



19 August 2011
[15-11]

APPLICATION A1051 FOOD DERIVED FROM HERBICIDE-TOLERANT SOYBEAN LINE FG72 ASSESSMENT REPORT

EXECUTIVE SUMMARY

Main points are:

- **The Application seeks approval for food derived from a genetically modified (GM), herbicide-tolerant soybean line.**
- **The Safety Assessment did not identify any potential public health and safety concerns.**
- **This Report recommends the preparation of a draft variation to the Code to include food derived from soybean line FG72 in Standard 1.5.2.**
- **At present, there is no approval to grow this GM soybean 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 soybean line would have to be labelled as GM if it contains novel DNA or novel protein.**

Purpose

Food Standards Australia New Zealand (FSANZ) received an Application from Bayer CropScience Pty Ltd (Bayer) on 30 June 2010. 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) soybean line FG72, conferring herbicide-tolerance.

This Application is being assessed under the General Procedure and will include one round of public consultation.

Safety Assessment

The primary objective of FSANZ in developing or varying a food regulatory measure, as stated in s 18 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), is the protection of public health and safety. Accordingly, the safety assessment forms the central component in considering an application.

A new genetically modified (GM) soybean line, FG72, is tolerant to two herbicides, glyphosate and isoxaflutole. Tolerance to glyphosate is achieved through expression of a 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) encoded by the *2mepsps* gene derived from *Zea mays* (corn). The *epsps* gene has been widely used in the genetic modification of a number of crop species.

Tolerance to isoxaflutole is achieved through expression of a modified p-hydroxyphenylpyruvate dioxygenase (HPPD) encoded by the *hppdPF W336* gene originally derived from the soil bacterium *Pseudomonas fluorescens*.

FSANZ has completed a comprehensive safety assessment of food derived from soybean line FG72 (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 soybean line FG72 compared with that of conventional soybean cultivars. No public health and safety concerns have been identified in this assessment.

On the basis of the available evidence, including detailed studies provided by the Applicant, food derived from soybean line FG72 is considered as safe and wholesome as food derived from other commercial soybean cultivars.

Other assessment considerations

In assessing the Application, FSANZ has, in addition to considering the safety of food derived from soybean line FG72, had regard to the following matters as prescribed in s 29 of the 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.
- Whether there are other measures that would be more cost-effective than a variation to Standard 1.5.2 and could achieve the same end.
- Any relevant New Zealand standards.
- Any other relevant matters.

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 soybean line FG72, if approved, would be required to be labelled as genetically modified if novel DNA or novel protein is present in the final food.

Preferred Approach

To prepare a draft variation to Standard 1.5.2 - Food produced using Gene Technology, to include food derived from herbicide-tolerant soybean line FG72 in the Schedule.

Reasons for Preferred Approach

On the basis of the available evidence, the development of a draft variation to the Code to give approval to the sale and use of food derived from herbicide-tolerant soybean line FG72 in Australia and New Zealand is proposed, for the following reasons:

- The Safety Assessment did not identify any public health and safety concerns associated with the genetic modification used to produce soybean line FG72.
- Food derived from soybean line FG72 is equivalent to that derived from the conventional counterpart and other commercially available soybean cultivars in terms of its safety for human consumption and nutritional adequacy.
- Labelling of food derived from soybean line FG72 will be required in the ingredients list or in conjunction with the name of the food, if it contains novel DNA or novel protein.
- Two regulatory options were considered: (1) rejection of the Application; or (2) approval of food derived from soybean line FG72. 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.
- 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 and could achieve the same end.

Consultation

Public submissions are now invited on this Assessment Report. Comments are requested on the scientific aspects of this Application, in particular, information relevant to the safety assessment of food derived from soybean line FG72.

As this Application is being assessed under a General Procedure, there will be one round of public comment. Responses to this Assessment Report will be used to develop the Approval Report for the Application.

