clause 2 of the Standard.

2.2 Overseas approvals

Submissions on cotton line T304-40 have been made to the appropriate agencies for food, feed and environmental approvals in the United States of America (Food and Drug Administration, Department of Agriculture) and Canada (Health Canada and the Canadian Food Inspection Agency). The Applicant has advised that further submissions for import approvals in other key international markets will also be made.

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

The US Environmental Protection Agency (EPA) granted an exemption from a food tolerance for Bt Cry1Ab protein in all food and feed commodities on August 2, 1996 (EPA, 1996)[3]. The tolerance exemption is published in the Code of Federal Regulations 40CFR 174.511 since 2008, formerly 40CFR 180.1173 (EPA, 2007)[4]. In September 2001, the EPA completed a reassessment of this tolerance exemption considering all of the existing data, public literature, and public comments. The reassessment determined that the tolerance exemption met all the scientific and regulatory standards. This tolerance exemption for the Bt Cry1Ab protein is not event-specific and therefore applies to all events producing the Cry1Ab protein that might be found in the food supply (http://www.epa.gov/oppbppd1/biopesticides/pips/bt10_statement.htm).

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)[5]. The tolerance exemption is published in the Code of Federal Regulations 40CFR 174.522 since 2008, formerly 40CFR 180.1151 (EPA, 2007)[4].

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.

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[3] EPA. (1996) *Bacillus Thuringiensis* CryIA(b) Delta-Endotoxin and the Genetic Material Necessary for Its Production in All Plants; Exemption from Requirement of a Tolerance. *Federal Register* 61(150):40340-40343, available online at http://www.epa.gov/fedrgstr/EPA-PEST/1996/August/Day-02/pr-838.html.

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

[5] 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, available online at http://www.epa.gov/EPA-PEST/1997/April/Day-11/p9373.htm.

4. Assessment questions

In completing the assessment of this application, three 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 T304-40 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 T304-40 has been evaluated according to the safety assessment guidelines prepared by FSANZ[6] and is provided in **Supporting Document 1**[7]. 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 T304-40, 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 T304-40 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 T304-40 contains two novel genes cassettes. One contains a modified *cry1Ab* gene that encodes an insecticidal crystal protein and the other contains a *bar* gene that encodes a protein conferring tolerance to herbicides containing glufosinate ammonium.

[6] FSANZ (2007) Safety Assessment of Genetically Modified Foods – Guidance Document. http://www.foodstandards.gov.au/_srcfiles/GM%20FINAL%20Sept%2007L%20_2_.pdf
[7] SD1 Safety Assessment for A1028 http://www.foodstandards.gov.au/foodstandards/applications/applicationa1028oild4457.cfm

Comprehensive molecular analyses of cotton line T304-40 indicate that there is a single insertion site containing two almost complete copies of the *cry1Ab* cassette, an almost complete copy of the *bar* cassette and an isolated partial terminator sequence from the *cry1Ab* cassette. The introduced genetic elements are stably inherited from one generation to the next. There are no antibiotic resistance marker genes present in line T304-40.

Expression analyses of the two novel proteins produced in line T304-40 showed that PAT is expressed in all plant parts tested but is highest in young leaves (61.4 µg/g fresh weight). Cry1Ab is not detectable in any plant parts except the seed (3.7 µg/g fresh weight).

Studies have demonstrated that the Cry1Ab and PAT proteins conform in size and amino acid sequence to that expected, do not exhibit any post-translational modification including glycosylation and, in the case of PAT, exhibit the expected enzymatic activity. The activity of the expressed Cry1Ab protein was unable to be tested because the protein was not isolated in enough quantity to perform an insect assay; this was not a concern because of the weight of evidence from other sources regarding the authenticity of the Cry1Ab protein.

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 Cry1Ab and PAT proteins are unlikely to be toxic or allergenic to humans.