Invitation for Submissions

FSANZ invites public comment on this Report and the draft variations to the Code based on regulation impact principles for the purpose of preparing a variation to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in further considering this Application. Submissions should, where possible, address the objectives of FSANZ as set out in s 18 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable.

Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection.

If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information, separate it from your submission and provide justification for treating it as confidential commercial material. Section 114 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Changing the Code tab and then through Documents for Public Comment.

Alternatively, you may email your submission directly to the Standards Management Officer at submissions@foodstandards.gov.au. There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 30 September 2011

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

Submissions received after this date will only be considered if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at standards.management@foodstandards.gov.au.

If you are unable to submit your submission electronically, hard copy submissions may be sent to one of the following addresses:

**Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222**

**Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6143
NEW ZEALAND
Tel (04) 978 5636**

CONTENTS

INTRODUCTION	2
1. THE ISSUE / PROBLEM.....	2
2. CURRENT STANDARD.....	2
2.1 <i>Background</i>	2
2.2 <i>Overseas approvals</i>	3
3. OBJECTIVES	3
4. QUESTIONS TO BE ANSWERED	3
RISK ASSESSMENT.....	4
5. RISK ASSESSMENT SUMMARY	4
5.1 <i>Safety Assessment Process</i>	4
5.2 <i>Outcomes of the Safety Assessment</i>	4
RISK MANAGEMENT	5
6. ISSUES	5
6.1 <i>Labelling</i>	5
6.2 <i>Detection Methodology</i>	6
7. IMPACT ANALYSIS	6
7.1 <i>Affected Parties</i>	6
7.2 <i>Benefit Cost Analysis</i>	7
7.3 <i>Comparison of Options</i>	8
COMMUNICATION AND CONSULTATION STRATEGY.....	8
9. <i>Communication</i>	8
10. <i>Consultation</i>	9
10.1 <i>World Trade Organization (WTO)</i>	9
CONCLUSION	9
11. CONCLUSION AND PREFERRED OPTION	9
11.1 <i>Reasons for Preferred Approach</i>	9
12. IMPLEMENTATION AND REVIEW	10
ATTACHMENT 1 - DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE.....	11

SUPPORTING DOCUMENT

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/applicationa1051food4902.cfm>

SD1: Safety Assessment Report: Application A1051 – Food Derived from Herbicide-Tolerant Soybean Line FG72

INTRODUCTION

On 30 June 2010, Bayer CropScience Pty Ltd (Bayer) submitted an Application seeking approval for food derived from soybean line FG72 under Standard 1.5.2 – Food produced using Gene Technology, in the *Australia New Zealand Food Standards Code* (the Code).

Soybean line FG72 is tolerant to two herbicides, glyphosate and isoxaflutole. Tolerance to glyphosate is achieved through the introduction of the *2mepsps* gene, from *Zea mays* (corn), expressing the protein 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS). EPSPS proteins have been widely used to confer glyphosate tolerance in a range of crop species. Tolerance to isoxaflutole is achieved through the introduction of a modified *hppd* gene (*hppdPf W336*), originally from *Pseudomonas fluorescens*, expressing p-hydroxyphenylpyruvate dioxygenase (HPPD). Homologues of the *hppd* gene occur ubiquitously in nature, including in soybean. The expression of the *hppdPf W336* gene provides an excess of HPPD which allows the plant to remain functional in the presence of isoxaflutole. FSANZ has not previously assessed this protein.

The purpose of the genetic modification is to provide a broad spectrum weed management system in the soybean crop.

This Assessment includes a full scientific evaluation of food derived from soybean line FG72 according to FSANZ guidelines (FSANZ, 2007) to assess its safety for human consumption. Public comment is now sought on the safety assessment and proposed recommendations prior to further consideration and completion of the Application.

1. The Issue / Problem

The Applicant has developed GM soybean line FG72. 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 soybean line FG72 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.