Detailed compositional analyses were done on fuzzy seed[8] derived from T304-40 cotton plants. Analyses were done of proximates (crude protein, crude fat, ash and total carbohydrates), ADF, NDF, 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. Additionally, levels of analytes were measured in processed commodities derived from control and GM cottonseed, although the results from these commodities were not analysed statistically. 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 line T304-40 when compared with conventional cotton cultivars currently on the market.

Although not essential for establishing the safety of the food, one broiler feeding study with T304-4 cotton 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 from cotton T304-40 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.

Conclusion

No potential public health and safety concerns have been identified in the assessment of cotton line T304-40. On the basis of the data provided in the present Application, and other available information, food derived from cotton line T304-40 is considered as safe for human consumption as food derived from conventional cotton cultivars.

[8] the linted cottonseed remaining after the ginning process, which removes fibres for textile production.

RISK MANAGEMENT

6. Issues raised

6.1 Risk Management Strategy

In accordance with general labelling provisions, food derived from cotton line T304-40, if approved, would be required to be labelled as genetically modified if novel DNA or novel protein is present in the final food.

7. Options

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

7.1 Option 1 – Maintain the *status quo*

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 T304-40, with or without specified conditions in the Table to clause 2 of the Standard.

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.

Cotton line T304-40 has been developed primarily for agricultural production overseas and, at this stage, the Applicant has no plans for cultivation of this variety in either Australia or New Zealand. The cultivation of cotton T304-40 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 by various New Zealand Government agencies including the Environmental Risk Management Authority (ERMA) and the Ministry of Agriculture and Forestry (MAF) before commercial release in either country could be permitted.

8.2 Benefit Cost Analysis

8.2.1 Option 1 – Maintain the status quo

Consumers: Possible restriction in the availability of imported cottonseed products to those products that do not contain cotton line T304-40.

No impact on consumers wishing to avoid GM foods, as food from cotton line T304-40 is not currently permitted in the food supply.

Potential increase in price of imported cottonseed foods due to requirement for segregation of cotton line T304-40.

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 T304-40 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 T304-40.

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 T304-40 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 T304-40 would ensure no conflict with WTO responsibilities.

This option could impact on enforcement resources, as certain foods derived from cotton line T304-40 will be required to be labelled as genetically modified and there are likely to be increased costs associated with the additional monitoring required to ensure compliance with the labelling provisions of the Code.

Industry: Importers of processed foods containing cottonseed derivatives would benefit as foods derived from cotton line T304-40 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 T304-40 would be required to be labelled.

8.3 Comparison of Options

As food from cotton line T304-40 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 T304-40 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 T304-40 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 T304-40 is therefore the preferred option.

8.4 Proposed changes to legal drafting in Standard 1.5.2

FSANZ is aware that there is an inconsistency in the wording of existing cotton entries in the Table to clause 2 of Standard 1.5.2. In some instances the approval is stated as being for 'oil and linters derived from...' and in other instances it is stated as being for 'food derived from...'. In order to rectify this inconsistency and to standardise the wording used for all cotton entries, FSANZ will vary the wording to state only 'food derived from...'

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. The decision of the FSANZ Board to approve the variation to Standard 1.5.2 will be notified to the Ministerial Council. If a request to review the decision is not made by the Ministerial Council, gazettal of the variation to the Code will occur. Stakeholders, including the Applicant and submitters, will be advised of the notification and gazettal in the national press and on the FSANZ website.

10. Consultation

10.1 Public Consultation

The Assessment Report was advertised for public comment between 16 December 2009 and 10 February 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 T304-40.

As this Application was assessed under a General Procedure, there was one round of public comment.

A total of 12 submissions were received. A summary of these is provided in **Attachment 2** to this Report. FSANZ has taken the submitters' comments relevant to food safety into account in preparing the Approval Report for this Application. The Office of the Gene Technology Regulator in Australia and the Ministry of Agriculture and Forestry 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 the nature and source of data used to inform the Safety Assessment, are available from the FSANZ website (see Table 1). In relation to the data required for an 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 *Application Handbook*[9]*.* In turn, these requirements are guided by concepts and principles developed through the work of the OECD, FAO, WHO and the Codex Alimentarius Commission in relation to the assessment of GM foods.

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

Issue	General area of FSANZ website where information can be found	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 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/

[9] http://www.foodstandards.gov.au/foodstandards/changingthecode/applicationshandbook.cfm

The main issues raised in submissions are discussed below.

10.1.1 Safety of GM food

One private submitter suggests that food derived from cotton T304-40 or any genetically modified organism (GMO) may accelerate the ageing process in cells or have a degenerative effect on neural function. Several submitters raise the issue of the safety of GM foods, in general and as evidence allude to research carried out in other GM crops e.g. a paper by Spiroux de Vendomois et al (2009)[10] regarding GM corn lines NK603, MON810 and MON863.

10.1.1.1 Response

There is no evidence in the scientific literature to suggest that consumption of food derived from any GMO, including GM cotton, has been implicated in cell ageing or loss of cognitive function.

FSANZ has assessed the Spiroux de Vendomois *et al* paper[11] and concluded that the authors have misrepresented the toxicological significance of their results by placing undue emphasis on the statistical treatment of data, and failing to take other relevant factors into account. Despite claims, no new evidence of adverse effects has been put forward by this research. A 2010 report by the GMO Panel of the European Food safety Authority[12] has similarly concluded that the authors' claims about toxicity are not supported by the data.

It should also be noted that it is not always appropriate to generalise conclusions between different genetic modifications in different species and that the safety of a GM food should be assessed on a case-by-case basis using specific evidence from a variety of experimental approaches.

10.1.2 Future findings that may influence an approval decision

Two private submitters and the Hon. Lynn MacLaren MLC are concerned about further GM approvals being made until the findings of the Review of Food Labelling Law and Policy are released, and the findings of research conducted by Dr Judy Carman become publicly available.

10.1.2.1 Response

The labelling Review committee met for the first time in November 2009 and, as yet, there is no timeline for completion of the Review. While there has been some publicity surrounding Dr Judy Carman's latest findings concerning GM food, it is the understanding of FSANZ that these findings have not yet been published.

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. In the case of food derived from cotton line T304-40, FSANZ considers that sufficient evidence has been provided to allow completion of a safety assessment.

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[10] Spiroux de Vendomois J, Roullier F, Cellier D and Séralini G-E, A Comparison of the Effects of Three GM Corn Varieties on Mammalian Health. *Int J Biol Sci.* 5:706-726.

[11] http://www.foodstandards.gov.au/educationalmaterial/factsheets/factsheets2009/fsanzresponsetoseral4647.cfm

[12] http://www.efsa.europa.eu/en/events/event/gmo100127-m.pdf

However, FSANZ remains open to receive or review any new information pertinent to the GM applications that have been approved, or are in the process of being considered. If necessary, FSANZ would not hesitate to withdraw an approval or not approve a GM food where the decision could be supported by robust scientific evidence.

10.1.3 Proteins used to raise antibodies

The New Zealand Food Safety Authority (NZFSA) raises a question about the source of proteins used to generate antibodies in the protein characterisation studies (Section 4.3 of the Safety Assessment).

10.1.3.1 Response

The source of the protein (i.e. whether from a bacterial or plant source) is immaterial unless the plant protein were to be glycosylated, in which case a microbially-derived protein would not be identical. Evidence from the experimental work submitted, indicated that the plant protein was not glycosylated. Further to this, the polyclonal nature of the primary antibody would ensure that, should there be any isoforms present in the protein being tested, these would be readily detected.

10.1.4 Use of proteins from 'TwinLink'™

NZFSA seeks assurance that it was appropriate to use proteins isolated from 'TwinLink'™ for the protein equivalence study (Section 4.3.2 of the Safety Assessment).