Soybean line FG72 is intended for cultivation in major soybean-growing countries. Before its release into commercial markets, the Applicant is seeking regulatory approval for the line in a number of trading markets, including Australia and New Zealand. This is necessary because, once it is cultivated on a commercial-scale, processed soybean products imported into Australia and New Zealand could contain components derived from soybean line FG72. The Application is being 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 Schedule of the Standard.

2.2 Overseas approvals

Applications concerning soybean line FG72 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) and Korea (Food and Drug Administration, Rural Development Administration). These applications are still currently under consideration. Further applications for food import approvals in other key international markets may also be made.

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 s 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. Questions to be answered

In completing the Assessment of this Application, the following questions were 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 soybean line FG72 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 soybean line FG72 has been assessed according to the safety assessment guidelines prepared by FSANZ (2007). The full Safety Assessment 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

The Safety Assessment of soybean line FG72 included the following key elements: a characterisation of the transferred genes, their origin, function and stability in the soybean 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 the newly expressed proteins to be either allergenic or toxic in humans.

The assessment of soybean line FG72 was restricted to food safety and nutritional issues. Any risks related to the release into the environment of GM plants used in food production, the safety of animal feed, or animals consuming feed derived from GM plants, or the safety of food derived from the non-GM (conventional) plant have not been addressed in this assessment.

5.2 Outcomes of the Safety Assessment

The two novel gene cassettes were contained within a single linear fragment and were introduced into the parent line 'Jack' using a biolistic technique. Comprehensive molecular analyses of soybean line FG72 indicate there is a single insertion site comprising two partial sequences in a head to head orientation, followed by two complete copies of the linear fragment, arranged in a head to tail orientation. In addition, a genomic fragment from 'Jack' has translocated to a new position and is flanked at one end by 158 base pairs of a promoter sequence from the introduced linear fragment. Breeding over a number of generations has confirmed stability of the introduced genetic elements and segregation data indicate their Mendelian inheritance. There are no antibiotic-resistance marker genes present in the line.

Soybean line FG72 expresses two novel proteins, HPPDPf W336 and 2mEPSPS, both of which were detected in all plant parts that were analysed. HPPDPf W336 was lowest in the seed (approximately 1.5 µg/g dry weight) and highest in younger leaves (approximately 38 µg/g dry weight). 2mEPSPS protein concentrations were much higher than those for HPPDPf W336. The leaves contained the highest levels (older leaves contained approximately 660 µg/g dry weight) while roots contained the lowest levels (approximately 40 µg/g dry weight). The level of 2mEPSPS in the seed was approximately 150 µg/g dry weight. During processing of the seed, the HPPDPf W336 protein may be concentrated to a small degree in hulls and protein isolate, and is undetectable in other processed fractions. Levels of the 2mEPSPS protein are reduced in all fractions during processing, being undetectable in toasted meal, crude lecithin and all forms of oil.

Both proteins conform in size and amino acid sequence to that expected, are immunoreactive to the corresponding antibody and are not glycosylated.

For both proteins, bioinformatic studies confirmed their lack of any significant amino acid sequence similarity to known protein toxins or allergens and digestibility studies demonstrated that the proteins would be rapidly degraded in the stomach following ingestion. Acute 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 combined with their lack of similarity to known protein toxins or allergens and the loss of enzyme activity with heating, this does not raise any safety concerns. Taken together, the evidence indicates that HPPDPf W336 and 2mEPSPS are unlikely to be toxic or allergenic to humans.

The residues generated on soybean line FG72 as a result of spraying with isoxaflutole are the same as those found on conventional crops sprayed with isoxaflutole. Residue data derived from supervised trials indicate that the residue levels in seed are below the limit of quantitation and that there is some concentration of residue in meal and aspirated grain fractions but not in other processed commodities. In the absence of any measurable exposure to either parent herbicide or metabolites the risk to public health and safety is likely to be negligible.

Detailed compositional analyses indicated that the seeds of soybean line FG72 are compositionally equivalent to those of the parental line. Mean levels of a range of analytes were also obtained for processed products derived from soybean seed. There were no meaningful differences between the control and the GM line for any analyte measured in processed products used for human consumption. In addition, no difference between seeds of soybean line FG72 and 'Jack' were found, in terms of presence and mean level of endogenous allergens.