10.1.4.1 Response

The use of proteins isolated from TwinLink™ is entirely appropriate for the equivalence study. 'TwinLink'™ was produced by the conventional crossing of line T304-40 with another GM line (GHB119[13]) containing the *cry2Ae* gene. The presence of event T304-40 in material derived from 'TwinLink'™ was confirmed by PCR using appropriate primers, and the authenticity of the Cry1Ab and PAT proteins from 'TwinLink'™ was confirmed through a number of different experimental approaches of which immunoreactivity is probably the most powerful. In addition, with regard to migration on an SDS-PAGE gel and immunoreactivity, proteins derived from 'TwinLink'™ and T304-40 were indistinguishable.

10.1.5 Broiler feeding study

Queensland Health notes a reliance on small studies and cites the broiler feeding study accompanying the Application (Section 6.1 of Safety Assessment) as an example.

10.1.5.1 Response

The broiler study was undertaken using appropriate, internationally recognised Good Laboratory Practice regulations pertinent to the execution of feeding studies. These types of studies are designed to specifically measure carcass characteristics and are not intended to be toxicity studies. The number of birds selected for carcass analysis was based on that necessary to achieve sufficient statistical power to detect differences between treatments.

[13] Food derived from line GHB119 is currently under assessment (A1040) by FSANZ (http://www.foodstandards.gov.au/foodstandards/applications/applicationa1040food4719.cfm)

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 T304-40 was based on the totality of evidence, including a consideration of protein characterisation and compositional analysis. The broiler study was included in the Safety Assessment because it had been submitted by the Applicant, not because it represented an essential component of the safety consideration.

10.1.6 Benefit Cost analysis

Queensland Health requests more quantitative detail to support the conclusions of the Benefit Cost Analysis in the Assessment Report.

10.1.6.1 Response

The Benefit Cost Analysis included in the Assessment Report is not intended to be an exhaustive, quantitative dollar analysis of the options and, in fact, most of the impacts that are considered cannot be assigned a dollar value. Rather, the analysis seeks to highlight the qualitative impacts of criteria that are relevant to each option. These criteria are deliberately limited to those involving broad areas such as trade, consumer information and compliance and do not, for example include any consideration of the impact of growing the crop (either to the farmer or to the environment).

10.1.7 Detection methodology

The Soil and Health association of NZ is concerned that there are no diagnostic tools available for detection of GM foods by consumer advocates, and dietary and health practitioners.

10.1.7.1 Response

As part of the Application, the Applicant is required to confirm that there is detection methodology for the GM food. For cotton line T304-40, 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 restricted to specialist laboratories. This is not different from the routine testing of food samples for a variety of chemicals or organisms, which is done by specialist laboratories.

10.1.8 Enforcement costs

Queensland Health has concerns about the impact on monitoring resources if the Application is approved.

10.1.8.1 Response

FSANZ believes it is important to recognize that, because GM foods are continually entering international trade, the costs of monitoring are largely unavoidable and will arise irrespective of whether or not GM foods are approved in Australia and New Zealand.

In the case of approved GM foods, monitoring is required to ensure compliance with the labelling requirements, and in the case of GM foods that have not been approved, monitoring is required to ensure they 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. Any regulatory decision take by FSANZ is therefore unlikely to significantly affect the cost impact on jurisdictions, in terms of their responsibilities to enforce the Code.

10.1.9 Textual errors

NZFSA points out a number of ambiguities in the wording of results for the statistical analyses associated with some of the analytes in Section 5 of the Safety Assessment.

10.1.9.1 Response

FSANZ is grateful to NZFSA for pointing out these ambiguities and has clarified the wording in the relevant sections of the Safety Assessment.

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 T304-40 to be imported into Australia and New Zealand and sold, where currently it is prohibited. For this reason it was determined there is no need to notify this Application as a Sanitary and Phytosanitary (SPS) measure in accordance with the WTO SPS Agreement.