Although not essential for establishing the safety of the food, one broiler feeding study using seedmeal from soybean line FG72 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 seedmeal derived from soybean line FG72 was nutritionally adequate, and equivalent to that derived from a non-GM control soybean 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 soybean line FG72. On the basis of the data provided in the present Application, and other available information, food derived from soybean line FG72 is considered as safe for human consumption as food derived from conventional soybean cultivars.

RISK MANAGEMENT

6. Issues

6.1 Labelling

In accordance with general labelling provisions, food derived from soybean line FG72, if approved, would be required to be labelled as genetically modified if it contains novel DNA or novel protein.

Soybean FG72 is intended primarily for use as a broad-acre commodity (field soybean) to produce products derived from cracked soybeans, and is not intended for vegetable or garden purposes where food-grade products may include tofu, soybean sprouts, soy milk, and green soybean (e.g. edamame). This latter type of soybean generally has a different size, flavour and texture to field soybean. The main food product from field soybean is refined oil in which, because of the production process, protein and DNA are not likely to be present. Products such as protein concentrate, protein isolate and textured flour are likely to contain protein and DNA.

6.2 Detection Methodology

Recently, the Implementation Sub-Committee (ISC), a sub-committee of the Australian Government Food Regulation Standing Committee, agreed to the formation of an Expert Advisory Group (EAG), involving laboratory personnel and representatives of the Australian and New Zealand jurisdictions, that would identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including GM applications. As part of its remit, the EAG will make recommendations to Australian and New Zealand enforcement agencies on suitable methods of analysis. To date this EAG has not yet been formed but, as part of an application, the Applicant is required to confirm there is a method of analysis that is fit-for-purpose.

For soybean line FG72, this methodology involves the use of the polymerase chain reaction for DNA detection and immunoassay 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. Impact Analysis

The impact analysis represents likely impacts based on available information. The impact analysis is designed to assist in the process of identifying the affected parties, any alternative options consistent with the objective of the proposed changes, and the potential impacts of any regulatory or non-regulatory options. The Office of Best Practice Regulation (OBPR), in a letter to FSANZ dated 24 November 2010 (reference 12065) provided an exemption from the need of the OBPR to be informed about GM food applications made to FSANZ.

There were no non-regulatory options for this Application. Two regulatory options identified in relation to the proposed variations to Standard 1.5.2 were:

Option 1 – Reject application

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

Option 2 – Prepare a draft variation

Prepare a draft variation to Standard 1.5.2 to permit the sale and use of food derived from soybean line FG72.

7.1 Affected Parties

The affected parties may include the following:

- Consumers of soybean-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 soybean-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 intention that soybean line FG72 be commercially cultivated in major soybean-producing countries. There is currently no intention to apply for approval to cultivate this variety in either Australia or New Zealand. 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.

7.2 Benefit Cost Analysis

FSANZ has a statutory obligation under s 29 of the FSANZ Act to consider the cost/benefit of both options. This 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.

7.2.1 Option 1 – Reject Application

Consumers: Possible restriction in the availability of imported cottonseed products to those products that do not contain soybean line FG72.

No impact on consumers wishing to avoid GM foods, as food from soybean line FG72 is not currently permitted in the food supply.

Potential increase in price of imported soybean foods due to requirement for segregation of soybean line FG72.

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 soybean food products if soybean line FG72 were to be commercialised overseas.

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

7.2.2 Option 2 – Develop a draft regulatory measure

Consumers: Broader availability of imported soybean products as there would be no restriction on imported foods containing soybean line FG72.

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

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

Government: Benefit that if soybean line FG72 was detected in soybean imports, approval would ensure compliance of those products with the Code. This would ensure no potential for trade disruption on regulatory grounds.