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 T304-40 in the Table to clause 2.

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 T304-40 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 T304-40

- food derived from insect-protected herbicide-tolerant cotton line T304-40 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 T304-40 will be required 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

- there are no relevant New Zealand standards, 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.

ATTACHMENTS

1. Draft variation to the *Australia New Zealand Food Standards Code*
2. Summary of issues raised in public submissions

Attachment 1

Draft variation to the *Australia New Zealand Food Standards Code*

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

To commence: on gazettal

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

[1.1] *inserting in the* Table to clause 2 –

Food derived from insect-protected and herbicide-tolerant cotton line T304-40	

[1.2] *omitting wherever occurring in* Column 1 *of the* Table to clause 2 –

Oil and linters derived from

substituting –

Food derived from

Attachment 2

Summary of Public Submissions on Assessment Report

Submitter	Comments
Christine Bennett (Private)	• The presence of genetically modified crops in Australia is having deleterious effects on the bee population.
David Savill (Private)	• The current labelling laws regarding GM foods are inadequate and do not allow consumers to avoid foods produced using gene technology. • There have been no long term studies on GM foods. • Expresses concern that the scientific studies accompanying the Application are not independent.
Paul Elwell-Sutton (Private)	• There is no evidence to demonstrate that such food would not accelerate the ageing process in cells or have a degenerative effect on neural development • . The current labelling laws regarding GM foods are inadequate and do not allow consumers to avoid foods produced using gene technology.
Shirley Collins (Private)	• Requests that an embargo be placed on GM food until outstanding issues are resolved concerning: a) Labelling, especially with regard to any findings of the current labelling review b) Safety of GM food to humans (cites, in particular, a paper by Spiroux de Vendomois et al (2009) on GM corn lines NK603, MON810, MON863, also makes reference to a forthcoming but, as yet, unpublished paper by Dr Judy Carman)..
New Zealand Food Safety Authority	• Does not object to the Application. • Suggests that information on the source of the 'native' proteins used to generate antibodies could be included in the Safety Assessment. • Seeks a reason why novel proteins isolated from 'TwinLink' cotton rather than from T304-40 were appropriate for the protein equivalence studies (Section 4.3.2) • Clarity on the consistency of wording in Sections 5.3.2, 5.3.3 and 5.3.4, regarding the results of statistical analysis, is sought.
Ryan Hamilton (Private)	• Against the approval of any GM food • Requests clear labelling of GM food
Michelle Denise (Private)	• Requests deferral of a decision on the Application until the outcomes are known of the current labelling review and the findings of a research paper by Dr Judy Carman are published.
Australian Food & Grocery Council	• Supports the Application on the basis that there is no identified risk to public health and safety.
Queensland Health (whole of Government response)	• Does not object to the application. • Expresses concern that the scientific studies accompanying the Application are not independent and not long term. • Suggests that the broiler feeding study is too small. • Requests that more (quantitative) detail be provided in the Benefit Cost Analysis to support the conclusion reached. • Has concerns about the impact on monitoring resources if the Application is approved.

Submitter	Comments
The Hon Lynn MacLaren MLC, Member for South Metropolitan, Parliament of WA	• Requests deferral of a decision on the Application until the outcomes are known of the current labelling review and the findings of a research paper by Dr Judy Carman are published. • Expresses concern that the scientific studies accompanying the Application are not independent. • States that decisions on food safety must be based on hard evidence data not assumptions. • States that there is no reliable scientific evidence that GM foods are safe. • Suggests that there should be mandatory labelling in Australia of all foods derived from gene technology
The Soil and Health Association of NZ	• Opposes approval of the Application on a number of grounds: – Inadequate safety testing – Lack of independent studies – Lack of long term testing – Lack of diagnostic tools for detecting the presence of the GM food – The Application is deficient in many consumer, practitioner and health parameters.
Food Technology Association of Australia	• Supports the Application