Approval of soybean line FG72 would ensure no conflict with WTO responsibilities.

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.

Industry: Importers of processed foods containing soybean derivatives would benefit as foods derived from soybean line FG72 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 soybean products or imported foods manufactured using soybean derivatives.

Possible cost to food industry as some food ingredients derived from soybean line FG72 would be required to be labelled.

7.3 Comparison of Options

As food from soybean line FG72 has been found to be as safe as food from conventional cultivars of soybean, 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 soybean line FG72 by other countries could limit the availability of imported soybean products in the Australian and New Zealand markets. In addition, Option 1 would result in the requirement for segregation of any products containing soybean line FG72 from those containing approved soybean lines which would be likely to increase the costs of imported soybean foods.

Based on the conclusions of the Safety Assessment, the potential benefits of Option 2 outweigh the potential costs. A variation to Standard 1.5.2 giving approval to herbicide tolerant soybean line FG72 was therefore the preferred option.

COMMUNICATION AND CONSULTATION STRATEGY

9. Communication

The communication strategy applied to this Application involves advertising the availability of assessment reports for public comment in the national press and placing the reports on the FSANZ website. In addition, FSANZ will issue a media release drawing journalists' attention to this Application.

From 1 May 2011, FSANZ is placing all new applications on the FSANZ website. Over time applications received before 1 May 2011, particularly those that have attracted a lot of public interest will be added to the website. The dossier for A1051 is already available on the website at

<http://www.foodstandards.gov.au/foodstandards/applications/applicationa1051food4902.cfm>

The draft variation will be considered for approval by the FSANZ Board taking into consideration public comments received on this Assessment Report.

The Applicant and individuals and organisations that make submissions on this Application will be notified at each stage of the assessment. If the draft variation to the Code is approved by the FSANZ Board, that decision will be notified to the Ministerial Council. If the approval of food derived from herbicide-tolerant soybean line FG72 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

Public submissions are invited on the draft variations to the Code. Comments are also specifically sought on the scientific aspects of this Application, in particular, information relevant to the safety assessment of food derived from herbicide-tolerant soybean line FG72.

10.1 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 herbicide-tolerant soybean line FG72 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 Preferred Option

Preferred Approach

To prepare a draft variation to Standard 1.5.2 - Food produced using Gene Technology, to include food derived from herbicide-tolerant soybean line FG72 in the Schedule.

11.1 Reasons for Preferred Approach

The development of a variation to the Code to give approval to the sale and use of food derived from herbicide-tolerant soybean line FG72 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 soybean line FG72.

- Food derived from soybean line FG72 is equivalent to that derived from the conventional counterpart and other commercially available soybean cultivars in terms of its safety for human consumption and nutritional adequacy.
- Labelling of food derived from soybean line FG72 will be required in the ingredients list or in conjunction with the name of the food, if it contains novel DNA or novel protein.
- Two regulatory options were considered: (1) rejection of the Application; or (2) approval of food derived from soybean line FG72. 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.
- 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 and could achieve the same end.

12. Implementation and Review

Following the consultation period for this document, an Approval Report will be completed and the draft variation will be considered for approval by the FSANZ Board. The FSANZ Board's decision will then be notified to the Ministerial Council. Following notification, the proposed draft 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

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.

ATTACHMENTS

1. Draft Variation to the *Australia New Zealand Food Standards Code*

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



Food Standards (Application A1051 – Food derived from Herbicide-tolerant Soybean Event FG72) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated XXXX

[Signature to be inserted]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

1 Name

This instrument is the *Food Standards (Application A1051 – Food derived from Herbicide-tolerant Soybean Event FG72) Variation*.

2 Variation to Standards in the Australia New Zealand Food Standards Code

The Schedule varies the Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

This variation commences **on the date of gazettal**.

SCHEDULE

[1] *Standard 1.5.2 is varied by inserting in numerical order in the Schedule –*

	7.x	Food derived from herbicide-tolerant soybean line FG72	
--	-----	--	--